The Feasibility, Clinical Utility, Tolerability, and Initial Clinical Efficacy of Virtual Reality Distraction with Children Undergoing Medical Procedures at a Specialized Pediatric Orthopedic Hospital

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ABSTRACT

Healthcare technologies have innovated the quality and delivery of care to patients driving the promotion of safe and cost-effective care. Virtual reality (VR) technology has been leveraged in the healthcare setting as a distraction tool to manage undertreated and preventable procedural pain and anxiety. Our integrative review found 56 studies of varying methodological quality have been conducted testing the use of VR during various medical procedures received by children, including burn wound care (n = 12), post-burn injury physiotherapy (n = 5), dental (n = 7), cancer-related (n = 19), needle-related (n = 17), and pre-operative (n = 2) procedures. However, a gap remains and VR efficacy warrants investigation in children with chronic and complex musculoskeletal condition. These under-researched children remain at heightened risk of repeated exposure to painful and anxiety-inducing medical procedures as part of their long-term care. Before integration into clinical practice, hospitals must secure clinical buy-in with end-users, who will integrate the use of innovative tools into practice. Herein lies our interest in introducing VR distraction at the Shriners Hospitals for Children®-Canada for use by children undergoing painful or anxiety- inducing medical procedures. A mixed-methods study, concurrent triangulation design, guided by the VR-CORE methodological framework, was piloted across various clinics to test the feasibility, clinical utility, tolerability, and initial clinical efficacy of virtual reality as a distraction tool. Quantitative and qualitative data derived from children (n = 44), their parents (n = 26), and healthcare professionals (n = 11) were collected using validated questionnaires, fieldnotes, semi-structured interviews, and focus group. This thesis presents a rich and rigorous account of a triad perspective on the use of VR during intravenous insertion (n = 30), pin/wire removal (n = 7), Botox injections (n = 2), blood-draw (n = 3), dressing change (n = 1), and urodynamic test (n = 1). Findings reveal that VR use: (1) is feasible as VR is easily implemented in the current clinical workflow, (2) is clinically useful as VR is easy to use and accepted by stakeholders, (3) is tolerable as VR does not cause physical or emotional adversities, and (4) supports VR analgesic and anxiolytic benefit in procedural pain and anxiety management. These results will inform the creation of policies and procedures for VR use in practice and a sustainable implementation across the Shriners Healthcare network. Finally, a larger comprehensive clinical trial may ensue to test clinically relevant outcomes.

ABREGÉ

Les technologies utilisées dans les milieux de soins de santé favorisent l'innovation dans la qualité et la prestation des soins aux patients en promouvant des soins efficaces, rentables et sécuritaires. La réalité virtuelle (RV) est une technologie qui a été mobilisée dans ce milieu en tant qu'outil de distraction afin de mieux gérer la douleur et l'anxiété sous-traitées et inévitablement engendrées par les procédures médicales. Notre revue intégrative de la littérature a identifié 56 études de qualité méthodologique mixte qui ont examinées l'utilisation de la RV lors de diverses procédures médicales, y compris les soins des plaies (n = 12), la physiothérapie suite aux blessures par brûlures (n = 5), les procédures dentaires (n = 7), les procédures liées au cancer (n = 9), les procédures de ponction à l'aiguille (n = 17) et les procédures préopératoires (n = 2). Il reste cependant un écart dans la littérature. L'efficacité de la RV chez les enfants atteints d'une condition musculosquelettique chronique et complexe nécessite d'approfondir les recherches. En effet, cette population est à risque accru d'exposition à ces procédures, qui font partie de leurs soins standard. Avant d'intégrer la RV à la pratique clinique, il faut obtenir l'engagement des principaux intervenants, qui vont, ensuite, adopter l'utilisation d'outils innovants lors de la prestation des soins. Ainsi, nous désirons introduire la distraction par RV aux Hôpitaux Shriners pour enfants®-Canada pour les enfants recevant des procédures médicales douloureuses ou causant de l'anxiété. Une étude à méthodologie mixte suivant le design de triangulation et guidé par le cadre méthodologique VR-CORE a été pilotée à diverses cliniques afin d'examiner la faisabilité, l'utilité clinique, la tolérance et l'efficacité clinique initiale de la réalité virtuelle en tant qu'outil de distraction. Des données quantitatives et qualitatives ont été collectées auprès des enfants (n = 44), de leurs parents (n = 26) et des professionnels de la santé (n = 11) en utilisant des échelles et des questionnaires validés, des notes d'observations, des entrevues semi-structurées et un groupe de discussion. Cette thèse fait état d'un rapport riche et rigoureux de la perspective des intervenants principaux sur l'utilisation de la RV pendant des ponctions intraveineuses (n = 30), des retraits des broches percutanées (n = 7), des injections Botox (n = 2), des prises de sang (n = 3), un changement de pansement (n = 1) et un test urodynamique (n = 1). Les résultats de l'étude soulignent que l'utilisation de la RV (1) est faisable, car la technologie est facilement implémentée dans le flux du travail clinique, (2) est cliniquement utile, car son utilisation est simple et acceptée par les intervenants principaux, (3) est tolérable vu qu'elle ne cause pas d'effets secondaires physiques ou émotionnels et (4) aide à mieux gérer la douleur et l'anxiété pendant les procédures médicales. Ces conclusions vont façonner la création de mesures

politiques et procédurales quant à l'utilisation de la RV en pratique clinique et l'implémentation durable dans tous les réseaux des soins de santé Shriners. Finalement, un essai clinique exhaustif pourra s'ensuivre afin de tester des variables cliniques pertinentes.

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First, I would like to thank both of my thesis supervisors, Dr. Reggie Hamdy and Dr. Argerie Tsimicalis. Dr. Hamdy has allowed me to take part in his vision of bringing virtual reality technology at the Shriners Hospitals for Children®-Canada. Through this project, I discovered a new passion for bringing innovations in the clinical setting to ultimately improve patient care. Thank you for giving me the environment and resources that have led to my success. I am also incredibly grateful for having Argerie as my mentor since my undergraduate studies at McGill. Under her supervision, I saw the importance of building meaningful relationships with other healthcare professionals to bring to life multi-disciplinary projects that are clinically impactful. She provided me with numerous opportunities to present and share my work to various healthcare professionals, hospital administrators, and academics, allowing me to grow and learn from every single encounter. This thesis was made possible with her consistent support and advice. Thank you for making my masters an absolute pleasure.

I would also like to thank the other members of my research advisory committee. I am thankful for Mrs. Kelly Thorstad, the Director of Patient Care and Nursing Services at the Shriners, who despite her crazy-packed schedule, has found the time to help with the virtual reality project. I am also grateful for Dr. Sylvie Le May, whose expertise in the use of virtual reality distraction helped in the review of this thesis' manuscripts, refining them before publication. Thank you to Dr. Jean-Simon Fortin, and the team at Paperplane Therapeutics, who have generously allowed us to use their virtual reality game, DreamLand. Finally, thank you to Ms. Khadidja Chougui, Mrs. Claudette Bilodeau, the health care professionals, children and their parents who participated in the study and helped move this project forward.

I would like to dedicate this thesis to my parents who have always supported me in my post-secondary studies. They have shown me what a strong work ethic looks like, and that with resilience and perseverance, anyone can achieve their goals.

PREFACE

Contribution to Original Knowledge

I certify that this thesis contains no material previously published, unless where references or acknowledgements are made.

Contribution of Authors

This thesis consists of two manuscripts to be submitted for publication:

The first manuscript is an integrative literature review of 56 clinical studies investigating the efficacy of virtual reality in managing pediatric procedural pain and anxiety during various medical procedures. The review was conducted by Ms. Sofia Addab. The manuscript was drafted by Ms. Sofia Addab and reviewed by Dr. Argerie Tsimicalis, Mrs. Kelly Thorstad, and Dr. Reggie Hamdy. The second manuscript describes a mixed-methods study investigating the: (1) feasibility, (2) clinical utility, (3) tolerability, and (4) initial clinical efficacy of the use of virtual reality during medical procedures performed on children with chronic and complex musculoskeletal conditions receiving care at a specialized pediatric orthopedic hospital. The authors' contribution is as follows:

- Conception or design of the work: Dr. Reggie Hamdy, Ms. Sofia Addab, Dr. Argerie Tsimicalis, and Mrs. Kelly Thorstad
- Ethics Oversight: Dr. Argerie Tsimicalis
- Recruitment and Data collection: Ms. Sofia Addab and Mrs. Claudette Bilodeau
- Data management, analysis and interpretation: Ms. Sofia Addab and Dr. Argerie Tsimicalis
- Drafting the manuscripts: Ms. Sofia Addab and Dr. Argerie Tsimicalis.
- Critical revision of the manuscripts: Ms. Sofia Addab, Dr. Argerie Tsimicalis, Dr. Sylvie Le May, Mrs. Kelly Thorstad, and Dr. Reggie Hamdy

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LIST OF ABBREVIATIONS

CSSQ	Child Simulator Sickness Questionnaire
FAS	FACES Anxiety Scale
FPS-R	FACES Pain Scale-Revised
GRS	Graphic rating scale
HCP	Healthcare professional
HMD	Head-mounted display
OI	Osteogenesis imperfecta
SHC-C	Shriners Hospitals for Children®-Canada
VR	Virtual reality

CHAPTER I: INTRODUCTION

1.1 Background and Rationale

Healthcare technologies have revolutionized and transformed how care is delivered to patients. Institutions must carefully plan the implementation of new innovations into practice to promote safe, cost-effective, and quality care to their patients (1). Further, technologies must be accepted by end-users, such as healthcare professionals and patients, to ensure seamless adoption and integration into practice (1). Resistance to new technologies should be anticipated. Institutions and individuals may be reluctant to accept these technologies due to a number of factors, such as scarcity of resources for implementation, staff resources, and time requirements (2).

Feasibility studies allow for the identification of barriers and facilitators to implementing technologies in the context of the delivery of care (3). Such early testing lends critical insight into how an innovation will affect clinical workflow, interactions between healthcare professionals and patients, and the perceptions and attitudes of intended end-users. Further, feasibility studies permit an assessment of the resources and structures required for successful implementation into respective clinical settings. Feasibility findings may be used to refine, adapt, and tailor a technology to a specific hospital environment. Larger comprehensive clinical trials may then ensue to test clinically relevant outcomes.

In the last two decades, virtual reality (VR) has emerged as a valuable distraction tool in healthcare delivery to reduce procedural pain and anxiety. While the underlying mechanism of the analgesic and anxiolytic effects of VR distraction remains to be elucidated, the current evidence is promising (4). In the context of a medical procedure, VR distracts a patient from painful and anxiety-inducing stimuli to an immersive virtual world where pleasant sensory stimuli are experienced (5) As VR poses high demands on conscious attention, limited cognitive resources are left to process painful and anxiety stimuli (6). Further, VR avoids the side-effects of typical pharmacological interventions, saves clinical time, and provides a more humanistic approach to patient care (7).

The clinical efficacy of VR in reducing pain and anxiety during medical procedures has a growing body of evidence; however, a significant gap remains in using VR distraction with children with chronic and complex musculoskeletal conditions (4). The Shriners Hospitals for Children-Canada (SHC-C) is a specialized pediatric orthopedic hospital which provides care to this patient population. Medical procedures, which may be very distressing and perceived as painful or anxiety-provoking, occur frequently across all clinics. These procedures include pin and wire

removals, intravenous treatments, blood draws, dressing changes, Botox injections, and urodynamic tests. which have not been rigorously tested in the literature. While other distraction techniques exist for pain and anxiety management (8, 9), most are not immersive and interactive like VR, hence the constant need to introduce new innovative evidence to promote safe, cost-effective, and quality care.

Here lied our interest in introducing VR distraction at the SHC-C. The Virtual-Reality Clinical Outcomes and Research Experts (VR-CORE) methodological framework was followed to design a feasibility trial (3). The study served as the first step of a sequentially, phased- approach to implement VR in clinical practice through the testing of feasibility, followed by the creation of hospital-specific VR policies and guidelines, and full-scale evaluation with the ultimate goal of improving the quality of care.

1.2 Objectives and Research Questions

The main objective of this thesis was to introduce VR distraction at SHC-C as a new tool to help pediatric patients with chronic and musculoskeletal conditions manage their procedural pain and anxiety. Before starting the feasibility study, which constitutes the majority of this thesis, an in-depth integrative literature review was conducted (Chapter II). The goals of the review were to understand the use of the VR software, equipment, intervention, explore the application of VR in varying pediatric healthcare settings, and delineate the clinical efficacy of VR. The synthesized knowledge informed the design and pilot of a mixed-methods study, concurrent triangulation design. The findings are reported in Chapter IV. The study was guided by the VR-CORE methodological framework and the research questions were:

1.2.1 What is the *feasibility* of VR for children undergoing a medical procedure from the perspectives of patients, parents, and healthcare professionals in a pediatric orthopaedic hospital setting.

1.2.2 What is the *clinical utility,* in terms of acceptability, ease of use, VR understanding and satisfaction, of VR for children undergoing a medical procedure from the perspectives of patients, parents, and healthcare professionals in a pediatric orthopaedic hospital setting.

1.2.3 What is the *tolerability* of the use of VR during medical procedures from the perspectives of patients, parents, and healthcare professionals in a pediatric orthopaedic hospital setting.

1.2.4 What is the *initially clinical efficacy*, in terms of pain, anxiety and distraction, of VR

for children undergoing a medical procedure from the perspectives of patients, parents, and healthcare professionals in a pediatric orthopaedic hospital setting.

1.3 Triangulated Outcome Data Sources

1.3.1 Feasibility was determined using patient and healthcare professional perceptions questionnaires (10), fieldnotes and observations, semi-structured interviews, and focus group.

1.3.2 Clinical Utility was evaluated using patient and healthcare professional perception questionnaires (10), fieldnotes and observations, semi-structured interviews, and focus group.

1.3.3 Initial Clinical Efficacy was assessed using the FACES Pain Scale-Revised (FPS-R) (11), FACES Anxiety Scale (FAS) (12), Graphic Rating Scale for Pain (GRS) (13), fieldnotes and observations, and semi-structured interviews.

1.3.4 Tolerability will be assessed using the Child Simulator Sickness Questionnaire (CSSQ) (14), fieldnotes and observations, and semi-structured interviews.

CHAPTER II: INTEGRATIVE LITERATURE REVIEW

The Use of Virtual Reality in Managing Pediatric Procedural Pain and Anxiety: An Integrative Literature Review

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2.0 ABSTRACT

Aims/Objectives: This integrative review aimed to identify, analyze, and synthesize studies investigating the clinical efficacy of virtual reality (VR) distraction for children undergoing varying painful and anxiety-inducing medical procedures across different hospital settings and to identify implications for research and practice.

Background: Virtual reality has been leveraged as a distraction tool in the healthcare setting to help patients manage procedural pain and anxiety. Initial studies in the burn wound care setting showing VR analgesia led to the use of VR during various other medical procedures.

Design/Methods: An integrative review of the literature was conducted across four electronic data bases. Published studies between 2000 and 2020 investigating the clinical efficacy of VR in managing pediatric procedural pain or anxiety were included for review. **Results:** Reviewed studies collectively included 2, 976 patients aged 6 months-65 years undergoing burn wound care, post-burn physiotherapy, dental, cancer-related, needle-related, and pre-operative procedures. Overall, studies supported the efficacy of VR in managing procedural pain and anxiety.

Conclusion: This review identified a gap in the use of VR with children with chronic conditions receiving orthopedic procedures as part of their standard care. If VR proves to be an effective distraction tool, it may help reduce the occurrence of undertreated pain and anxiety in pediatric patients visiting the hospital.

2.1 INTRODUCTION

Technological innovations play an instrumental role in helping healthcare institutions improve the quality of care delivered to patients. One of the earliest healthcare innovations was the stethoscope invented by a physician who was unable to hear the heartbeat of an overweight patient (1). Now, widely adopted by many healthcare professionals, the stethoscope has been integrated into the healthcare system as an indispensable tool to patient care. A more recent technology that has gained wide applications in healthcare is virtual reality (VR).

2.1.1 Overview of Virtual Reality Systems and Devices

Virtual reality allows users to explore and interact in a virtual, three-dimensional, computer-generated world that feels real. Virtual reality works by simulating sensory human experiences such as sight, hearing, and touch. A VR system is inherently immersive, mentally removing users from the real world (2). Altogether, the VR system immerses the user into the virtual world by inducing a sense of presence distracting them from the real world (2). A typical VR system comprises of a head-mounted display (HMD), earphones, a motion tracking system, and a hand-held device to interact with the virtual world (3). Head-mounted displays resemble a pair of goggles where users can see into a three-dimensional virtual word. Earphones are often integrated in the HMD allowing the user to hear three-dimensional audio. As the user navigates through the virtual world, the visual and auditory information is constantly updated to reflect their perspective (3). The VR system is updated by gathering information about the user's movements and head orientation through a motion tracking system (3). Several hand-held devices exist that allow the user to interact with virtual objects, such as a computer mouse, controllers, and haptic gloves. While a wide range of VR systems are available on the market, these systems vary in degree of immersion quality and level of interaction. The optimal system will depend on the user's needs, intended use, and funding.

2.1.2 Virtual Reality as a Distraction Tool in Child Healthcare Settings

Virtual reality has been leveraged as a distraction tool to help children manage one of the most common medical complaints: procedural pain and anxiety (4, 5). Hoffman and colleagues were pioneers in bringing VR distraction to help manage procedural pain associated with burn wound care. According to the cognitive-affective model of the interruptive function of pain, an individual's has a limited cognitive resource of attention, and the inputs of painful processing consume a lot of their limited attention resources (6). Thus, an individual's attention is diverted

when VR is used moving away from the painful stimuli towards a pleasant virtual world, reducing the pain experience. Based on this theory, Hoffman and colleagues provided the first evidence for VR efficacy, which catalyzed many subsequent studies, warranting the need for a review summarizing and comparing the findings on VR clinical efficacy in reducing procedural pain and anxiety in children's healthcare settings. Hence, the purpose of this integrative literature review was to systematically review, appraise, and synthesize the findings of studies investigating the use of VR distraction for children undergoing varying painful or anxiety-inducing medical procedures in different settings and to identify implications for practice and research.

2.2 METHODS

2.2.1 Study Design

An integrative review design was conducted to systematically review, appraise, extract, and synthesize the existing data on the use of VR distraction for procedural pain and anxiety management. The methodological rigour of integrative reviews is similar to that of systematic reviews; however, the former allows for the inclusion of findings from quantitative, qualitative, mixed-methods studies, and case reports (7).

2.2.2 Information Sources and Search Strategy

To identify relevant studies, a search strategy was devised with the help of a librarian scientist. The following four electronic data bases were searched: Medline via Ovid (2019 – November 2020), EMBASE via Ovid (2019 – November 2020), CINAHL via EBSCOhost (2019 – November 2020), and PsychInfo via Ovid (2019 – November 2020). The search terms included MeSH headings, subject headings, and key words relevant to virtual reality, procedural pain, procedural anxiety, and distraction. The search was limited to studies with samples including children (aged between 0 and 18 years) and published in English or French since the year 2000. No efforts were made to locate unpublished materials or contact researchers for unpublished studies. All citations were imported and organized using the bibliographic software EndNote X9.

2.2.3 Study Selection

Study titles and abstracts were screened by one reviewer for inclusion. In the case of uncertainties, the reviewer sought the help of another member of the research team and together they discussed until they reached a consensus.

2.2.4 Eligibility Criteria

2.2.4.1 Types of participants. Studies were considered for review if the sample included patients aged 18 years and below undergoing a medical procedure with VR distraction. Studies with adult participants were still considered for review if authors also reported data on children.

2.2.4.2 Types of outcome measures. Any study design that investigated the use of VR distraction in managing procedural pain or anxiety was eligible.

2.2.4.3 Types of studies. Quantitative, qualitative, and mixed-methods studies and case reports were considered for review. There was no minimum threshold for quality appraisal score.

2.2.5 Methods of the Review

Titles and abstracts were screened by one reviewer for eligibility. Full-text articles of selected titles and abstracts were sought. The interlibrary loan services offered by McGill University were used if full-text articles could not be found. The full-text articles were then read by one reviewer to determine inclusion. Further, references of selected full-text articles were scanned to identify other relevant studies for inclusion. The assistance of the research team was sought when the reviewer was unsure of the inclusion of articles for review.

2.2.5.1 Data Extraction. Studies considered for review were first categorized in EndNote X9 by types of medical procedures. Data were extracted and inserted into tables created on Microsoft Word. A different table was created for each subgroup of medical procedures. One reviewer completed data extraction and a second reviewer verified the extracted data for each study, including: authors, study-design, sample characteristics, VR equipment and intervention, and pain and anxiety outcomes.

2.2.5.2 Quality Appraisal. Studies were appraised by one reviewer using the Mixed Methods Appraisal Tool 2018 (MMAT 2018) (8) and the Joan Briggs Institute (JBI) Critical Appraisal Tool Checklist for Case Reports (9). The MMAT was designed for the quality appraisal stage of systematic reviews of mixed studies, including qualitative, randomized or non-randomized controlled trials, quantitative descriptive, and mixed methods studies (8). Each study was assessed by 5 criteria, with scores ranging from 0% (no criterion met) to 100% (all criteria met). The JBI critical appraisal checklist is a peer-reviewed appraisal tool for case reports included in integrative reviews (9). Each case report was evaluated based on 8 questions, with scores ranging from 0% (no questions addressed) to 100% (all 8 questions addressed). Despite the quality appraisal score, all studies and case reports were retained for analysis.

2.2.5.3 Data Analysis. Data extracted into tables were descriptively analyzed for sample

and study characteristics following Whittemore and Knafl's constant comparison method, generating MMAT and JBI quality scores (7). Data were first reduced into subgroups of medical procedures to facilitate analysis, and further divided into VR intervention and equipment, followed by pain and anxiety outcomes. Data were displayed using tables and figures to identify patterns of similarities and differences through an iterative process. Finally, after constant comparison of findings and considering potential confounding variables, generalized conclusions were achieved and presented as themes.

2.3 RESULTS

2.3.1 Search Outcomes

A total of 3996 articles was imported into EndNote X9 (Figure 1). Following the removal of duplicates, 3367 titles and abstracts and 112 full text articles were screened for eligibility. Of these articles, 38 studies met the eligibility criteria and were included in the review. Eighteen additional references were identified by screening the references of included studies. A total of 56 studies were included in the final review.

2.3.2 Methodological Quality

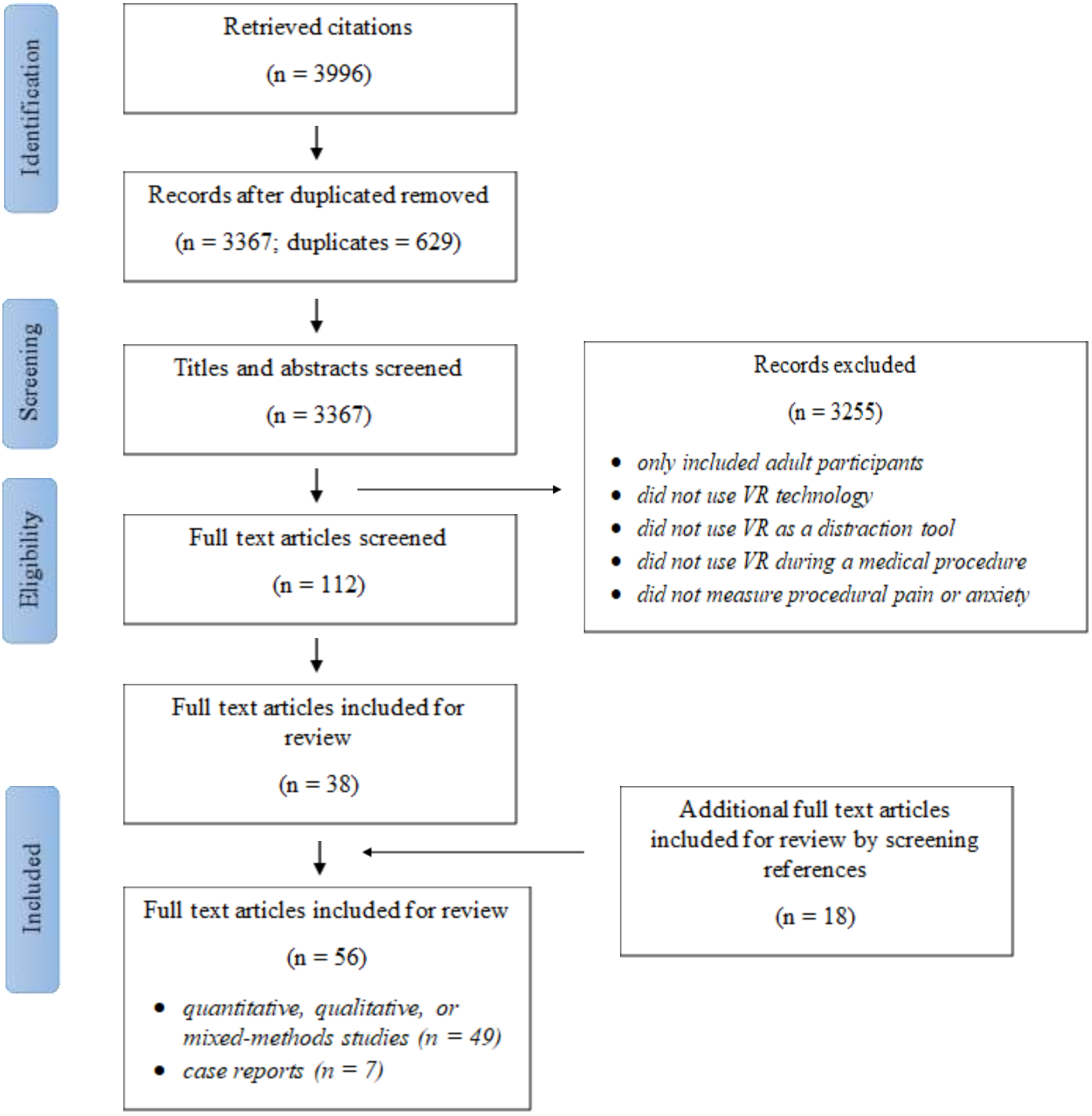
The MMAT 2018 yielded 49 studies with quality scores ranging from 20% (one criterion met) to 100% (five criteria met), with an average score of 77.8%. The JBI critical appraisal checklist for case reports generated seven case reports with scores ranging from 75% to 100%.

2.3.3 Study and Sample Characteristics

This review included studies published between 2000 and 2020 that were conducted in North America (n = 28), Asia (n = 13), Europe (n = 10), Australia (n = 4), and South America (n = 1). The studies varied in design, including: within-subject randomized controlled trials (n = 14), between-subject randomized controlled trials (n = 20), mixed-methods randomized controlled trials (n = 6), interventional/observational studies (n = 4), quasi-experimental studies (n = 3), mixed methods interventional studies (n = 2), retrospective chart review (n = 1), and case reports (n = 7). A total of 2469 patients aged between 6 months and 18 years used VR distraction during one of the following medical procedures: burn wound care procedures (n = 9), post-burn injury physiotherapy (n = 1), dental procedures (n = 7), cancer-related procedures (n = 7), needle-related procedures (n = 17), pre-operative procedures (n = 2), and other procedures (n = 3). Ten of the 56 studies (18%) investigating VR use during burn wound care (n = 3) (10-12), post-burn physiotherapy (n = 4) (2, 13-15), cancer-related procedures (n = 2) (16, 17), and

needle-related procedures (n = 1) (18), included data on 507 patients aged between 6 and 65 years, for which pediatric data could not be excluded.

Figure 1. Flow Diagram of Study Selection

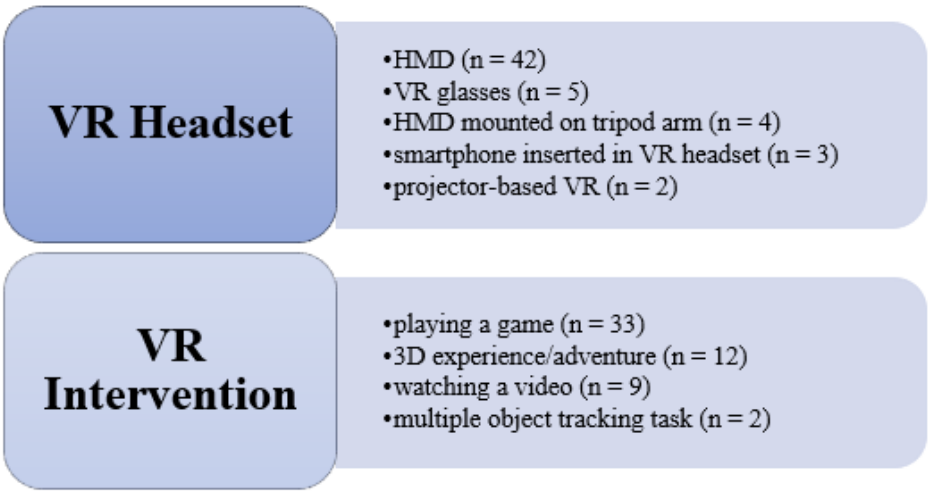


2.3.4 Virtual Reality Equipment and Interventions Used in Studies

Overall, the studies varied in the equipment used to deliver the VR distraction intervention (Figure 2). Majority of studies (n = 42, 75%) used a HMD, which blocks environmental cues and immerses the user in the virtual world. Four studies mounted the HMD on a tripod arm, allowing children with head or facial burn injuries to use VR by looking into the HMD (14, 19-21). Four studies used a water-friendly VR system during hydrotherapy sessions for burn wound care, including photonic and project-based VR systems (12, 19, 22, 23). Five studies used VR glasses, which transform images on a computer in 3D (17, 24-27). Finally, in three studies, a smartphone was inserted into a disposable VR headset (28-30).

Various games were delivered through VR, ranging in degree of interaction (Figure 2) to facilitate distraction. Majority of studies used a VR game (n = 33, 58.9%), such as SnowWorld (n = 12), Virtual Gorilla Program (n = 3), SpiderWorld (n = 2), or other games, all of which required children to interact with or shoot virtual objects using a controller. SnowWorld was the first immersive VR game designed for pain reduction in patients undergoing burn wound care (12). In other studies, children experienced a VR adventure during their medical procedure, such as going on a rollercoaster ride, swimming underwater, travelling around the world, or enjoying nature (17, 27-29, 31-37). Finally, some children selected a cartoon or movie to watch during their dental or needle-related procedure (n = 9) (25, 38-45).

Figure 2. Virtual Reality Headset and Intervention Used in 56 Studies Conducted in Children's Healthcare Settings



Note. Various VR headsets and interventions were used to distract 2,976 healthy and chronically-ill children undergoing painful or anxiety-inducing medical procedures. HMD = head-mounted display.

2.3.5 Pain and Anxiety Outcomes During Virtual Reality Distraction

Pain and anxiety were the main clinical outcomes investigated in the reviewed studies. These outcomes are presented by medical procedure and disease sub-groups as VR efficacy may depend on the type of medical procedure received or underlying disease.

2.3.6 Use of virtual reality with children receiving burn wound care

Overall, eight randomized clinical trials (11, 12, 19, 20, 23, 24, 46, 47), one quasi-experimental study (22), two case reports (31, 48), and one interventional study (10) investigated the effect of a VR intervention in managing the pain of children receiving burn wound care (Table 1). Burn wound care procedures included wound dressing changes (10, 11, 20, 24, 31, 46-48) , wound debridement (12, 22, 23), and hydrotherapy (12, 19, 22, 23). Most studies (n = 9) used a within-subject design, wherein a participant experienced both the VR intervention and the control condition (11, 12, 19, 22-24, 31, 46, 49). Further, some studies used a within wound care design, wherein both VR and control conditions were administered during the same session (12, 19, 23, 24, 46, 49), while other studies compared the two conditions in different sessions, sometimes during different days too (10, 46). Two studies opted for a between-subjects design, wherein the subjects were randomly assigned to an intervention or control group (20, 47). Usually, studies compared a VR intervention group to a standard distraction group or standard of care group, whereas two case reports had no comparison group (22, 31). The two case reports in Hoffman et al. (2000) compared VR distraction to Nintendo game distraction.

Virtual Reality Adjunct to Standard Analgesia Improves Pain Associated with Burn Wound Care Procedures

Overall, 11 studies found that VR combined with standard analgesia can reduce the pain associated with burn wound care. When comparing VR combined with analgesia to another form of distraction, such as watching a video or playing with toys, three studies found that VR greatly reduced pain during a burn wound care session (17, 22, 23). Two of those studies assessed the different components of pain, showing that the effect of VR in reducing sensory (worst pain, average pain) (17, 23), affective (unpleasantness, bothersomeness) (17, 23), and cognitive pain (time spent thinking about pain) (17) was greater than other methods of distraction. Jeffs et al. (2014) reported that this difference was statistically significant ($p = 0.029$). That being said, van Twillert et al. (2007) found that although VR did significantly reduce pain ($p < 0.001$), VR was not significantly better than passive distraction (watching television). Five studies compared the

use of VR combined with analgesia to analgesia only during burn wound care (11, 18-21). Four studies found that compared to analgesia only, a VR intervention led to statistically significant lower pain ratings compared to the standard of care group (11, 18-20). However, Chan et al. (2007) found that while pain intensity was lower during and after wound dressing changes with VR compared to the control condition, this difference was not statistically significant.

Two studies investigated the use of VR during burn wound care without a comparison group (24, 25). Khadra et al. (2018) found that a projector-based VR intervention for children (mean age = 2.2 years) resulted in low mean pain scores. However, there was no significant difference in the pain scores before, during, and after the VR intervention. Scapin et al. (2017) reported on two cases of VR during wound dressing changes and found that VR worked in reducing pain. Other studies assessed whether the analgesic effect of VR wore off after repeated use. Faber et al. (2013) found that worst pain intensity ratings were significantly lower on days 1, 2, and 3 of wound dressing changes. Thus, VR continues to be effective over multiple days of treatments. Similarly, Hoffman et al. (2020) found that children reported lower pain ratings with every burn wound care session with VR distraction.

Virtual Reality Helps Manage Anxiety Associated with Burn Wound Care Procedures

Four randomized clinical trials, one quasi-experimental study, and one case report assessed the effect of VR on procedural anxiety (14, 17, 20, 21, 23, 25). In the two case reports presented in Hoffman et al. (2000), VR significantly reduced anxiety ratings. Das et al. (2005) found that parents believed VR helped manage their child's anxiety. Both Chan et al. (2007) and Khadra et al. (2018) observed that children were more calm with VR distraction. For instance, nurses reported that children allowed them to complete the procedure, did not tense their body, and remained calm after dressing change (21). Jeffs et al. (2014) and Khadra et al. (2018) found a positive correlation between procedural pain and anxiety. van Twillert et al. (2007) reported no significant reduction of anxiety with VR distraction.

2.3.7 Use of virtual reality with children receiving post-burn physiotherapy

Four randomized controlled trials and one case study investigated the use of VR distraction during post-burn injury physiotherapy (2, 9, 12, 13, 26) (Table 2). All studies conducted a within-subject design, comparing VR distraction and analgesia to standard analgesia during range-of-motion exercises. Some studies conducted within physiotherapy session designs, where VR and standard analgesia were examined within a single physiotherapy session (13-15,

50), while others compared VR and standard analgesia during different sessions (15, 21). Sharar et al. (2007) pooled the data from three within-subject randomized trials which all compared VR to standard analgesia during range-of-motion exercises.

Virtual Reality Adjunct to Standard Analgesia Improves Pain Associated with Post-Burn Injury Physiotherapy

All studies reported that VR distraction lead to a significant reduction for worst pain (13, 15), pain unpleasantness (13-15), and time spent thinking about pain (13-15) during range-of-motion exercises. Similarly, Hoffman et al. (2001) reported significantly lower pain ratings during VR distraction compared to standard analgesia during three days of physiotherapy, and others reported that the magnitude of pain reduction was sustained with repeated VR use over different physiotherapy sessions (2, 13). Consistent with other findings, Hoffman et al. (2014) also found a reduction in pain intensity in a case report.

2.3.8 Use of virtual reality with children receiving dental procedures

Overall, seven studies investigated the use of VR distraction during dental procedures received by children, including tooth extraction (n = 3) (39, 41, 51), restorative procedures (n = 3) (38, 42, 51), and pulp therapy (n = 3) (25, 40, 41) (Table 3). Most studies conducted a within-subject randomized controlled trial (n = 4), comparing VR distraction to standard analgesia or anesthesia (38-40, 51). More specifically, Koticha et al. (2019) conducted a split-mouth design, wherein participants' mouth was split in two, with one tooth extracted with VR distraction, and the other tooth extracted with standard anesthesia. Two studies conducted between-subject randomized controlled trials, with Shetty et al. (2019) comparing VR to standard anesthesia and Nunna et al. (2019) comparing VR to counter stimulation. Rao et al. (2019) conducted a behavioural interventional study, where VR was administered to all participants and outcome measures were compared between study timepoints.

Virtual Reality Adjunct Improves Pain Associated with Dental Procedures

Six studies examined the effect of VR distraction on pain perception (25, 38-40, 42, 51). Of those studies, three studies found that VR distraction significantly reduced pain perception compared to standard of care (25, 38, 40). Similarly, Atzori et al. (2018) reported significantly lower "worst pain" and "pain unpleasantness" during VR distraction compared to standard analgesia only. While Nunna et al. (2019) reported a decrease in pain perception during VR distraction, there was no significant difference compared to counter stimulation. Finally, Rao et

al. (2019) observed a significant reduction in pain between study timepoints (baseline, during, and after procedure).

Virtual Reality Improves Anxiety Associated with Dental Procedures

Six studies assessed the ability of VR in managing anxiety during dental procedures (25, 38-42). Four studies found that VR significantly reduced state anxiety (25, 38, 40, 41). Further, Nunna et al. (2019) found that VR was better than counter stimulation for anxiety management. While Koticha et al. (2019) found that VR significantly reduced physiological parameters of state anxiety (pulse and oxygen saturation), this was not supported by children's self-report. Finally, Rao et al. (2019) found a significant reduction in state anxiety between study timepoints (baseline, during, and after procedure).

2.3.9 Use of virtual reality with children receiving cancer-related procedures

Overall, eight studies and one case study investigated the effect of VR in managing pain or anxiety during cancer-related procedures, including lumbar punctures (n = 1) (17), port access (n = 5) (16, 26, 27, 52, 53), venipuncture (n = 3) (26, 27, 54), intravenous cannulation (n = 1) (43), and total pancreatectomy islet auto-transplantation (n = 1) (55) (Table 4). Six studies conducted within-subject or between-subject randomized trials, with four studies comparing VR distraction to standard of care (17, 43, 53, 54), one study comparing several distractors (including VR) to standard of care (53), and one study comparing VR distraction to non-VR distraction, and standard of care (16). Two of the randomized trials used mixed methods for data collection (17, 27). Nilsson et al. (2009) conducted a mixed-methods non-randomized trial, assigning children to receive VR or standard of care. Kucher et al. (2020) conducted an interventional study examining VR distraction only. Finally, Gershon et al. (2003) conducted an ABCA case study design comparing VR to non-VR distraction, and standard of care.

Virtual Reality is Better than other Distraction Methods in Managing Pain Associated with Cancer-Related Procedures

Most studies found that VR distraction helped reduce procedural pain (26, 52-55). Atzori et al. (2018) found that VR led to significant reductions in sensory (intensity), affective (unpleasantness), and cognitive (time) pain. Despite finding lower pain scores with VR distraction, three studies found no significant difference between VR distraction and standard of care (17, 26, 27). That being said, Windich-Biermeier et al. (2007) compared standard of care to selected distractors, which included blowing bubbles and videogames, and thus the study does

not directly speak of the effect of VR distraction on procedural anxiety. Wolitzky et al. (2005) collapsed pain and anxiety ratings into a distress score and found that VR was effective in reducing procedural distress. Gershon et al. (2004) only found significant pain reduction during VR distraction based on nurses' ratings, but children in the "no distraction group" were observed to have significantly more muscle tension in their torso and leg than in the VR and Non-VR distraction groups.

Virtual Reality Helps Manage Anxiety Associated with Cancer-Related Procedures

Some studies also reported on the effects of VR distraction on anxiety. Both Gershon et al. (2003) and Kucher et al. (2020) reported lower anxiety scores following a VR intervention. Three studies found a significant difference in anxiety scores between VR distraction and standard of care (16, 43, 53), however Gershon et al. (2004) found no significant difference between VR distraction and non-VR distraction. Windich-Biermeier et al. (2007) only found a significant difference in parents and nurses' ratings of children's fear and distress with selected distractors (including VR distraction). While Gershon et al. (2004) and Wolitzky et al. (2005) found a significant difference in pulse rate between VR and standard of care, this difference was not reported by Nilsson et al. (2009) and Wong et al. (2020).

2.3.10 Use of virtual reality with children receiving needle-related procedures

There were 19 studies investigating the effect of VR in reducing procedural pain or anxiety during needle-related procedures, including venipuncture (n = 7) (30, 33, 34, 36, 37, 56, 57), blood draws (n = 8) (18, 32, 35, 44, 45, 57-59), vascular access (cannulation or catheterization) (n = 4) (33, 45, 60, 61), immunization (n = 1) (28), Botulinum toxin injections (n = 1) (29) and lumbar punctures (n = 1) (45) (Table 5). The sample of the studies reviewed included children visiting the emergency department (n = 6) (33, 34, 36, 37, 57, 60), phlebotomy clinic (n = 3) (18, 35, 44), pre-operative clinic (n = 2) (60, 61), nephrology clinic (n = 2) (58, 59), radiology clinic (n = 2) (56, 60), pathology clinic (n = 1) (33), hemophilia treatment center (n = 1) (57), and other outpatient or inpatient clinic (n = 5) (28, 29, 32, 45, 60). The majority of studies conducted between-subject randomized controlled trials, comparing VR distraction to standard of care or another form of distraction. Standard of care procedures included: watching television/video (n = 4) (18, 30, 36, 37), distraction provided by a child life specialist or nurse (n = 2) (36, 61), playing a game on a smart device (n = 3) (30, 36, 37), topical anesthesia (n = 3) (45, 56, 61), nonprocedural talk (n = 2) (57, 60), verbal comforting (n = 1) (34), reading a book

(n = 1) (37), and blowing bubbles (n = 1) (30). Gerceker et al. (2018) compared VR distraction to external cold vibrations and a control condition during blood draws. Two studies conducted quasi-experimental designs (56, 57), comparing VR to passive distraction (57) or standard of care (56, 57) during blood draws. Chad et al. (2018) and Toledo del Castillo et al. (2019) conducted observational studies and Chau et al. (2018) conducted a retrospective chart review on the use of VR distraction during Botox injections.

Virtual Reality Distraction Helps Manage Pain Associated with Needle-Related Procedures

When comparing VR distraction to standard of care procedures, eight studies found that VR distraction statistically significantly reduced procedural pain (18, 32-34, 45, 56, 58, 62). Five studies however found no statistically significant difference between VR distraction and standard of care procedures (30, 35, 36, 57, 60, 61). Gerceker et al. (2018) found that pain scores were lower following the VR intervention compared to standard of care, however no significant difference was obtained between VR distraction and external cold vibrations. Piskorz et al. (2020) reported that both active and passive VR distraction significantly reduced pain, however this difference was not significant. Knight et al. (2020) observed fewer pain-related behaviours during VR distraction compared to standard of care distraction. Chad et al. (2018) found that anticipated and actual pain ratings improved with the use of VR distraction in the majority of their participants undergoing immunization. Chau et al. (2018) found that behavioural pain scores correlated with children's positive, neutral, and negative experiences with VR.

Virtual Reality Helps Manage Anxiety Associated with Needle-Related Procedures

Some studies also investigated the use of VR in managing anxiety-related outcomes, including procedural anxiety, stress, and fear of pain. Three studies reported that VR distraction significantly reduced procedural anxiety compared to standard of care procedures (18, 35, 45), while two other studies found no such differences (30, 36). Two studies reported significantly less stress in children undergoing a VR intervention compared to standard of care procedures (58, 59). Three of four studies investigating the ability of VR in reducing fear for the painful procedure found that children in the VR group experienced significantly less fear compared to children in the standard of care group (34, 35, 57).

2.3.11 Use of virtual reality with children receiving pre-operative procedures

One randomized-controlled trial (63) and one case report (64) (Table 6) assessed VR during anesthetic induction. In Jung et al. (2020), the control group received conventional patient

education prior to anesthetic induction delivered without VR. In the case report by Gupta et al. (2019), the patient used VR during transport to the induction room, up until induction.

Virtual Reality May Help Manage Pre-Operative Procedural Anxiety

When comparing VR to standard of care procedures, Jung et al. (2020) found that VR significantly reduced pre-operative anxiety. In the case report by Gupta et al. (2019), the child was described as calm and showing no signs of anxiety or distress during transport to the operating room and induction.

2.3.12 Use of virtual reality with children receiving other procedures

Three studies investigated the effect of VR distraction during nasal endoscopy (65), dressing change (66), and post-surgical physiotherapy (67) (Table 7). In a randomized controlled trial, Liu et al. (2020) found that children in the VR condition had a significant decrease in pain and anxiety during nasal endoscopy compared to children receiving standard of care. Hua et al. (2015) reported that children undergoing dressing changes with VR distraction had significant reductions in pain and anxiety. Finally, the study by Steele et al. (2003) presented the case of a 16-year old boy who reported 42.2% less pain during post-surgical physiotherapy with VR distraction.

2.4 DISCUSSION

The present integrative review systematically reviewed, appraised, extracted, and synthesized the data from 49 studies and seven case reports examining the use of VR distraction for pediatric procedural pain and anxiety management. Virtual reality was tested during several medical procedures and in different clinical settings, showcasing the widespread utility of this non-pharmacological innovation to prevent undertreated procedural pain and anxiety in healthy and chronically-ill children. Overall, this integrative review helped summarize the current evidence for VR use during pediatric medical procedures, delineate clinical efficacy outcomes, and subsequently identify implications for research and clinical practice.

2.4.1 Virtual Reality and Procedural Pain

Overall, studies included for review support the analgesic efficacy of VR across different medical procedures. Factors hypothesized to contribute to VR analgesia include the degree of immersion and level of interaction (68, 69). A meta-analysis showed that a heightened sense of presence in the virtual world may be accomplished with a high-quality VR headset that blocks visual and auditory pain cues present in a clinical setting, contributing to pain attenuation (70).

This finding was corroborated by 38 studies reporting a significant reduction in pain with VR delivered through a HMD compared to standard of care. In contrast, 12 studies reported that while immersive VR reduced procedural pain, no significant difference was found compared to other forms of active and passive distraction, or pharmacological interventions (11, 17, 24, 27, 36, 41, 47, 56, 57, 60, 61). Studies done with adult populations show similar findings, reporting significant pain reductions when an immersive VR headset is used during burn wound care procedures (71-74), post-burn injury physiotherapy (75), dental procedures (76-78), cystoscopy (79), episiotomy repair (80), and dressing change (81, 82). However, five studies using immersive VR report no significant reduction in pain during burn wound care (83), post-burn injury physiotherapy (84), peri-operative procedures (85, 86), and bone marrow aspiration/biopsy (87). The literature indicates children may be more sensitive to visual and auditory medical cues, and thus would benefit more from immersive VR than adult patients.

Dahlquist et al. (2007) demonstrated that an interactive VR experience led to increased pain tolerance during cold pressor pain experiments. Similarly, Law et al. (2011) compared passive to interactive VR and found increased pain tolerance when using an interactive intervention. A heightened level of interactivity engages more cognitive resources, increasing pain processing interference (68, 69, 88). This theory is consistent with findings of studies that used an interactive game as their VR intervention across the pediatric (2, 10, 12-15, 18-20, 23, 46, 51, 53, 54, 58, 59) and adult (71-73, 75, 77) populations. However, studies using passive VR distraction (i.e. cartoons, videos, or virtual experiences) also reported pain reduction in pediatric (25, 32-35, 38, 40, 43-45) and adult (74, 76, 78-80, 82) patients. When comparing VR to standard passive distraction (i.e. watching TV, playing a game on a smart device), only 9 studies showed no significant difference in pain scores (11, 16, 27, 36, 37, 47, 57, 59, 60). While interactive VR provided procedural analgesia, perhaps it is sufficient to deliver an immersive VR experience in which the user feels present in the virtual world.

Children with chronic conditions, such as cancer or burn injuries, may benefit from VR distraction during medical procedures. Children with cancer experience more pain and signs of behavioural distress compared to children without a chronic condition (89) and are subjected to many repeated and painful procedures. Three randomized controlled trials showed VR during port access, peripheral intravenous cannulation, and blood draws was superior to standard care, which included procedure explanation, verbal comforting, non-procedural talk, and no

distraction (43, 53, 54). Further, one observational study (55) and one case report (52) reported a decrease in procedural pain with VR during total pancreatectomy islet auto-transplantation and port access. Another chronically-ill population who significantly benefited from VR was the children with burn injuries. The majority of studies (n = 11/12) reported a positive effect of VR as an adjunct to analgesia in managing pain associated with wound care. This is similar to the adult burn population who have shown to benefit from VR distraction (4).

2.4.2 Virtual Reality and Procedural Anxiety

The literature supports the use of distraction to manage procedural anxiety (5, 90, 91), which is consistent with the findings of this review showcasing VR as an effective anxiolysis. Virtual reality distraction is a pleasant experience, removing the user from the anxiety-provoking medical environment (49), thereby reducing negative emotions, such as anxiety (92). Of the randomized controlled trials comparing VR to standard of care, 14 studies reported that VR significantly reduced procedural anxiety, stress, or fear in pediatric populations (16, 18, 24, 25, 27, 35, 38-41, 43, 53, 58, 59). The evidence for VR procedural anxiolysis is not as strong in adult populations, with only three studies providing evidence during dental procedures (76), operative procedures (93), and chemotherapy (94). Studies included for review evaluating patient-reported anxiety during VR all used immersive VR, but not all delivered interactive interventions. Thus, interactive distraction did not seem to play a role in VR anxiolysis.

Moreover, anxiety can exacerbate pain perception (92, 95). It is thus hypothesized that VR analgesia results from the anxiolytic effect created by the pleasant virtual world. This is consistent with findings of 10 studies included for review which demonstrated that VR helped manage both pain and anxiety in varying settings (18, 25, 38, 40, 41, 43, 44, 53, 58, 59). Finally, Jeffs et al. (2014) showed that a predisposition toward state anxiety in children may lead to reduced engagement in VR, minimizing the analgesic effect of VR. On the contrary, Gershon et al (2004) reported that children with increased anxiety sensitivity benefited the most from VR analgesia.

2.4.3 Research and Clinical Implications

Ongoing research is required to establish the conditions, such as medical diagnoses, procedure types, or intervention type, in which VR distraction is most clinically effective. An existing gap in the research is the limited data available on the efficacy of VR during peri-operative procedures. Indeed, this review found only two studies that evaluated VR effect on

pain and anxiety attenuation during induction of general anesthesia (64, 96). Further, our review identified no studies using VR during orthopedic procedures, including percutaneous pin removals and casting. Support for VR analgesia and anxiolysis during burn wound care may not be generalizable to peri-operative or orthopedic procedures. Moreover, future studies should consider patient characteristics that may impact VR efficacy, including sex, age, medical diagnosis, and pain or anxiety sensitivity. For instance, Gershon et al. (2004) noted that children with higher anxiety sensitivity had better outcomes with VR. For children with chronic conditions, that require frequent medical interventions and thus are at heightened risk for undertreated pain and anxiety (89), more studies should evaluate whether VR benefits are sustained with repeated VR exposure over time. Additionally, as distraction is thought to modulate pain processing, researchers should continue to compare different VR interventions, with varying levels of immersion and interactivity, to identify the most effective type of intervention for different patient population. Finally, due to the nature of VR interventions, blinding is almost impossible. As such, future research should consider complementing subjective reports with objective physiological markers of pain, anxiety, and distraction to avoid bias.

Virtual reality has the potential to help reduce the high frequency of undertreated procedural pain and anxiety amongst pediatric patients. Considering the well-documented link between pain and anxiety, the ability of VR to interfere with pain processing will also help reduce fear associated with medical interventions, ultimately preventing healthcare avoidance in adulthood. Using VR alone or as an adjunct to pharmacological analgesia will reduce the added costs and physical side-effects associated with medication. Moreover, several studies highlighted an improved satisfaction with care from patients, families, and healthcare professionals. Children distracted with VR facilitates and accelerates procedure completion. However, successful clinical use of VR will be contingent on the transfer of the latest evidence for VR use to clinicians through hospital policies, procedures, and other knowledge translation strategies. Healthcare professionals must learn how to identify signs of cybersickness, the ideal time dosing of VR interventions depending on medical procedure, defining a safe space for VR use in clinical settings, and how to properly disinfect VR equipment between patient uses.

2.4.4 Strengths and Limitations

The review presented with some strengths and limitations. Studies of varying designs

were included, allowing for an exhaustive summary of the current state of VR distraction research in pediatric medical procedures. This led to the identification of gaps in the literature that warrant further investigation. Focusing on studies with pediatric samples helped reveal the efficacy of VR specifically in children, who are vulnerable to procedural pain and anxiety. The review had some limitations. First, this review did not exclude studies with poor appraisal scores, thus the evidence presented may originate from studies of poor methodological quality, limiting validity of findings. Second, we did not explore in great detail the VR systems used, which may impact the level of distraction and thus efficacy of VR analgesia and anxiolysis. Some studies included adult participants, and isolation of pediatric data was not possible. Lastly, the search excluded studies not published in French or English, thus we may have missed important findings regarding the research topic.

2.5 CONCLUSION

With a growing body of evidence supporting VR distraction, clinicians will be able to leverage VR technology to reduce the high rates of pain and anxiety associated with medical procedures. Further research is needed to fine tune VR interventions for different patient populations and medical procedures. A sustainable implementation of VR into clinical practice guided by knowledge translation principles will improve delivery of care and patient outcomes.

2.6 DATA EXTRACTION TABLES

Table 1. Studies Using Virtual Reality during Burn Wound Care Procedures: Characteristics and Findings

Study Authors	Design	Procedures	Sample Characteristics	Pain	Anxiety
Chan et al., 2007	• within-subject randomized controlled trial • within wound care design • condition order randomized • VR + analgesia vs analgesia only	• one wound dressing change session	• n = 8 • mean age = 6.54 years	• no significant difference in pain intensity during and after the procedure	• anxiety was better managed with VR during and after the procedure
Das et al., 2005	• within-subject design • within wound care design • condition order randomized • VR + analgesia vs analgesia only	• one wound dressing care session	• n = 7 • age range = 5-16 years	• average FPS scores were significantly lower in the VR group (1.3, SD 1.8) vs analgesia only group (4.1, SD 2.9) • parent and nurses interviews: VR helped reduce child's pain	• parent and nurse interviews: VR helped reduce child's anxiety
Faber et al., 2013	• within-subject design • baseline-post treatment quantitative comparison • baseline session: analgesia only • up to 7 sessions with VR + analgesia	• bandage changes and wound cleaning (more than one session per patient)	• n = 36 • age range = 8-57 years	• worst VAT pain ratings during procedure were significantly lower on day 1, 2, and 3 (VR) of treatment vs day 0 (no-VR) • worst VAT pain ratings were lower (not significantly) beyond day 3	
Hoffman et al., 2000	• within-subject design case report • within wound care design: • condition order randomized	• dressing change	• n = 2 • age range = 16-17 years	• lower VAS (10-cm) scores reported for worst pain, average pain, pain unpleasantness, bothersomeness, and time spent	• lower anxiety with VR

	• 3 mins VR + analgesia vs 3 min Nintendo + analgesia			thinking about pain with VR	
Hoffman et al., 2008	• within-subject design • within wound care design • condition order randomized • 3 mins VR + analgesia vs analgesia only	• wound debridement in a hydrotank	• n = 11 • age range = 9-40 years	• significant reductions in GRS mean ratings for worst pain, pain unpleasantness, and time spent thinking about pain with VR	
Hoffman et al., 2019	• within-subject design • within wound care design • condition order randomized • VR + analgesia vs analgesia only	• burn wound cleaning in a hydrotank for at least one session, up to 10 days	• n = 48 • age range = 6-17 years	• significant reductions in GRS worst pain on day 1 with VR (5.10, SD 3.27) vs analgesia only (8.52, SD 1.75)	
Jeffs et al., 2014	• between-subject design • three-arm, randomized controlled trial • standard of care (communication with nurse) vs passive distraction (movie) vs VR distraction	• burn wound care session	• n = 28 • age range = 10-17 years	• VR significantly reduced APPT-WGRS pain scores compared to passive distraction	• SSAIC significant negative correlation between distraction engagement and trait anxiety and procedural pain
Khadra et al., 2018	• within-subject, quasi-experimental design • VR + analgesia	• wound cleaning and debridement in a hydrotank	• n = 15 • age range = 0.9-2.4 years	• low mean FLACC pain scores (2.9, SD 2.8) during procedure	
Khadra et al., 2020	• within-subject design • randomized crossover trial	• wound cleaning and	• n = 38 • age range = 6	• VR significantly (p = 0.026) reduced FLACC procedural	

	• within-wound care design • condition order randomized • 10 mins VR + analgesia vs analgesia only	debridement, and physical exercises in a hydrotank	months – 7 years	pain levels • no significant difference in nurses NRS rating of child's pain	
Kipping et al., 2012	• between-subject design • randomized controlled trial • VR + analgesia vs standard care + analgesia (TV, stories, music, caregivers, or no distraction)	• wound dressing change	• n = 41 • age range = 11-17 years	• lower VAS self-reported and caregiver pain scores in the VR group (not significant) • nurses FLACC pain scores were significantly lower in VR group	
Scapin et al., 2017	• within-subject design • case reports • VR	• wound dressing change	• n = 2 • age range = 8-9 years	• VR reduced pain between study time points	
van Twillert et al., 2007	• within-subject design • randomized controlled trial • condition order randomized • VR + analgesia vs standard care + analgesia (TV, music, conversation, distraction by child life specialist, or no distraction)	• two wound dressing change sessions (2 different days)	• n = 19 • age range = 8-65 years	• VR and TV both significantly reduced VAT pain scores • no significant difference between VR and TV	• SSAIC no significant reduction in anxiety

Note. Not all studies reported on procedural anxiety, hence the empty fields. FPS = Faces Pain Scale; VAT = Visual Analogue Thermometer; VAS = Visual Analogue Scale; GRS = Graphic Rating Scale; APPT-WGRS = Adolescent Pediatric Pain Tool; SSAIC = Spielberger State-Anxiety Inventory for Children; FLACC = Face, Legs, Activity, Cry, Consolability scale; NRS = Numerical Rating Scale

Table 2. Studies Using Virtual Reality during Post-Burn Injury Physiotherapy: Characteristics and Findings

Study Authors	Design	Procedures	Sample Characteristics	Pain	Anxiety
Hoffman et al., 2014	• within-subject design • case study • VR + analgesia vs analgesia only	• range-of-motion exercises for 3 days: (1) analgesia only, (2) VR + analgesia, (3) analgesia only	• n = 1 • age = 11 years	• GRS pain intensity reduced from severely painful during no-VR to moderately painful with VR • GRS moderately unpleasant with no-VR to mildly unpleasant with VR	
Hoffman et al., 2001	• within-subject design • within physiotherapy session design • condition order randomized • VR + analgesia vs analgesia only	• range-of-motion exercises for 3 days	• n = 7 • age range = 9-32 years	• VAS time spent thinking about pain, pain unpleasantness, and worst pain were significantly lower with VR	
Schmitt et al., 2011	• within-subject design • randomized controlled trial • within physiotherapy session design • condition order randomized • VR + analgesia vs analgesia only	• range-of-motion exercises for 1-5 days	• n = 54 • age range = 6-19 years	• significant decrease in GRS pain ratings on day 1 with VR	
Sharar et al., 2007	• within-subject design • randomized controlled trial • condition order randomized • note: data pooled from three studies	• range-of-motion exercises	• n = 88 • age range = 6-65 years	• GRS significant reduction in worst pain, pain unpleasantness, and time spent thinking about pain with VR	

	• VR + analgesia vs analgesia only				
Soltani et al., 2018	• within-subject design • randomized controlled trial • within physiotherapy session design • condition order randomized • VR + analgesia vs analgesia only	• range-of-motion exercises	• n = 39 • age range = 15-66 years	• GRS (100) lower mean scores for worst pain, pain unpleasantness, and time spent thinking about pain with VR	

Note. No studies reported on procedural anxiety, hence the empty fields. VAS = Visual Analogue Scale; GRS = Graphic Rating Scale

Table 3. Studies Using Virtual Reality during Dental Procedures: Characteristics and Findings

Study Authors	Design	Procedures	Sample Characteristics	Outcomes Pain	Anxiety
Asl Aminabadi et al., 2012	• within-subject design • randomized controlled trial • condition order randomized • VR + analgesia vs analgesia only	• during the 2nd and third consecutive restorative treatments	• n = 120 • age range = 4-6 years	• significant decrease in WB-FACES pain perception with VR	• significant decrease in Faces MCDAS state anxiety with VR
Atzori et al., 2018	• within-subject design • randomized trial • condition order randomized • VR + analgesia vs analgesia only	• dental filling or tooth extraction on two different days	• n = 5 • age range = 11-17 years	• significantly lower GRS worst pain and pain unpleasantness ratings with VR	
Koticha et al., 2019	• within-subject design • randomized controlled trial • split-mouth design	• 3 consecutive treatments:	• n = 30 (60 teeth) • age range = 6-		• significant reduction in anxiety according to pulse rate measures, but not

	• VR + anesthesia vs anesthesia only	tooth extraction	10 years		according to children's self reports (Venham's picture test)
Niharika et al., 2018	• within-subject design • randomized controlled crossover trial • group 1: VR + anesthesia, then anesthesia only • group 2: opposite order	• 3 consecutive treatments for pulp therapy	• n = 40 • age range = 4-8 years	• significant decrease in WB-FACES pain perception with VR	• significant decreased in Faces MCDAS state anxiety with VR
Nunna et al., 2019	• between-subject design • randomized interventional clinical trial • VR + anesthesia vs counter stimulation + anesthesia	• pulp therapy or tooth extraction	• n = 70 • age range = 7-11 years	• no significant difference between groups (VAS and WB-FACES)	• significant reduction in anxiety with VR (mean pulse rate and Venham's clinical anxiety rating scale)
Rao et al., 2019	• behavioural interventional study • parallel design • VR + anesthesia	• restorative treatment	• n = 30 • age range = 6-10 years	• significant reduction in WB-FACES and FLACC pain between study timepoints (baseline, during, and after procedure)	• significant reduction in anxiety between study timepoints (pulse rate and oxygen saturation)
Shetty et al., 2019	• between subject design • randomized controlled trial • VR + anesthesia vs anesthesia only	• pulp therapy	• n = 120 • age range = 5-8 years	• significant reduction in WB-FACES pain perception with VR	• significant reduction in MCDAS state anxiety with VR • significant decrease in salivary cortisol levels with VR

Note. Atzori et al. (2018) and Koticha et al. (2019) did not report on procedural anxiety and pain respectively, hence the empty fields. VAS = Visual Analogue Scale; GRS = Graphic Rating Scale; FLACC = Face, Legs, Activity, Cry, Consolability scale; WB-FACES = Wong-Baker FACES scale; MDCAS = Modified Child Dental Anxiety Scale

Table 4. Studies Using Virtual Reality during Cancer-Related Procedures: Characteristics and Findings

Study Authors	Design	Procedures	Sample Characteristics	Pain	Anxiety
Atzori et al., 2018	• within-subject design • condition order randomized • VR vs standard care (non-medical conversation with nurse)	• blood draw or venous access on two different days	• n = 15 • mean age = 10.92 years • diagnosis: onco-hematological disease	• significant reduction in VAS time spent thinking about pain, pain unpleasantness, and worst pain with VR	
Gershon et al., 2003	• case study • ABCA design: • A = no distraction • B = non-VR distraction (VR game on computer) • C = VR distraction	• port access during four consecutive appointments	• n = 1 • age = 8 • diagnosis: acute lymphocytic leukemia	• nurse, parent, and child reported lowest VAS pain rating with VR distraction • lowest CHEOPS observed pain during VR distraction	• nurse and parent reported lowest VAS anxiety rating with VR distraction • child rated lowest VAS anxiety during non-VR distraction • lower pulse rate with VR distraction
Gershon et al., 2004	• between-subject design • three-arm, randomized controlled trial • VR distraction vs non-VR distraction (VR game on computer) vs treatment as usual (no distraction)	• port-access	• n = 59 • age range = 7-19 years • diagnoses: leukemia, lymphoma, and solid mass tumors	• nurses rated significantly lower VAS pain for children in the VR and non-VR distraction groups, but no significant different between VR and non-VR distraction • no significant difference in CHEOPS behavioural pain scores • but, children in the no distraction group exhibited significantly more muscle tension in their torso vs VR and	• significantly lower anxiety (pulse rate) with VR, compared to treatment as usual, but not significantly different to non-VR distraction

				more leg tension vs VR and Non-VR distraction	
Kucher et al., 2020	• interventional study • VR experience	• post-surgery total pancreatectomy islet auto-transplantation	• n = 3 • age range = 8-18 years • diagnoses: pediatric cancers	• net decrease in WB-FACES pain scores after VR	• net decrease in anxiety scores after VR (Novel Nature-based anxiety scale)
Nilsson et al., 2009	• between-subject design • non-randomized mixed-methods trial • VR vs standard care (cold spray or EMLA cream)	• venous puncture or subcutaneous venous port device	• n = 42 • age range = 5-18 years • diagnoses: hematological diseases, leukemia, lymphoma, tumours	• child self-reported CAS and nurse observed FLACC pain scores were lower with VR (but no significant difference)	• no significant differences in pulse rate
Sander Wint et al., 2002	• between subject design • pilot mixed-methods randomized trial • VR + standard care vs standard care only (fentanyl, midazolam, EMLA cream, explanation of procedure, and parental presence)	• lumbar punctures	• n = 30 • age range = 10-19 years • diagnoses: various pediatric cancers	• VAS pain scores were lower in the VR group, but no significant difference • VR was a helpful distractor	
Windich-Biermeier et al., 2007	• between-subject design • mixed-methods randomized trial	• port access or venipuncture	• n = 50 • age range = 5-18 years	• CAS pain scores were not significantly different between groups	• Glasses Fear Scale rating no significant difference in child and parent ratings; significant

	• self-selected distractor + standard care vs standard care only • self-selected distractor: bubbles, I Spy: Super Challenger book, music table, video games, or VR • standard care: explanation of procedure, parental presence, and topical anesthetic		• diagnosis: leukemia	• 12 participants thought the distractor was helpful	difference in nurse ratings
Wolitzky et al., 2005	• between-subject design • randomized controlled trial • VR vs control	• port access procedure	• n = 20 • age range = 7-14 years • diagnoses: pediatric cancers	• VAS pain and anxiety scores were reduced to a distress score • lower VAS distress scores with VR • lower CHEOPS pain scores with VR	• lower VAS distress scores with VR • lower pulse with VR
Wong et al., 2020	• between-subject design • randomized controlled trial • VR + standard care vs standard care only (explanation of procedure and verbal comforting)	• peripheral IV cannulation	• n = 108 • age range = 6-17 years • diagnoses: pediatric cancers	• significant reduction in VAS pain with VR	• significant reduction in anxiety with VR (state anxiety scale for children) • no group difference in pulse rate during procedure

Note. Not all studies reported on procedural anxiety, hence the empty fields. VAS = Visual Analogue Scale; CAS = Colour Analogue Scale; FLACC = Face, Legs, Activity, Cry, Consolability scale; CHEOPS = Children's Hospital Of Eastern Ontario Pain Scale; WB-FACES = Wong-Baker FACES scale.

Table 5. Studies Using Virtual Reality during Needle-Related Procedures: Characteristics and Findings

Study Authors	Design	Procedures	Sample Characteristics	Pain	Anxiety
Aydin et al., 2019	• between-subject design • randomized controlled trial • VR vs control	• blood draw	• n = 120 • age range = 9-12 years	• VAS and Wong-Baker FACES pain scores significantly lower in the VR group	
Caruso et al., 2020	• between-subject design • randomized controlled trial • VR vs standard care (nonprocedural talk and coaching, television/movies, and CCLS consultation)	• vascular access	• n = 220 • age range = 2-18 years	• no significant difference between groups in FPS-R pain after the procedure	• no significant difference in CFS post-procedure fear
Chad et al., 2018	• interventional study • VR distraction	• immunization	• n =17 • age > 6 years (except for two participants)	• anticipated and actual Wong-Baker FACES pain was reduced in 94.1% of participants	• anticipated and actual CFS fear was reduced in 94.1% of participants
Chan et al., 2019	• report 2 between-subject, randomized controlled trials with qualitative feedback • VR vs standard care (age-appropriate distraction, such as child-life therapy, toys, books, and electronic devices)	• venipuncture or cannulation in the emergency department (ED) and pathology unit	• N = 264 • ED: n = 123 • pathology unit: n = 131 • age range = 4-11 years	• ED: significant decrease in FPS-R pain in VR group • pathology unit: the increase in FPS-R pain from baseline was significantly less in VR group • qualitative feedback consistent	• ED and pathology units: significant decrease in VAT anxiety VR group
Chau et	• retrospective chart review	• Botox injections	• n = 14	• FLACC behavioural pain	

al., 2018	• VR distraction		• age range = 4-13 years	scores ranged from 1-10 out of 10	
Chen et al., 2020	• between-subject design • randomized controlled trial • VR vs standard care (children comforted verbally)	• intravenous injections in the ED	• n = 136 • age range = 7-12 years	• WB-FACES pain scores were significantly lower in the VR group (child, parent, and nurse ratings)	FS fear scores were significantly lower in the VR group (child, parent, nurse ratings)
Dumoulin et al., 2019	• between-subject design • three-arm, randomized trial • VR vs TV vs distraction by child life specialist (non-procedural talk, I-Spy books, or 20-questions ball)	• venipuncture or blood draw in the ED	• n = 59 • age range = 8-17 years	• significant reduction in VAS pain intensity in VR group, but no significant difference between groups	• significant reduction in VAS fear of pain in VR group compared to other groups
Dunn et al., 2019	• between-subject design • randomized controlled trial • VR vs standard distraction (bubbles, smart devices, videos)	• venipuncture	• n = 25 • age range = 6-18 years	• both VR and standard distractions had a positive influence on procedural pain (modified VAS/FACES scale)	• both VR and standard distractions had a positive influence on procedural anxiety (modified VAS/FACES scale)
Gerceker et al., 2019	• between subject-design • three-arm randomized controlled trial • VR vs control	• blood draw	• n =136 • age range = 5-12 years	• lower WB-FACES pain scores in both VR groups vs control	• significant difference between groups in CAT anxiety and CFS fear scores after the procedure (researcher, parent, child ratings)
Gerceker et al., 2018	• between-subject design • three-arm, randomized controlled trial	• blood draw	• n = 121 • age range = 7-12 years	• significant difference in WB-FACES pain scores between VR group and control only, no	

	• VR vs external cold vibrations vs control			difference between VR and external cold vibrations	
Gold et al., 2006	• between-subject design • randomized controlled trial • VR + topical anesthesia vs topical anesthesia only	• venipuncture	• n = 20 • age range = 7-12 years	• significant increase in FPS-R pain in control group only • no significant difference between groups on affective pain	• no significant difference between groups on VAS anticipatory anxiety
Gold and Mahrer, 2018	• between-subject design • randomized controlled trial • VR vs standard care (TV in patient room)	• blood draw	• n = 143 • age range = 10-21 years	• significant decrease in procedural pain with VR (VAS, CAS, FPS-R)	• significant decrease in procedural anxiety with VR (VAS and FAS)
Goldman et al., 2020	• between-subject design • randomized controlled trial • VR vs standard care (videos, television, iPad, child life specialist)	• intravenous insertions in the ED	• n = 66 • age range = 6-16 years	• FPS-R pain scores were similar between groups	• Venham Situational Anxiety scale anxiety scores were similar between groups
Knight et al., 2020	• between-subject design with 2 equivalent groups • quasi experimental non-randomized trial • VR vs traditional distraction (play specialist, book, game, computer)	• various ED procedures, including cannulation and venipuncture	• n = 40 • age ≥ 5 years	• fewer reactive FLACC pain behaviours observed by staff in the VR group	
Piskorz and Czub, 2018	• between-subject, quasi-experimental study • VR vs control	• blood draw	• n = 38 • age range = 7-17 years	• significantly lower VAS pain intensity in VR group	gnificantly lower VAS stress in VR group

Piskorz et al., 2020	• between-subject, quasi-experimental study • VR vs control	• blood draw	• n = 57 • age range = 7-17 years	• both VR groups had significantly lower VAS pain intensity scores than control • no significant difference between active and passive VR groups, but active VR has greater perceived benefits	• both VR groups had significantly lower VAS stress scores than control
Toledo del Castillo et al., 2019	• between-subject design • observational, analytical prospective cohort study • VR + topical analgesia cream vs topical analgesia cream	• blood draw, venous catheter, or lumbar puncture	• n = 58 • age range = 4-15 years	• significant decrease in WB-FACES or VAS pain scores with VR (healthcare professional, parent, and child ratings)	• significant decrease in CFS anxiety scores with VR (healthcare professional, parent, and child ratings)
Walther-Larsen et al., 2019	• between-subject design • randomized controlled trial • VR + standard care vs standard care only (topical anesthesia, positioning, distraction by nurse)	• venous cannulation	• n = 64 • age range = 7-16 years	• no significant difference in VAS pain scores between groups	

Note. Not all studies reported on procedural anxiety, hence the empty fields. VAS = Visual Analogue Scale; WB-FACES = Wong-Baker FACES scale; FPS-R = Faces Pain Scale-Revised; FLACC = Face, Legs, Activity, Cry, Consolability scale; CAS = Colour Analogue Scale; CAT = Colour Analogue Thermometer; CFS = Child Fear Scale

Table 6. Studies Using Virtual Reality during Pre-Operative Procedures: Characteristics and Findings

Study Authors	Design	Procedures	Sample Characteristics	Anxiety
Gupta et al., 2019	• case report • VR distraction	• distraction during transportation to operating room and anesthetic	• n = 1 • age = 10 years	• patient remained calm, and showed no signs of anxiety or distress

		induction		
Jung et al., 2020	• between-subject design • randomized controlled trial • VR vs standard care (parental presence)	• distraction during anesthetic induction	• n = 71 • age range = 5-18 years	• change in mYPAS pre-operative anxiety scores from baseline to time of induction was significantly lower with VR

Note. mYPAS = modified-Yale Preoperative Anxiety Scale

Table 7. Studies Using Virtual Reality during Other Procedures: Characteristics and Findings

Study Authors	Design	Procedures	Sample Characteristics	Outcomes Pain	Anxiety
Hua et al., 2015	• between-subject design • randomized controlled trial • VR vs standard distraction (VR game on computer)	• dressing changes in children with chronic wounds on lower limbs	• n = 65 • age range = 4-16 years	• significant decrease in pain with VR	• significant decrease in anxiety with VR (and lower pulse rate)
Liu et al., 2020	• between-subject design • randomized controlled trial • VR + topical analgesia vs topical analgesia only	• nasal endoscopy	• n = 53 • age range = 7-17 years	• significant decrease in pain with VR	• significant decrease in anxiety with VR
Steele et al., 2003	• within-subject design • case study • within physiotherapy session design • VR + analgesia vs analgesia only	• post-surgical physiotherapy over 6 days	• n = 1 • age = 16 years	• pain scores were lower in the VR condition	

Note. Steele et al. (2003) did not report on procedural anxiety, hence the empty field.

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CHAPTER III: METHODOLOGY

3.1 Virtual Reality Clinical Outcomes and Research Experts Model

A mixed-methods study, concurrent triangulation feasibility design was piloted at the Shriners Hospitals for Children-Canada® (SHC-C). The study was guided by the VR-CORE model, a three-part methodological framework for the design of VR studies in healthcare (3). This framework was developed by a multi-disciplinary panel of experts in the field of VR development and testing across different clinical expertise. The panel met through an online platform to discuss the current state of VR clinical research, gaps, and improvements. The resulting framework is stratified into three VR trials: VR1, VR2, and VR3. A VR1 trial is conducted to collaboratively devise a VR intervention with the end-users. The results lend insight into VR2 trial, which is an early testing of the VR intervention, focusing on feasibility, acceptability, tolerability, and initial clinical efficacy. Finally, a more definitive and rigorous randomized-controlled VR3 trial is conducted to evaluate the clinical efficacy of the VR intervention.

Prior to this VR2 study, Dr. Hamdy led in-depth, consultations with the healthcare professionals, managers, and decision maker to understand how VR can be used at SHC-C and to delineate the varying medical procedures, which would benefit from VR. These findings (unpublished), along with the in-depth integrative review (Chapter II), helped inform the design of the present study. Meanwhile, Dr. Sylvie Le May led other VR1 and VR2 studies (15, 16) using a rigorously tested, award-winning, VR game called DreamLand® developed locally by Paperplane Therapeutics Inc. (2016). The game was collaboratively developed with end-users to serve as a distraction intervention for pediatric patients undergoing painful or anxiety-inducing medical procedures, and be appropriate for use in a hospital setting. Altogether, this preliminary work fulfilled the VR1 requirements and allowing to design and conduct of a VR2 trial.

3.2 Virtual Reality 2 Trial

The study presented in the second manuscript of this thesis (chapter IV) is a VR2 trial. There are six best practice recommendations for VR2 trials, with the first two suggesting researchers test the VR intervention in the intended clinical setting and targeted population. The long-term goal of the study is to offer a VR intervention to children undergoing painful or

anxiety-inducing medical procedures at the SHC-C. As this hospital specializes in orthopedic and musculoskeletal care, this study was conducted in clinics across the hospital providing treatments to children with such conditions. The last four recommendations for conducting a VR2 trial are VR-specific clinical outcomes, which informed the objectives of the present study: the assessment of the feasibility, acceptability, tolerability, and initial clinical efficacy of the VR intervention. Within each objective, more specific outcome measures are delineated (Table 1). Further, VR2 trials are not meant to definitely test whether a VR intervention is efficacious or effective, however it offers an early opportunity to measure efficacy within the context of a small clinical trial. Hence, our final study objectives were to assess the (1) feasibility, (2) clinical utility, (3) tolerability, and (4) initial clinical efficacy of the use of VR for children undergoing a medical procedure from the perspectives of patients, parents, and healthcare professionals in a pediatric orthopaedic hospital setting.

Table 3.1 Summary of VR2 Trial Best Practice Recommendations for Study Objectives

Best Practice Recommendation	Specific Outcome Measures	Methods Suggested
Feasibility	• identify barriers and facilitators to using VR in clinical setting • dosing or frequency of VR treatment	• interviews with patients and healthcare professionals • observations
Acceptability (clinical utility)	• patient willingness to try VR treatment • reasons for finding the VR treatment acceptable (or not)	• focus groups • cognitive interviews • structured questionnaires
Tolerability	• prevalence of physical and emotional adverse effects of VR treatment (software and hardware) • discomfort or inconvenience related to VR equipment	• Simulator Sickness Questionnaire
Initial Clinical Efficacy	• clinically relevant and validated patient-reported outcomes	• depending on the PRO, use validated instrument measures • measure PROs before and after the VR treatment

3.3 Mixed-Methods Design

Mixed methods research combines quantitative and qualitative data collection and analysis in a single study (17). This design was chosen because as clearly illustrated by the VR-CORE model, both quantitative and qualitative methods are necessary for a rigorous investigation of a VR2 trial and fulfils a void in the literature where often studies only test using quantitative data sources. The quantitative and qualitative data were collected concurrently in one phase. As such, no priority was given to quantitative or qualitative data collection or analysis as both were instrumental in answering each objective of the research problem and showcasing the fit of a VR2 trial tailored to the study population and setting.While mixed-methods studies are increasingly popular in healthcare research, many studies fail to integrate the two data sets produced (17). Integration is a crucial step in mixed- methods study, as it is the point where the quantitative and qualitative components of a study interact. Failure to integrate undermines the initial rationale for conducting a mixed-methods study, where the combination of data sets produces a deeper understanding of the research question. As such, a triangulation protocol was followed at the interpretation phase of data analysis to integrate quantitative and qualitative findings (18, 19).

3.4 Data Analysis

The manuscript in chapter IV briefly outlines data analysis methods. Below is a more detailed account of the data analysis approach.

3.4.1 Quantitative Analysis

Descriptive statistics were used to analyze all quantitative data collected using the RStudio statistical software (Version 4.0.2 for Windows). Quantitative data included: sociodemographic and clinical questionnaire, FPS-R (11), FAS (12), GRS for pain (13), Patient and Healthcare Professional Perception Questionnaire (10), and CSSQ (14).

3.4.2 Qualitative Analysis

Semi-structured interviews, fieldnotes, and focus group data were analyzed using directed content analysis (20). The semi-structured interviews and focus group audio-recordings were transcribed verbatim and thoroughly read to familiarize with the data collected. Initially, a deductive approach was used assigning codes on the margins of the

transcripts. The deductive codes were derived from the clinical outcomes outlined by the VR-CORE methodological framework and previous research and were defined both before and during the analysis. Then, inductive codes were assigned to data that did not fit into the existing deductive codes. The generated deductive and inductive codes were collated by clinical outcomes (feasibility, clinical utility, tolerability, and initial clinical efficacy). Redundant codes were clustered together. Themes were identified, with a focus on thematic frequency and patterns of similarities and differences between stakeholder perspectives. Relevant quotes and observations used to support each theme were identified and translated from French to English.

3.4.3 Triangulation Protocol

As mentioned above, a triangulation protocol was followed to integrate the quantitative and qualitative components of the study (19). This resulted in a convergence coding matrix, allowing for the comparison of the findings from the qualitative and quantitative data sources. More details on the triangulation protocol is reported in the manuscript found in chapter IV. Convergence of results from different data sources indicated a strong validity of the finding. Discrepancy of results invited further analysis drawing a final conclusion. Complementarity of results led to a more complete understanding of the research question. When one data source revealed a finding that did not emerge using the other data source, a ‘silence’ code was assigned. This highlighted the importance of using a mixed- methods design to uncover all parts of the research questions.

CHAPTER IV: MIXED-METHODS STUDY MANUSCRIPT

The Use of Virtual Reality During Medical Procedures in a Pediatric Orthopedic Setting: A Mixed-Methods Pilot Feasibility Study

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4.0 ABSTRACT

Purpose: To assess the feasibility, clinical utility, tolerability, and initial clinical efficacy of the use of virtual reality (VR) distraction during medical procedures received by children with chronic and complex musculoskeletal conditions.

Methods: A mixed-methods pilot study, concurrent triangulation design was conducted at a pediatric orthopedic hospital. Quantitative and qualitative data sources were collected from children undergoing a medical procedure, their parents, and healthcare professional. Descriptive statistics and directed content analysis were used to analyze quantitative and qualitative data, respectively. The triangulation protocol ensured to triangulate key findings, producing final meta-themes.

Results: A total of 44 children and their parents undergoing intravenous insertions (n = 30), pin removals (n = 7), blood draws (n = 3), Botox injections (n = 2), dressing change (n = 1), and urodynamic test (n =1) were recruited along with 11 healthcare professionals performing the medical procedure. The VR intervention was (1) feasible because VR was easily implemented into the clinical workflow, (2) clinically useful as VR was accepted by stakeholders and easy to use, (3) tolerable as VR caused minimal discomfort, and (4) showed initial clinical efficacy in managing procedural pain and anxiety.

Conclusions: The findings will inform policies and procedures for VR use in practice and a sustainable implementation across the Shriners Healthcare network.

4.1 INTRODUCTION

Medical procedures, such as intravenous insertions or percutaneous pin removals, cause pain and anxiety in children (1, 2). Although preventable, children continue to report high rates of procedural pain in the hospital setting (3). A plethora of evidence for effective pharmacological and non-pharmacological pain interventions exist, however these interventions are underutilized in the clinical setting (3-5). Undertreated procedural pain is associated with anxiety and fear for future medical procedures (6). Further, recalls of painful or anxiety-inducing experiences may lead to patient and family dissatisfaction, emotional stress, and delayed healing (5). The state anxiety that accompanies painful procedures and the negative memories formed during a first painful experience lead to traumatic recalls and exaggerated painful memories (7, 8). A cyclic effect ensues with heightened fear and pain perception during future medical procedures, and avoidance of future healthcare encounters persisting well into adulthood (9).

For children with chronic conditions, who undergo repeated procedures as part of their standard care, they remain at heighten risk of undertreated, procedural pain and anxiety (10). A study comparing the pain perceived during venipuncture in children with and without a chronic condition showed that children with a chronic condition experienced more pain and displayed more signs of behavioural distress (8). These findings contradict some healthcare professionals who believe that repeated pain exposures lead to an increased pain tolerance and lower pain perception (8). Such misconceptions about procedural pain experiences highlight the need for providing feasible and clinically effective pain interventions during routine medical procedures for the care of chronic illnesses.

Distraction is a cognitive intervention that has been introduced in hospitals as a procedural pain and anxiety management tool as it avoids the undesirable side-effects and costs of pharmacological interventions, while also proving a humanistic approach to care. This cognitive tool works by diverting one's attention away from unpleasant stimuli to more enjoyable ones. In the context of medical procedures, distraction tools take the attention away from the procedure and hospital setting, reducing the perception of pain and anxiety. Reviews support the efficacy of various distraction interventions for procedural pain and distress in children and adolescents (3, 4, 11, 12) including the use of virtual reality (VR).

Virtual reality is a powerful and novel form of active and immersive distraction that has

emerged in the healthcare setting. Through a VR headset that conveniently blocks cues from the physical environment, the user experiences a computer-generated virtual world. During a medical procedure, a VR experience diverts the patients' attention away from painful stimuli and immerses them in a pleasant virtual world, thereby decreasing their pain perception (13). Hoffman and colleagues pioneered the use of VR distraction during burn wound care procedures (14). Later, VR distraction use expanded to other painful and anxiety-inducing procedures received by pediatric patients, including post-burn physiotherapy (15-19), dental (20-26), cancer-related (27-36), needle-related (37-54), and pre-operative (55-62) procedures (63). Considering the well-documented link between pain and anxiety, VR has been leveraged as an anxiolytic tool, which may also be used during medical procedures (64, 65).

Despite the growing body of research and evidence for the use of VR distraction during painful and anxiety-inducing medical procedures in children (63), a gap remains in the use of VR distraction in children with complex and chronic musculoskeletal conditions, who undergo routine and repeated medical procedures as part of their long-term care. Before implementing VR at the study site, a pilot feasibility trial must be conducted to ensure key stakeholders will welcome and use the distraction tool. The study purpose was to investigate the feasibility,clinical utility, tolerability, and initial clinical efficacy of using VR with children undergoing a medical procedure.

4.2 METHODS

4.1.1 Study Design and Setting

Following ethical approval from the institutional review board (A06-M31-19B), a mixed-methods, concurrent triangulation study was piloted at a university-affiliated, non-for-profit, pediatric orthopaedic hospital located in Montreal, Quebec. The study was guided by the Virtual Reality-Clinical Outcomes Research Experts (VR-CORE) methodological framework (66). The selected design permitted the concurrent, one-phase collection and analysis of different quantitative and qualitative data sources (67).

4.2.2 Participants

Convenience sampling techniques were used to prospectively recruit participants working (n = 8-12), or seeking healthcare (n = 44), in the varying clinics at the study site. Participants included key stakeholders in VR use: children, their parents/caregivers, and healthcare professionals (HCPs). Children were included in the study if they: (1) were between the ages of 5

and 21 years old, (2) had a scheduled medical procedure (i.e., pin removals, cast changes, dressing changes, pressure ulcer debridement, intravenous insertions, blood draws, staples removal, installation of traction, or urodynamic test), and (3) were fluent in French or English.

Children were excluded if they had a cognitive, auditory, or visual impairment preventing them from using VR, had an epilepsy diagnosis, or if they were unable to sit semi-upright during their medical procedure. HCPs were included if they performed or supported the child participant undergoing a medical procedure. Not all parents remain present during medical procedures; thus, parent participation was not mandatory. Parents, whose child participated in the study, were invited to share their perspective. The sample size estimate range of 10 to 40 was justified based on the VR-CORE Model (66), prior studies with similar designs, and different data sources proposed to be collected.

4.2.3 Study Procedures & Data Collection

The HCPs helped identify potential eligible participants according to a printed study information sheet provided by the research team. With the families' permission, a member of the research team explained the study, and if agreeable, obtained informed consent and/or assent. Baseline sociodemographic and clinical information were subsequently collected using hospital charts and patient/parent reports. Then, baseline patient-reported pain and anxiety was collected using the FACES Pain Scale-Revised (FPS-R) (68) and FACES Anxiety Scale (FAS) (69) for children, respectively. Children were asked to report on their baseline simulator sickness prior to using VR, using the Child Simulator Sickness Questionnaire (CSSQ) (70). The VR intervention was explained, and the headset was fitted to the child, ensuring they could clearly see the depicted VR world. Children were instructed to move their head to aim at the objects depicted in the VR game (e.g. red balloons, yellow diamonds, and purple trolls) and to press on the controller to shoot.

Each child had about five minutes of immersive play before the HCP could start the medical procedure (conducted as per standard hospital protocol). Throughout the VR intervention, the researcher remained on stand-by for the child and HCP, answered any questions, troubleshooted, and recorded the observations and fieldnotes. When possible, direct quotes were transcribed verbatim. Children played the VR game for the duration of the medical procedure, unless they voluntarily removed the VR headset or requested to stop the VR intervention.

Following the medical procedure, the VR headset was removed, and the equipment was disinfected using alcohol wipes available at each clinic. Post-intervention outcomes were then collected immediately after the medical procedure and included the same baseline outcome measures (i.e. the CSSQ, FPS-R, FAS) followed by the Graphic Rating Scale (GRS) for pain (17), and Patient Perception Questionnaire (71). Then, children and their parents participated in short, audio-recorded semi-structured interviews. HCPs filled out a perception questionnaire (71) after each medical procedure conducted with the use of VR and debriefed with the researcher. A mid-study focus group discussion was conducted with the HCPs to review their experience, questions, or concerns with the use of VR in their clinic. Notes from the discussions were summarized on the data collection form with the help of transcribed audio-recordings.

4.2.4 Instruments

Patient Sociodemographic and Clinical Questionnaire

Children's age, sex, date of birth, race/ethnicity, medical diagnosis, and scheduled medical procedure were collected. Pain and anxiety medications taken prior to the medical procedure or as part of the standard procedures were noted.

FACES Pain Scale-Revised

The FACES Pain Scale-Revised is a 1-item self-report measure of pain intensity that may be used in children aged four and above (68). The scale has six faces placed on a scoring metric (0 to 10), showing different levels of pain intensity ranging from someone that feels 'no pain' (0) to someone that feels 'very much pain' (10). The FPS-R is recommended for use in research due to its utility and psychometric features. Moreover, studies have showed that the FPS-R is responsive to pain-increasing events, such as medical procedures, and pain-decreasing events, such as the use of VR (72).

The FACES Anxiety Scale (FAS) for Children

The FACES Anxiety Scale for Children is a 1-item self-report measure of state anxiety (69) scored from 1 to 5. The scale shows five faces with increasing levels of anxiety, with the first face showing no anxiety (a score of 1) and the last face showing extreme anxiety (a score of 5). Patients were instructed to rate their anxiety level. If they did not understand what anxiety meant, they were asked how scarred they were of and during the medical procedure. This alternate, more developmentally appropriate language for younger children is used in the Child

Fear Scale developed by McMurtry et al. (2011), which is an adaptation of the FAS.

Graphic Rating Scale for Multidimensional Pain Assessment

The Graphic Rating Scale (GRS) (17) is a self-report measure of fun, nausea, and three subjective pain dimensions consisting of cognitive ('time spent thinking about pain'), affective ('pain unpleasantness') and sensory ('worst pain'). Each item is rated on a 10cm line, with a scoring metric ranging from 0 to 10. Along the line, descriptive markers are added, such as 'mild,' 'moderate,' and 'severe' to help participants make the appropriate self-assessment.

Child Simulator Sickness Questionnaire

A 7-item questionnaire developed by Hoeft et al. (2003) was used to assess the presence of cybersickness (70). The items are grouped into three symptom categories: (1) nausea, (2) oculomotor, and (3) disorientation. A score of three or greater, in any one of the three categories, signals the presence of simulator sickness.

Patient Perception Questionnaire

A 5-item questionnaire modified from Ford et al. (2018) was used to assess patients' perception and satisfaction with the VR intervention. Each item is scored on a 4-point Likert scale.

HCP Perception Questionnaire

A 5-item questionnaire modified from Ford et al. (2018) was used to assess HCPs' perception of the feasibility of the VR intervention. Each item is scored on a 4-point Likert scale.

4.2.5 Fieldnotes and Interview Guides

Fieldnotes

The fieldnotes guide was developed by the research team and reviewed by HCPs prior to use to record observations of key stakeholders during the VR intervention (Supplemental Material). Items notes included the following: (a) removal of VR headset; (b) interruptions to VR treatment; (c) use of pharmacological or non-pharmacological analgesia; (d) barriers and facilitators to VR implementation; (e) stakeholders' attitude toward VR; (f) interactions among HCPs and between HCPs and patients; (g) the impact of VR on clinical workflow; (h) children pain and anxiety cues or request for pharmacological and non-pharmacological analgesics, (i) HCP and parental response to children's pain and anxiety; and (j) reasons for discontinuing the VR intervention. As the VR headset covered part of the children's face, only some of the pain

and anxiety cues were observable.

Semi-Structured Interview Guide

A brief, semi-structured interview guide was developed by the research team and reviewed by HCPs prior to use (Supplemental Material). The questions pertained to the feasibility, clinical utility (including acceptability and ease of use and understanding), and tolerability of the VR treatment from the child and parent perspective. Further, information was gathered on the patients' procedural pain and anxiety experience during the VR intervention.

Focus Group Guide

The guide was developed by the research team to collect data pertaining to the HCPs perception of the VR intervention (Supplemental Material). Questions and topics included: feasibility of using VR during medical procedures, HCP attitudes toward VR, advantages and disadvantages of VR, practicality issues, possible solutions to strategically implement the VR intervention in clinics, medical procedures for which VR was most beneficial (or not), who benefited the most from VR, and ways to improve VR clinical efficacy were discussed to better support HCPs.

4.2.6 Virtual Reality Intervention

Dreamland®, developed by Paperplane Therapeutics, was the selected VR intervention used during medical procedures. Dreamland® is a rigorously developed and tested VR game designed *with* and *for* children undergoing painful and anxiety-inducing medical procedures (Paperplane Therapeutics Inc., 2016). Already, the game had been adapted to meet the needs of the healthcare setting by: (1) reducing the speed to prevent cybersickness, (2) requiring a one hand controller, freeing the other hand for the procedure (e.g. an IV treatment), (3) using head movement only (i.e. no walking) to explore the virtual world. Children could hear background music and special effects every time they scored a

Figure 1. Virtual Reality Systems Used in the Study

point. Throughout the study, two different VR systems were used, the Oculus Rift and the Oculus Quest (Figure 1). The Oculus Rift, used with the first six participants, consisted of a mobile cart with a monitor and sensors, along with the VR headset and controller. The HCPs and parents could watch the child's interactions on the monitor. The Oculus Quest system was used with the remaining participants, which consisted of the VR headset and controller only controller only.

4.2.7 Data Analysis

Descriptive statistics were used to analyze the sociodemographic and questionnaire data (CSSQ, FPS-R, FAS, and GRS) using the RStudio statistical software (Version 4.0.2 for Windows). Quantitative data analysis led to a list of key findings, which were then compared against qualitative findings during the interpretation phase using triangulation. Directed content analysis was used to analyze qualitative data transcripts using initially a deductive approach followed by inductive coding (73). The generated codes were grouped according to the study objectives, derived from the VR-CORE clinical outcomes (66). Themes were then identified, with a focus on thematic frequency and patterns of similarities and differences between different stakeholder perspectives. Quotes and observations were extracted from the data to support each theme.

Following the separate analysis of quantitative and qualitative data, the triangulation protocol ensued to integrate all key findings (74). This resulted in the creation of three convergence coding matrix, allowing for the comparison of quantitative and qualitative key findings for each study objective. Finally, meta-themes that cut across quantitative and qualitative data were identified while maintaining the three-stakeholder structure, and when necessary meta-themes were broken down into sub-themes. Quantitative and qualitative findings were presented together under meta-themes as supporting or conflicting evidence in the results and discussion sections, providing a rich and thorough interpretation of the findings.

4.3 RESULTS

4.3.1 Sample Characteristics

In total, 47 eligible children were approached for study participation and 44 children consented and/or assented to participate in the study, for a participation rate of 94% (Figure 2. CONSORT Flow Diagram). Twenty-six children's parents shared their perception of VR during the semi-structured interviews. Children's age ranged from 5 to 21 years old, with a mean age of

11.95 years old (SD = 4.18). There was an equal number of male (n = 22) and female (n =22) participants (Table 1). The sample was diverse in medical diagnoses (n = 12) with the majority of participants diagnosed with osteogenesis imperfecta (OI; n = 30; 68.18%). Seven medical procedures were performed by either nurses or physicians, with at least one nurse present at all times and the majority of procedures were intravenous insertions (n = 30; 68.18%). Intervention adherence is summarized in Figure 2, and despite completion, discontinuation, or delayed use of the VR intervention, all study participants were included in the data analysis.

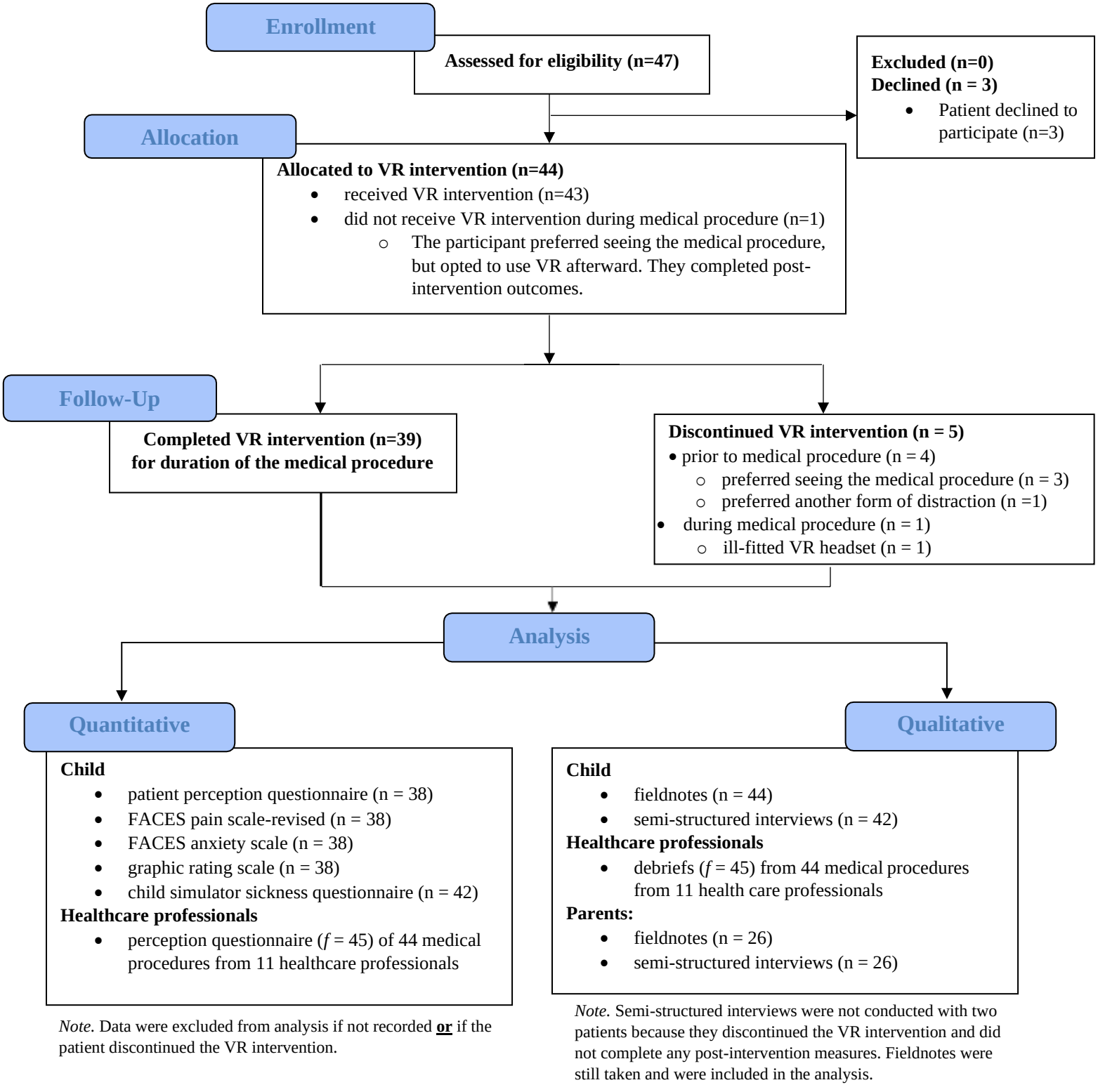
Eleven HCPs performed or assisted with a medical procedure during the VR intervention. The majority of these medical procedures (*f* = 27/44) were performed by one nurse (HCP1) in the Medical Day Center. However, 10 other HCPs conducted or assisted other medical procedures during VR distraction in a variety of clinics across the study site (Table 2).

Table 1. Sample Characteristics

N = 44	
Age (years)	
Mean	11.95
Standard deviation	4.18
Range	5-21
Sex (%)	
Male	22 (50)
Female	22 (50)
Race/Ethnicity (%)	
African American	3 (6.82)
Asian	1 (2.27)
Caucasian	37 (84.09)
Hispanic/Latino	1 (2.27)
Unknown	2 (4.55)
Medical Diagnosis (%)	
Bilateral club feet	1 (2.27)
Cerebral Palsy	1 (2.27)
Charcot Marie Tooth	4 (9.09)
Duchenne's Muscular Dystrophy	1 (2.27)
Joint Stiffness of the knee	1 (2.27)
Leg Length Discrepancy	1 (2.27)
Legg-Calve-Perthes Disease	1 (2.27)
Osteogenesis Imperfecta	30 (68.18)
Osteoporosis	1 (2.27)
Neurofibromatosis	1 (2.27)
Spina Bifida	1 (2.27)
Syndrome Aicardi-Goutieres	1 (2.27)
Medical Procedure (%)	
Blood draw	3 (6.82)
Botox injections	2 (4.55)
Dressing change	1 (2.27)
Intravenous injection	30 (68.18)
Pin removal	7 (15.91)
Urodynamics	1 (2.27)

Note. The majority of IV procedures were performed on children with osteogenesis imperfecta (n = 29). While all children were included in the qualitative analysis, only 38 children were included in the quantitative analysis due to incompletion of study questionnaires or discontinuation of VR intervention.

Figure 2. CONSORT Flow Diagram



Note. Data were excluded from analysis if not recorded **or** if the patient discontinued the VR intervention.

Note. Semi-structured interviews were not conducted with two patients because they discontinued the VR intervention and did not complete any post-intervention measures. Fieldnotes were still taken and were included in the analysis.

Table 2. Healthcare Professionals Characteristics

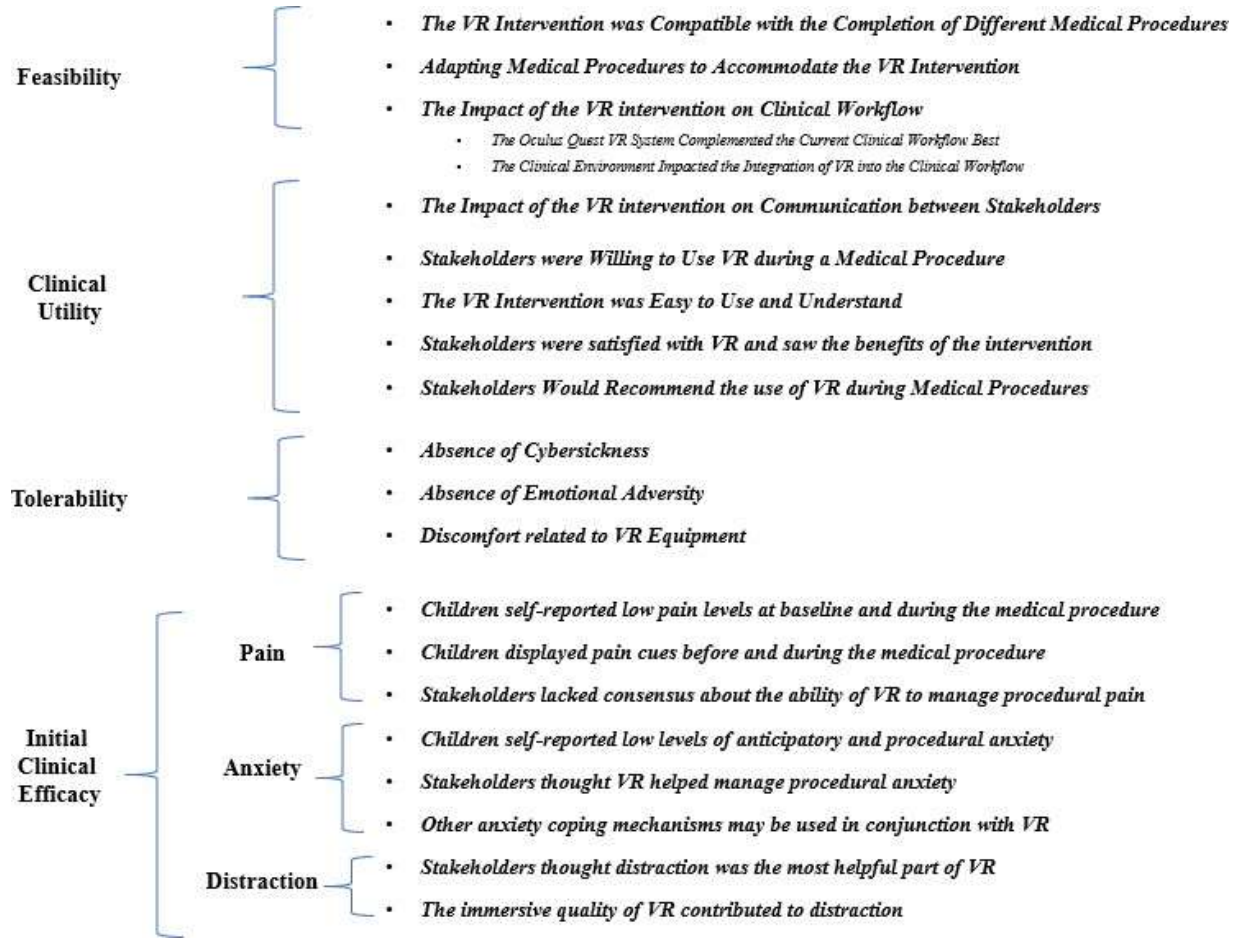
HCPs	Position	Practice Location	# Procedures Completed	Types of Procedures Completed
HCP1	Nurse	Medical Day Center	27	IV treatment Blood draw
HCP2	Nurse	Cast Room and Medical Day Center	8	Pin removal IV treatment
HCP3	Nurse	Cast Room and Inpatient Clinic	2	Pin removal Dressing change
HCP4	Child Life Specialist	Medical Day Center and Outpatient Clinic	3	IV treatment Botox Injections
HCP5	Nurse	Inpatient Clinic	1	Blood draw
HCP6	Nurse	Medical Day Center	3	IV treatment
HCP7	Nurse	Cast Room	2	Pin removal
HCP8	Nurse	Outpatient Clinic	1	Botox injection
HCP9	Doctor	Outpatient Clinic	1	Botox injection
HCP10	Nurse	Outpatient Clinic	1	Urodynamic test
HCP11	Nurse	Inpatient Clinic	1	IV treatment

Note. HCP = Healthcare professional. Some procedures required more than one HCP.

The Feasibility, Clinical Utility, Tolerability, and Initial Clinical Efficacy of the Use of Virtual Reality During Medical Procedures

Guided by the VR-CORE Model framework (66), the following VR clinical outcomes were identified: feasibility, clinical utility, tolerability, and initial clinical efficacy. Each outcome was further analyzed and organized into meta-themes and sub-themes, summarized in Figure 3.

Figure 3. Summary of Meta-Themes and Sub-Themes



4.3.1 Feasibility

Fieldnotes of stakeholder observations, HCP debriefs, and completed HCP Perception Questionnaires revealed information regarding the feasibility of implementing a VR intervention during medical procedures in varying clinics at the study site. This generated the following meta-themes:

The VR Intervention was Compatible with the Completion of Different Medical Procedures

Overall, HCPs perceived the VR intervention as being feasible because VR was compatible with the seven medical procedures performed. Results from the HCP Perception Questionnaire show that the majority of the time (*f* = 41 procedures, 91%), HCPs reported that VR did not interfere at all with their ability to complete the medical procedure (Table 3). There were only two instances where the VR intervention interfered "a little bit" with patient care (Table 3). Qualitative observations and semi-structured interviews revealed that some children (n =5) thought the VR headset was too big or heavy (VRF-11, 31, 33, 34, and 37) requiring readjustment (VRF-11, 31, and 34) or removal of the headset altogether (VRF-33 and 37). Despite causing interruptions to care, no HCPs reported that an ill-fitted VR headset interfered with their ability to complete a medical procedure.

Adapting Medical Procedures to Accommodate the VR Intervention

The VR game was possible to play during all the procedures studied. In some rare cases, HCPs adapted their medical procedure to accommodate the restrictive position imposed by the VR intervention (Table 3). For instance, a doctor administering Botox injections to one patient (VRF-32) would have preferred for the patient to be lying down for the procedure. Since lying down was not possible with VR, the doctor adapted the procedure, indicating the VR intervention only interfered "a little bit" with her ability to complete patient care. Another example occurred during a urodynamics test, where the child had to lie down to maintain proper bladder pressure (VRF-40). To simultaneously accommodate the medical procedure and VR, a pillow was placed behind the participant's head to improve her field-of-view (Table 3). Finally, a HCP asked a child receiving a zoledronate IV treatment (VRF-34) to keep her arm still while playing the VR game, as she was getting excited, making the medical procedure more challenging to complete.

Table 3. Healthcare Professional Perceptions of the VR Intervention Feasibility (*f* = 45).

Healthcare Professional Perception Questionnaire Items	Mean (SD)	Observations or Quotes
1. From your perspective, how much did the virtual reality experience distract the patient during the medical procedure?	2.51 (0.87)	HCPs agreed that VR distracted their patients, however it was less effective when the patient had past traumatic experiences related to the procedure.
2. From your perspective, how much did the virtual reality experience help decrease your patient's pain and distress during the procedure?	2.44 (1.01)	HCPs graded the ability of VR to reduce their patient's pain primarily based on overt pain cues from their patients.
3. Did the patient's use of virtual reality interfere with your ability to complete your patient's care?	0.18 (0.65)	One HCP said the VR interfered 'a lot' with their ability to complete patient care (VRF-01). The bulky Oculus Rift VR equipment used in a small private room may have interfered with the completion of care. An anxious patient (VRF-14) that "kept moving a lot" explained interference with completion of care in one case. VR requires the patient to be sitting at least semi-upright in order to have a full field-of-view. At times, this limitation interfered a little bit with the completion of care: (1) Botox injections (VRF-32) and (2) urodynamics test (VRF-40). HCPs accommodated their standard procedure for VR.
4. Overall, if it were an option, would you recommend using virtual reality for this particular patient for future care?	2.58 (0.81)	HCPs were less likely to recommend VR to patients that were very anxious or older.
5. Overall, how satisfied were you in using virtual reality for this particular patient?	2.64 (0.77)	Overall, HCPs were very satisfied with the VR intervention and were especially pleased with its distracting and immersive quality.

Note. A total of 45 questionnaires were filled out by healthcare professionals (n = 11). Each item is scored from 0 to 3. HCP = healthcare professional.

The Impact of the VR intervention on Clinical Workflow

The Oculus Quest VR System Complemented the Current Clinical Workflow Best

The length of the VR intervention, from set up to clean up, was on average 12.65 minutes (SD = 7.15 minutes) (Table 4). The VR play time was an average of 9.37 minutes (SD = 6.65 minutes). The type of medical procedure and children's voluntary decision to stop VR impacted the total length of the VR intervention (Table 4). Overall, there were no complaints from any child regarding the length of the VR intervention. However, the Oculus Quest was more feasible than the Oculus Rift, as it took less time to set up (mean = 1.32 minutes; SD = 0.75 minutes) and disinfect and store away (mean = 1.05 minutes; SD = 0.23 minutes) the equipment (Table 4). This time difference was especially noted during back-to-back use of the Oculus Rift VR, limiting the availability of VR to all children receiving care at the study site. The Oculus Quest system was more easily implemented into the clinical setting as it consumed minimal clinical time.

The Clinical Environment Impacted the Integration of VR into the Clinical Workflow

The clinical environment impacted the successful implementation of the VR intervention within the usual flow of care. In a busy clinic, with up to four patients present, HCPs were observed prioritizing the completion of medical procedures efficiently over the quality of the VR intervention. One HCP shared, "the only thing I am concerned with is, in the future it [VR intervention] has to be very simple" or else nurses will be reluctant to use VR during busy clinics. An environment that was not conducive to research and VR procedures, lead to reduced pre-procedure VR play time for patients, and ineffective distraction from the painful or anxiety-inducing procedure. This was observed during a pin removal procedure on a busy day, where nurses proceeded with the procedure without allowing pre-procedure play. The child's display of overt pain, reminded the nurses that giving sufficient VR play time for immersion was necessary for VR to work. Similarly, another child explained that with more pre-procedure VR play time, she would have better understood the game and likely not removed the VR headset (VRF-14).

Table 4. Descriptive Statistics and Qualitative Analysis Comparing the Feasibility of VR Systems (n = 43).

Time (minutes)	Oculus Rift	Oculus Quest	Overall
Mean Set up time	6.50 (5.13)	1.32 (0.75)	2.05 (2.63)
Observations	• Oculus Rift: the computer must be plugged in and turned on after each use, causing a bottleneck in the workflow. • Oculus Quest: ready for immediate use, facilitating integration into clinical workflow. Resetting the field-of-view was a technical issue, however this was quickly resolved. • Overall, the Oculus Quest was more feasible for use as it was more easily integrated into the current clinical workflow.		
Mean VR intervention time	9.50 (6.66)	9.35 (6.75)	9.37 (6.65)
Observations	• The intervention was cut short with some patients (n = 6) whom discontinued VR during their medical procedure, due to technological anxiety, procedural anxiety, or VR headset discomfort. • The VR system did not impact the length of the intervention.		
Mean Clean up time	2.14 (1.46)	1.05 (0.23)	1.23 (0.72)
Observations	• Oculus Rift: must be turned off, unplugged, disinfected, and organized back onto the cart before using it in another location. This consumed too much clinical time, and was an obstacle when VR was needed back-to-back with patients in different clinics across the hospital. • Oculus Quest: easily disinfected and packed into its designated compact compartment, and is easily moved across the hospital for use in different clinics. • Overall, the Oculus Quest was more feasible, as it was easily disinfected and taken down, making it rapidly accessible for use by other clinics within the hospital.		
Total time	18.33 (8.26)	11.68 (6.54)	12.65 (7.15)
Observations	• Botox injections and urodynamics procedures took longer than other procedures to complete (24.33 mins ± 13.01 vs 1.24 mins ± 0.73). There were no complaints about the length of VR procedures.		

The Impact of the VR intervention on Communication between Stakeholders

The VR intervention allowed for communication between all stakeholders. Communication was observed to be an integral part of nurses' and doctors' current workflow, as they often checked-in with their patients throughout the procedure while the patient was

immersed in VR, explained what they were doing, or gave instructions. During VR, some children asked questions about the medical procedure or asked HCPs to warn them before starting the procedure, “Can I count down from three. I don’t like surprises” (VRF-13). Moreover, HCPs engaged the patient in the VR game by asking them what they were seeing or encouraging them, “Are you shooting all the purple monsters?” Likewise, children were excited to share with their parents, HCPs, and the researcher what they were seeing in the game. HCPs could still communicate amongst each other to complete patient care together, as seen during procedures requiring more than one HCP, such as IV insertions, Botox injections, and pin removals.

4.3.3 Clinical Utility

Stakeholder observations, perception questionnaires, semi-structured interviews, and focus group data informed the clinical utility of the VR intervention, showcasing acceptability, ease of use and understanding, and satisfaction of VR by all stakeholders. The following meta-themes emerged:

Stakeholders were Willing to Use VR during a Medical Procedure

All children and their accompanying parent were willing to try the VR intervention during their care, regardless of their familiarity with VR. The children wore the VR headset and were seen exploring the virtual game by moving their head around. Parents and clinicians displayed a positive attitude toward VR, engaging in the intervention, asking children to describe what they saw, and encouraging them to score points. Some parents were laughing and taking pictures of their child immersed in the VR game.

There were six cases where the participants were no longer willing to use VR during their medical procedure. One participant, with prior experience with VR outside the hospital, displayed signs of anxiety with his body tensing and seeking maternal comfort before his IV treatment (VRF-39). Before putting on the VR headset, he changed his mind, indicating he was no longer willing to try VR, explaining “I prefer seeing … I just feel more comfortable.” Once the procedure was complete, he asked for the VR headset again. Similarly, four participants (9.09%) tried the VR prior to their intravenous treatment, but then asked to remove the VR headset before the HCP started performing the medical procedure. These children coped with their medical procedure by watching it, and thus VR was a barrier towards their coping

mechanisms. The removal of the VR headset was linked to anxiety, "it [watching the medical procedure] kinda helps my stress so I'm like not 'oh no when is it [*IV insertion*] coming, when is it coming,'" (VRF-11). One patient stopped the VR intervention, choosing to play a videogame they brought to their appointment (VRF-17).

Thirty-seven (97.37%) participants reported on the Patient Perception Questionnaire they were 'likely' or 'very likely' to request the VR intervention again for their next procedure, highlighting their openness to integrating the technology as part of their usual care (Table 5). Similarly, parents asked to have VR available for their child at their next appointment, "I would prefer to you know have this game next time as well. Cause I, I felt like he did much better." One child who reported VR was only 'a little bit' helpful in distracting them and reducing their pain, reported they were 'unlikely' to request VR during their next medical procedure (VRF-37). All HCPs were willing and open to use VR in their clinics. Nurses either set up a regular schedule for VR use in their clinic or called the research team every time they had an eligible patient. One nurse even booked the VR intervention months in advance for a planned urodynamic test. Physicians were also open to using VR during their Botox clinics. The Child Life Specialist facilitated the use of VR and integrated VR in their arsenal of distraction tools for patients. Altogether, these collective efforts showcased HCPs desire to use a novel technology as a means to deliver and improve patient care.

The VR Intervention was Easy to Use and Understand

The majority of children thought the VR equipment was easy to use and the VR game was easy to understand, many describing their VR experience as 'easy' and 'simple'. Regardless of previous experience using VR or age, participants quickly picked up the game. One participant shared, "you just have to figure out where the buttons are at first, and then um … it was really easy. It looks a lot like other videogame controllers, so … I quickly got the gist of it haha." (VRF-38) In rare cases, the ease of use or understanding was affected with complaints of the VR game being too complicated to understand, hard to aim or shoot objects in the game, or the virtual environment moving too fast. In one case, this led to VR headset removal for the remainder of the medical procedure.

Individuals administering the VR intervention encountered no issues related to ease of use or understanding, describing the technology as straightforward. When comparing the two VR

Table 5. Descriptive Statistics and Qualitative Analysis of Patient Perceptions of the Clinical Utility of the VR Intervention (N = 38).

Patient Perception Questionnaire Items	Mean (SD)	Observations/quotes
1. How much did the virtual reality game distract you during your medical procedure?	2.47 (0.73)	The most helpful quality of VR was that it distracted the participants from their medical procedure, "The fact that I have something else to look at is really helpful." (VRF-18). The interactive and immersive aspect of Dreamland® helped with distraction. • "Like I was looking, I was seeing things, I was looking all over the place. … It felt, it felt like, it felt like I was actually moving" (VRF-44). Some patients thought the game was not as distracting because the VR game was too easy or not age-appropriate. • One child (VRF-24) recommended, « there should be more age-appropriate levels, or maybe there shouldn't have purple trolls haha."
2. How much did the virtual reality game help lower your pain during your medical procedure?	1.68 (1.04)	There was no consensus in the ability of VR to reduce procedural pain.
3. Would you ask to play a virtual reality game for your next medical procedure?	2.61 (0.55)	The majority of participants were excited to use VR at their next appointment. Patients who removed the VR headset were still willing to try VR at their next appointment.
4. Would you recommend playing a virtual reality game to another patient like you?	2.81 (0.40)	The majority of patients would recommend the VR intervention to another patient, as they believed anyone could benefit from it. One child explained why, « well yeah because you know if someone is really stressed, VR takes away that stress a lot" (VRF-38)
5. How happy were you with playing the virtual reality game during your medical procedure?	2.70 (0.46)	The majority of patients were satisfied with their VR experience and had fun, but some were not pleased and cried because of pain or an ill-fitted VR headset.

Note. Each item is scored from 0 to 3.

systems used in the study, the Oculus Quest was easier to use because this VR system occupied less space and took less time to set up, and was thus more appropriate and practical in a clinical setting (Table 4).

Stakeholders were satisfied with VR and saw the benefits of the intervention

The majority of children reported being 'happy' or 'very happy' with their VR experience (n = 37, %) (Table 5). Children thought the VR intervention was helpful because itdistracted them 'some' or 'a lot' (n = 33; 86.84%) and reduced their anxiety (Table 5). Participants were especially pleased with the interactive components of Dreamland®, such as shooting the purple troll. Children enjoyed the feeling of being immersed and exploring the virtual world. Parents were grateful that their child was offered the VR intervention, "thankfully we had VR, or else it [medical procedure] would have been a lot harder" (VRF-06).

In some rare cases, children were not as satisfied with the VR intervention. Reasons for dissatisfaction included a lack of engagement in the VR game because it was not age-appropriate or too easy (Table 5). Further, it was unclear whether participants perceived VR to be helpful in reducing their pain, with scores distributed between 'not at all' and 'a lot' (Table 5). Some parents believed VR could have worked better if their child was given more time to get into the game, with one mother sharing, "I think that giving her [the patient] more time to play before … she would have had more time to get into the game. And maybe she wouldn't had – well, I am not saying that she wouldn't of had noticed it [medical procedure] at all- but maybe less" (VRF-24).

Stakeholders Would Recommend the Use of VR during Medical Procedures

Thirty-seven children, including children who removed the VR headset during the medical procedure, reported they were 'likely' or 'very likely' to recommend the VR intervention to another patient (Table 5). Reasons for recommending VR included the distraction and stress-relieving benefits of VR. Similarly, one parent (VRF-31) said that VR could be appropriate for a lot of patients and another recommended the use of VR during other medical procedures. Similarly, the HCPs said they would recommend the VR intervention to their patients again (f = 84.44%) (Table 3). HCPs were less likely to recommend the VR intervention to very anxious or older patients (f = 15.55%) and some suggested more age-appropriate games

(Table 3).

4.3.4 Tolerability

Tolerability was assessed using semi-structured interview and questionnaire data. The following three meta-themes were identified:

Absence of Cybersickness

Before the start of the VR intervention, most participants showed no signs of sickness and the majority (n = 39; 92.86%) scored less than three on the Child Simulator Sickness Questionnaire (CSSQ), indicating no simulator sickness (Table 6). In the event that a participant exhibited simulator sickness as measured by the CSSQ (n = 3), they were given the option to proceed with the intervention, and they all did with no further tolerance issues. No participant experienced simulator sickness during VR and the VR game was tolerable as measured by the CSSQ (Table 6). Nausea was not a prevalent issue, but one patient reported, "It was as if I was on a ride, and I felt a bit nauseous" (VRF-06) and another explained "I felt a bit dizzy cause I was like floating in the sky" (VRF-12). Two children complained of blurry vision.

Table 6. Comparison of Child Simulator Sickness scores before and after the VR intervention (n = 42)

	Pre-VR Intervention n (%)	Post-VR Intervention n (%)
Score < 3	39 (92.86)	42 (100.00)
Score ≥ 3	3 (7.14)	0 (0.00)

Note. A score of ≥ 3 of the CSSQ indicates the presence of simulator sickness.

Absence of Emotional Adversity

The majority of children enjoyed using VR during their medical procedure. Some were familiar with VR, while others were eager to try VR for the first time. Technology anxiety was present in a minority of children (n = 3), but if present, the anxiety led to VR refusal or interruptions, as with one child (VRF-33) who removed the VR headset because she preferred seeing the procedure.

Discomfort related to VR Equipment

The most common tolerance complaint was that the VR headset was ill-fitted, causing discomfort and inconvenience. Six children said the headset was too big or too heavy. They were younger (age range = 5-8 years old) and all diagnosed with OI. This led to the removal of the VR headset and complete cessation of the intervention for two participants (VRF-33 and -37). Other participants proceeded with the intervention but complained that "It [VR headset] was falling down … I had to keep it up myself" (VRF-24), highlighting that an ill-fitted VR headset may reduce intervention quality. Other reasons for removal of VR headset included personal preference, needing to blow nose, itchy eye, and removal of sweaters for procedure.

4.3.5 Initial Clinical Efficacy

Children self-reported low pain levels at baseline and during the medical procedure

Overall, the average pain self-reported by children using the FPS-R at baseline was 0.79 (SD = 1.60) and ranged from zero to six (Table 7). The majority of children (n = 29; 76.32%) reported no pain at all at baseline. Immediately after the medical procedure and VR intervention, children self-reported an average procedural pain of 3.54 (SD = 3.29), ranging from zero to ten. Ten children (26.32%) reported no procedural pain and the remaining 28 children (73.68%) reported an average procedural pain of 3.63 (SD = 2.85).

Table 7. Children's Self-Reported Pain and Anxiety Scores Before and After the Medical Procedure (N = 38)

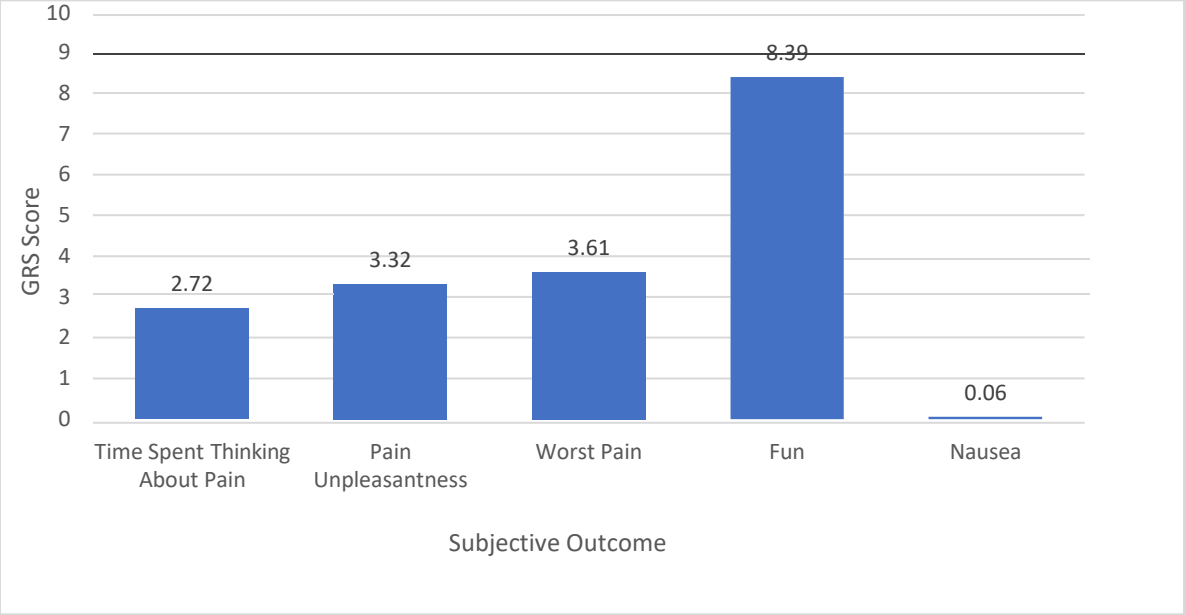
	Mean ± Standard Deviation (Range)
Baseline Pain	0.79 ± 1.60 (0-4)
Procedural Pain	3.54 ± 3.29 (0-10)
Anticipatory Anxiety	2.07 ± 1.03 (1-5)
Procedural Anxiety	1.68 ± 0.93 (1-5)

Note. Pain was measured using the FACES Pain Scale-Revised. Anxiety was measured using the FACES Anxiety Scale.

On average, the worst procedural pain experienced by children was rated as 'mild-to-moderate' (mean = 3.61; SD = 3.35; R = 0-10) and 'mildly unpleasant' (mean = 3.32; SD = 3.46;

R = 0-10) using the GRS (Figure 4). Participants spent 'some of the time' thinking about their procedural pain (mean = 2.72; SD = 2.46; R = 0-10) as measured by the GRS (Figure 4). Despite this, on average children reported having a lot of fun (mean = 8.39 SD = 1.72; R = 3-10) using VR during their procedure, with no nausea (mean = 0.06; SD = 0.32; R = 0-2) as measured by the GRS (Figure 4).

Figure 4. Children's Self-Reported Pain using the Graphic Rating Scale (N= 38) Immediately After their Medical Procedure



Children displayed pain cues before and during the medical procedure

The fieldnotes revealed that the majority of children (n = 30; 68.18%) displayed overt pain cues during their medical procedure. Most often, they verbally expressed their pain (n = 14; 31.82%) by saying "it hurts," or "ouch!" Non-verbal and covert pain expressions were less common but included: uneasiness or tenseness (n = 12;27.27%), facial expression (n = 11; 25.00%), withdrawing (n = 8; 18.18%), and crying or distress (n = 8; 18.18%). Moreover, some children (n = 6) momentarily stopped engagng in the VR intervention during the procedure due to their pain. For example, they stopped moving their head around to explore the virtual world, stopped using the controller, or let go of the controller. During these painful moments, parents comforted their children by patting them on the back, telling them the procedure was almost over, or encouraging them to keep playing the VR game.

Stakeholders lacked consensus about the ability of VR to manage procedural pain

During semi-structured interviews, only four children shared that VR helped reduce their pain, with one child saying that "[VR] took away the pain" (VRF-34). Six children said that VR helped a bit and owed this pain relief to the distraction that VR provided, **"**The fact that I have something else to look at is really helpful" (VRF-18). One child completely disagreed, saying, "No. I still felt everything" (VRF-23). In contrast, the majority of parents and HCPs thought VR was helpful in reducing their child or patient's pain. During the semi-structured interviews, parents recalled their children's past procedures without the VR intervention as a comparison. One set of parents saw their daughter quickly recover from her painful procedure, "She was yelling for a lot less time … I saw that things got better much quicker. That's right because the last time she got her pins removed, she was in pain for a long time!" (VRF-24). Only one parent disagreed, saying they preferred pharmacological interventions during their daughter's urodynamic tests (VRF-40). Further, HCPs thought the VR intervention helped reduced their patient's pain the majority of the time, except when patients displayed overt pain cues, such as crying or distress, screaming, agitation, and withdrawing during various procedures.

Children self-reported low levels of anticipatory and procedural anxiety

Children self-reported an average anticipatory anxiety of 2.07 (SD = 1.03) using the FAS prior to the medical procedure with the scores ranging from 1 (no anxiety) to 5 (extreme anxiety) (Table 7). Most children felt anticipatory anxiety (n = 26; 68.42%), and of those children, the average anticipatory anxiety reported was 2.56 (SD = 0.88). Immediately following the medical procedure and VR intervention, children self-reported a procedural anxiety average of 1.68 using the FAS (SD = 0.93; R = 1-5). About half of children (n = 20; 52.63%) reported no procedural anxiety at all. The remaining 18 children (n = 18; 47.37%) rated their procedural anxiety on average as 2.44 (SD = 0.86) as measured by the FAS.

Stakeholders thought VR helped manage procedural anxiety

Children's low self-reported levels of procedural anxiety was further supported by children's verbal reports, mainly speaking of reduced 'stress' or 'nerves' during the VR intervention. As one child explained, "Well it [VR] helps reduce stress" (VRF-02) and "It [VR] takes away a lot of the stress" (VRF-38). This was concurred by parents who noticed their child was more relaxed and less stressed compared to previous appointments without the VR

intervention, “Yeah, she would normally be like that [pointing to her other child crying]” (VRF-28) and “I didn’t think she would be this calm” (VRF-16). Some children said that the distraction of VR also helped with their anxiety, “Well it [VR] reduces stress and it [VR] is very distracting” (VRF-08). Parents agreed that having VR to focus on instead of the procedure helped reduce their child’s anxiety. One parent explained that despite his son being apprehensive, VR helped mitigate the anxiety, “Well I think it [VR] helped a lot because usually he has a lot of apprehension towards medical procedures … he’s been thinking about it for 2-3 days. Even earlier he didn’t want to do it [pin removal procedure], so thankfully now we have VR or else it would have been harder” (VRF-06).

Other anxiety coping mechanisms may be used in conjunction with VR

Despite overall reporting low levels of anxiety, the majority of children (n = 30; 68.18%) displayed some overt signs of anxiety before and during the medical procedure. Most often, the anxiety cues observed were covert or non-verbal, and included: uneasiness or tenseness (n = 12; 27.27%), facial expression (n = 11; 25.00%), withdrawing (n = 8; 18.18%), crying or distress (n = 8; 18.18%), and restlessness or agitation (n = 4; 9.09%). Other less common anxiety-related behaviours were observed amongst children and included repeatedly inquiring about the medical procedure during the VR intervention. Some children insisted that the HCP warn them before starting the medical procedure, “Can I count down from three? I don’t like surprises. I find that it hurts me more. When you count down, I feel better.” (VRF-13). Other children removed the VR headset as soon as they felt the HCP start the medical procedure or altogether stopped the VR intervention to see the medical procedure, “It’s not that I don’t like VR. It’s just that I like seeing what is going on” (VRF-11). Another coping mechanism observed was deep breathing and seeking comfort from parents. Some parents however noticed that VR helped calm down their child once the procedure was over, “I would say that right after [the pin removal procedure] she was much calmer, and she got back into the game right away” (VRF-24).

Stakeholders thought distraction was the most helpful part of VR

When asked what was helpful about the VR intervention, most participants mentioned the distractive quality of VR, “It was like in the back of my mind that I was having it [the procedure] but in the front of my mind I was playing the game.” (VRF-12) Children specified that VR helped shift their focus, making them forget about the procedure, “I barely payed attention [to

the IV insertion] because I was so focused on the game … it [VR] really diverts your attention" (VRF-38). Parents concurred, saying that their child focused on the game rather than the procedure, "[He was] less anxious and more distracted with the game instead of focusing on what's going on with his wrist. I think he did much better" (VRF-23). The benefits of distraction were further corroborated by the HCPs, but they also highlighted that VR distraction may not be efficacious if the patient had a past trauma related to the medical procedure. The child life specialist explained for one particular patient, "The patient was extremely anxious upon arrival. She was crying. The patient had experienced a past traumatic experience where she received ten pokes. Therefore, she still remembers her past experience and it was difficult for her to focus on the virtual reality." Another HCP agreed, "the patient started the virtual reality but was too scared and was not able to concentrate on the game." HCPs also realized for the distraction to work, they should allow immersive play time before starting the procedure, "it [VR] didn't work, probably because we started the procedure too quickly and the patient didn't have time to get into it [VR]" (VRF-24).

The immersive quality of VR contributed to distraction

Some participants reported that feeling present in the virtual world helped distract them from their medical procedure. One child explained what he liked most about the VR intervention, "Well I think that overall, it [VR] is immersive." (VRF-38). Similarly, parents also noticed that their children were engaged and immersed in the VR world, "and then he was still looking around, playing the game. He was more distracted" (VRF-25). Other parents agreed, "It was a very good distraction … the fact that he is completely immersed in it…" (VRF-30) and "You could tell she was engaged in the game" (VRF-35). During debriefs with HCPs, they also were impressed with the immersive quality of VR.

4.4 DISCUSSION

This study examined the feasibility, clinical utility, tolerability, and initial clinical efficacy of the use of VR during painful or anxiety-inducing medical procedures received by children with a chronic complex musculoskeletal condition. The results reflect a triad perspective from key stakeholders, showcasing the feasibility of a VR intervention depends on its compatibility with medical procedures, clinical setting, and communication. VR was clinically useful as depicted by stakeholders openly welcoming and requesting VR during care. The VR

intervention did not cause serious adverse effects, but ill-fitted VR equipment reduced tolerability. The majority of children reporting low levels of pain and anxiety both at baseline and during their medical procedure. However, verbal and behavioural expressions of pain and anxiety were prevalent throughout the medical procedures. Finally, stakeholders agreed that distraction was the most beneficial aspect of VR, suggesting a new outcome of the initial clinical efficacy of VR.

4.4.1 Feasibility

The present study showcased that VR was feasible for use during medical procedures because it consumed minimal extra clinical time, did not interfere with the completion or usual flow of care, and allowed for communication. These results are consistent with other VR feasibility studies (15, 27, 30, 44, 65, 71, 75-77). Contrary to our results, some studies reported that VR interventions consume significant clinical time, with some needing 10 minutes to set-up and clean-up the VR equipment (27, 78). However, bulky VR systems tethered to a computer were used in these cases, highlighting that a stand-alone VR system only requiring a VR headset, such as the Oculus Quest used in the present study, saves time and is thus more easily implemented within the clinical workflow (44, 71, 76). While the present study revealed that the VR intervention was compatible with a range of medical procedures in an orthopaedic setting, Mosadeghi et al. (2016) encountered low feasibility with pediatric patients with high illness severity. Similar to Ford et al. (2018), VR did not interfere with the completion or delivery of usual care showcasing the feasibility of introducing VR into practice with excellent partnerships with clinician. Agrawal et al. (2019) reported child life specialists played an important role in facilitating and encouraging the use of VR, which was found in the present study as well. While no other study has described the state of the clinical environment during a VR intervention, a busy clinic may lead to a low-quality intervention due to insufficient immersive play and reduced procedural compliance. Finally, consistent with other studies, the VR intervention allowed for usual patient and healthcare professional communication, allowing patients to set boundaries regarding interventions, such as being warned before the start of the procedure, stopping the intervention, sharing their excitement, or requesting the use of other coping mechanisms (79, 80).

4.4.2 Clinical Utility

Overall, consistent with other studies, the VR intervention was clinically useful during painful and anxiety-inducing medical procedures. All stakeholders deemed VR was acceptable to use during medical care, as seen with their willingness to try and use VR again at their next appointment, as reported elsewhere (27, 44, 71, 75, 79, 80). Similar to other studies, lower acceptability due to high patient anxiety or technology anxiety was observed (29, 71, 77). However, only a minority of our participants (n = 6; 13.64%) refused or discontinued the VR intervention during their medical procedure. Similar to Ford et al. (2018), when VR did not coincide with patient preferences for seeing their medical procedure, patients were less likely to consider VR as a coping tool. Mosadeghi et al. (2016) reported on the digital divide, with younger individuals more willing to use VR, however we found that age was not a factor in VR acceptability. Moreover, consistent with other studies, patients and healthcare professionals were satisfied or happy with the VR intervention and would recommend it to other patients (15, 71, 77, 79, 80). Patients especially enjoyed VR because it was an immersive, interactive, and distracting experience (15, 71, 77, 79, 80). This implies that immersive and interactive VR experiences may provide the optimal environment for patients to forget about their medical procedure. The literature shows that VR is generally easy to use and understand from a patient and researcher standpoint (27, 44, 79). As observed by Birnie et al. (2018), children may find it difficult to aim at virtual objects, however VR is easy to grasp as it is similar to videogames. An ill-fitted VR headset has also been reported to reduce ease of use as it may fall down during the intervention (79), but it was especially marked in our OI sub-sample which characteristically have a smaller stature.

4.4.1 Tolerability

Overall, there were a limited number of physical or emotional adverse events reported by patients during the VR intervention. This may be the result of using a VR game that was specifically designed with reduced speed, thereby decreasing the risk of cybersickness documented in other studies (48, 81). Tolerability issues are inconsistently reported in the literature with some researchers reporting simulator sickness and others finding no issues (27, 77, 79). Consistent with other studies, common tolerability complaints are ill-fitted and heavy VR headsets (77, 79). This may cause discomfort to patients and reduce the quality of the VR intervention.

4.4.4 Pain

Needle-related procedures are common and routine in the pediatric medical setting. While distraction is an effective method to manage needle pain in children (3), due to the more immersive and engaging quality of VR distraction, the researchers hypothesize that VR would be a more efficacious non-pharmacological analgesic (48). VR reduces pain perception by leveraging limited cognitive resources, consuming the majority of conscious attention, thereby diverting one's attention away from painful stimuli (16). However, researchers offer mixed results on the ability of VR to minimize needle-related pain, with some randomized controlled trials comparing VR to standard of care reporting a significant reduction in pain with VR (28, 35-37, 40, 42, 45, 46, 48, 51, 52) and others reporting no statistically significant difference in pain reduction between the VR and standard of care condition (30, 32-34, 38, 44, 47, 49).

Present study findings showcase that the mean self-reported procedural pain was relatively low during the VR intervention. Other studies assessing VR efficacy during needle-related procedures also demonstrated low mean self-reported pain scores, which ranged from 1.40 – 3.6 as measured by the FPS-R (31, 47-49), from 0.70 – 2.70 as measured by the 10-cm Visual Analogue Scale (33, 36, 43, 47, 48, 51-54), and from 1.00 – 3.35 as measured by the Wong-Baker FACES Pain Scale (37, 42, 45-47, 53). While the average pain score reported in the present study was low, scores remained on the higher end compared to other studies. These high scores may be explained by the medical procedures included in the study, such as pin removals (n = 7) and Botox injections (n = 2), and IV insertions with a population known to have challenges with venipuncture (n = 30), which have not been previously tested for VR efficacy. Such procedures may be perceived as more painful and thus may be more feared, leading to increased anticipatory anxiety which may increase the painful experience (82).

Few studies assessed the multidimensional aspects of pain during VR distraction. Children in the present study reported more sensory, affective, and cognitive pain compared to Atzori et al. (2018) who reported lower sensory (mean = 2.00, SD = 1.20), affective (mean = 0.93, SD = 1.16), and cognitive (mean = 1.33; SD = 1.05) pain during venipuncture in children. Two studies assessed affective pain during a needle-related procedure, defined as the worry and bother related to pain, and reported lower affective pain levels (47, 48). Similar to other studies, parents and healthcare professionals reported being satisfied with the VR intervention (40, 47,

48, 83). Further, even when children reported high levels of pain, their healthcare professional rated low pain levels during the VR intervention (30, 32). On the contrary, in some studies there was no difference in parents or nurses' ratings of their child or patient's pain between the VR and standard of care conditions (43, 44, 47).

4.4.5 Anxiety

There is a well-established link between anxiety and pain perception (84). In the context of medical procedures, anticipatory anxiety leads to greater pain perception (82). Effective distraction, such as virtual reality, can reduce anticipatory anxiety for a painful medical procedure and consequently reduce pain perception (3, 16, 85). However, few studies have investigated the efficacy of VR in managing anticipatory and procedural anxiety. Similar to VR efficacy during burn wound care (63), studies investigating the ability of VR in managing anxiety associated with needle-related procedures overall show ambiguous evidence with no conclusive support. The present study demonstrates low levels of anticipatory and procedural anxiety with the VR intervention. Children, parents, and healthcare professionals agreed that VR distraction helped with anxiety management. Other studies investigating VR distraction during needle-related procedures measured both pain-related fear and anticipatory anxiety. Gerceker et al. (2020) reported low mean levels of pain-related fear. However, contrary to the current study, the scores for anxiety prior to the medical procedure were moderate. Similarly, other studies also reporting on anxiety levels prior to the medical procedure revealed moderate scores, using various scales (35, 40, 43). As for procedural anxiety levels, other studies also report similar low scores (30, 31, 36, 37, 40, 45, 48, 49). Piskorz and Czub (2018) and Piskorz et al. (2020) specifically measured stress intensity during the medical procedure and found low stress levels with a VR intervention. Other studies measured pain-related fear during the medical procedure and similarly found low scores (34, 42, 43, 45, 53).

Children's procedural pain and anxiety experiences

A systematic review of children's experiences of acute procedural pain revealed that children can express their pain and use a variety of cognitive/behavioural and sensory/physical coping strategies to cope with their pain (86). In the present study, children verbally communicated their pain by using 'pain words' such as "ouch!" and "it hurts!". Further, children exhibited behaviours indicative of a psychological dimension to their pain, such as fear through

withdrawal of their arm or legs and tensing their posture in anticipation of pain. Similar observations were reported in Nilsson et al. (2009), however observational pain scores remained low overall. Chan et al. (2019) reported that children distracted by a VR intervention were seen withdrawing their arms when attempting venipuncture, and some children experienced some anxiety when first putting on the VR headset, but then settled into the distraction. Two studies using the Children Hospitals of Eastern Ontario Pain Scale to measure behavioural pain found higher scores in the standard of care group compared to the VR group, with one study specifying significantly more tension in the torso and legs (30, 35). Similar pain behaviours were reported in the present study. Windich-Biermeier et al. (2007) measured behavioural distress before, during, and after venipuncture/port-access using the Observation Scale of Behavioural Distress, and scores remained low throughout all timepoints.

Children's previous experience with pain influences their current expectation of pain during a medical procedure (86). This was observed in children with past traumatic experiences with a painful medical procedure who were fearful and anxious of the upcoming painful event and rated their perceived procedural pain high. Children may also rely on their parents or healthcare professional to help them get through a painful or anxiety-inducing experience (86, 87). This was observed with some children who sought comfort from their parents, remained physically close to them, or were communicating with them throughout the medical procedure. Children need to feel secure and have a sense of control before being effectively distracted (86, 87). For example, children were observed setting boundaries with their nurse for their medical procedure and VR intervention, such as warnings and once a sense of trust was established, children were more at ease and able to engage with the VR distraction. Similarly, when investigating the efficacy of VR during burn wound care with children, Ford et al. (2018) found that children want to voluntarily use VR and need to feel secure to stop the intervention at any time by openly communicating with healthcare professionals. In the present study, when children felt a lack of control over their procedure, some momentarily removed their VR headset to see their procedure, while others permanently removed their VR headset for the remainder of their procedure to attentively observe the procedure. Instead of distracting them, VR increased their anticipatory anxiety. This coping behaviour was also seen in other studies using VR during needle-related procedures with children (40, 44-46).

4.4.6 Distraction

Distraction emerged as a recurring theme in the qualitative data. Studies investigating the underlying mechanism for VR pain and anxiety relief point to the ability of VR in shifting one's attention away from unpleasant stimuli to the virtual world (13, 16). In this respect, the distraction provided by VR seems to mediate subjective pain and anxiety during medical procedures. In the present study, the majority of children said the most beneficial part of their VR experience when undergoing a medical procedure was distraction. Parents and healthcare professionals concurred saying distraction made the procedure easier for their child or patient than previous times. This is consistent with findings from other studies investigating the use of VR during needle-related procedures (32, 34, 44, 48, 52). Similar to our study findings, children and their parents said VR was able to take their mind off the procedure. Some studies found that distraction was associated with significant reductions of pain and anxiety (40, 44, 48, 52).

4.4.7 Clinical Implications

The use of VR in hospitals should be guided by policies and procedures based on research findings. One healthcare professional should coordinate VR use and assess where VR might be beneficial. As child life specialists already offer distraction and coping tools to patients, they would be the ideal lead. The clinical environment should be scanned for feasibility of the VR intervention, considering space and time resources depending on the VR system used. VR should be presented as one possible coping tool for procedural pain and anxiety. If a patient has a known history of anxiety or past traumatic experiences relating to medical procedures, the healthcare professional should assess whether VR would benefit the patient or cause more anxiety. As observed in this study, when experiencing procedural pain or anxiety while using VR, children may stop engaging with VR. Healthcare professionals should be able to identify pain and anxiety cues specific to VR, including reduced activity and movement of the head and hands, and letting go of VR equipment. Further, the timepoint at which the patient would like to use VR should also be discussed, as some patient may only benefit from using VR before, during, and/or after their medical procedure. A communication plan should be outlined, taking into consideration whether the patient prefers step-by-step explanations of the medical procedure, warnings before inserting a needle, check-ins, or complete immersion in the VR intervention. Finally, proper fit of the VR headset is essential for a smooth and tolerable

intervention with no interruptions to the completion of care.

4.4.8 Recommendations for Future Research

In order to assess the hospital-wide implementation of VR, future studies should continue to examine the feasibility, clinical utility, tolerability, and initial clinical efficacy of the VR intervention with various healthcare professionals, a diverse patient population, and during a variety of medical procedures. These future studies, tailored to the respective settings, would allow for the identification of important considerations and accommodations needed during not as rigorously tested medical procedures, including Botox injections and pin removals. Next studies should examine healthcare professional's acceptability towards administering the VR intervention themselves, without assistance from the researchers. History of anxiety and trauma related to medical procedure should be noted to investigate the feasibility and clinical utility of VR distraction with these patients. Future studies should opt to use VR systems that are mobile and ready for immediate use, to best suit clinical needs and reduce risks for interruptions.

Considering VR pain and anxiety relief is mediated by the distraction quality of VR, future research should use validated scales to measure the level of distraction during a VR intervention. This would shed light on the efficacy of VR distraction compared to passive modes of distraction, and which mode is most clinically effective for procedural pain and anxiety attenuation. Studies, to date, have collected data on distraction and distraction-adjacent factors (e.g. sense of presence, level of engagement, perception of procedure duration, and perceived realism) by using study-specific instruments, such as the Child Presence Scale (48). However, the same tool to measure distraction should be used for generalizability of the findings. Future studies should consider physiological indicators of pain and anxiety to strengthen self-reported and observed data, however more studies should collect qualitative data to describe children's procedural pain and anxiety experiences as these remain contextual and subjective matters.

4.4.8 Strengths & Limitations

The mixed-methods and triangulation study design allowed for the rigorous assessment of the use of VR and for the integration of quantitative and qualitative findings. This produced an enriched understanding of the research question, something that many studies fail to do (67). Further, for the first time, VR was tested for feasibility and initial clinical efficacy during pin removals, Botox injections, and urodynamic tests, which are procedures commonly done at the study site. Finally, this study shares the perspectives of three stakeholders, gaining a holistic

understanding of the feasibility, clinical utility, tolerability and initial clinical efficacy of VR.

The study was conducted at a tertiary pediatric hospital specialized in musculoskeletal care, liming the generalizability of the results. The majority of study participants had an OI diagnosis and underwent a needle-related intervention. While acceptability ratings were high among healthcare professionals, most procedures were completed by one nurse. This may skew the findings as with time and practice, healthcare professionals become more receptive to VR and have better integrated the technology in their clinic. Further, there were no control group to compare the initial efficacy of VR to standard of care procedures. The VR headset occupied part of the children's face, potentially covering some pain and anxiety cues. As such, from the data collected, it is unclear whether VR had any analgesic or anxiolytic effect. A between-subject randomized controlled trial (VR distraction vs standard of care) would demonstrate the clinical efficacy of VR.

5.0 CONCLUSION

Finally, the study showcased that the use of VR distraction is feasible, clinically useful, and tolerable to patients, parents, and healthcare professionals during painful and anxiety-inducing procedures. This early success is in part explained by the compatibility of VR with the medical procedures performed at the study site, an openness from stakeholders to try and adopt new technologies, and the use of a carefully designed VR software to reduce the risk of adverse effects. While children did not perceive VR as an effective pain management tool, they reported that VR helped distract them from their procedure and helped reduced their anxiety. The study contributes to the growing body of evidence for the benefits of VR distraction with children in the hospital setting, adding new descriptive data on VR use during pin removal, Botox injections, and urodynamic tests. Finally, policies and procedures for the use of VR at the study site will be refined to meet institution requirements and ensure patient safety.

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7.0 SUPPLEMENTAL MATERIAL

7.1 Fieldnotes Guide

FEASIBILITY: Implementation Barriers and Facilitators

Barriers/Facilitators	Cause	Solutions
Patient		
Staff		
Technical		
Operational		

Take note of the following:

- Interactions among staff
- Interactions between staff and patient
- Stakeholder's reactions/attitudes towards the VR
- How the VR intervention impacts clinical workflow

7.2 Supplemental Material: Patient Semi-Structured Interview Guide

1. Can you tell us if you have ever played with a VR game before? If so, in what context have you played a VR game? (For fun? During a medical procedure?) What was the VR game?
2. What did you find easy about using the VR game?
3. What did you find hard about using the VR game?
4. What did you find easy to understand about the VR game?
5. What did you find hard to understand about the VR game?
6. What did you like the most about using VR during your medical procedure?
7. What did you like the least about using VR during your medical procedure?
8. What would you change about your experience with VR?
9. Would you be willing to play a VR game again during another painful medical procedure?
10. Did the VR game help you forget about your medical procedure? Did it help you deal with the pain you were feeling or worries you had?
11. Would you recommend playing a VR game to someone else who needs to have a similar medical procedure as you?
12. Do you have any comments or concerns?

7.3 Supplemental Material: Healthcare Professional Focus Group Guide

VR PROVIDER:

1. Can you tell us about your experience administering the VR intervention?
2. What did you find easy about using the VR system?
3. What did you find hard about using the VR system?
4. What did you find easy to understand about the VR system?
5. What did you find hard to understand about the VR system?

HEALTHCARE PROVIDER:

6. How did the VR intervention impact your work (performing the medical procedure)? Did it make it easier? Or harder?
7. Do you think the VR intervention helped your patient feel less pain or less anxious? (potential benefits and outcomes)
8. Would you use a VR intervention again with other patients? If so, for what types of medical procedures do you see VR being useful for?
9. Would you consider implementing VR as a distraction tool into your everyday practice? If so, what would be the best way to integrate VR into your practice? What resources would you need?

EVERYONE:

10. How could we improve the delivery of the VR intervention?
11. Do you value VR as an intervention? Are innovations practical in a hospital setting?
12. Any last comments or concerns?

CHAPTER V: THESIS SUMMARY AND CONCLUSION

This thesis aimed to explore the use of VR technology in pediatric healthcare. A mixed-methods study investigating the feasibility of using VR distraction in children with chronic and complex musculoskeletal conditions undergoing medical procedures at the SHC-C was conducted. The integrative literature review reported on 64 clinical studies using VR distraction during various procedures to manage procedural pain and anxiety, including: burn wound care procedures, post-burn injury physiotherapy, dental procedures, cancer-related procedures, needle-related procedures, and pre-operative procedures. Studies included in the review offered mixed results on the clinical efficacy of VR distraction, however VR equipment or intervention used did not seem to impact the analgesic or anxiolytic effect of VR. The review highlighted a gap in VR distraction clinical research in children with chronic and complex musculoskeletal conditions. This patient population is subjected to routine and post-surgical procedures as part of their long-term care and are thus at risk of undertreated procedural pain and anxiety. Considering the clinical benefits of VR distraction reported in other studies, we desired to provide this tool to patients at the SHC-C by first testing its feasibility, clinical utility, tolerability, and initial clinical efficacy.

The findings of the mixed-methods study revealed that patients, their parents, and healthcare professionals at the SHC-C believe that VR distraction is a feasible, clinically useful, and tolerable tool, and should be available for the management of procedural pain and anxiety. Further, descriptive data on the pain and anxiety experiences of children during VR distraction highlighted that all stakeholders saw the initial clinical value and benefits of VR. The results of the study presented in this thesis will guide the creation of policies and procedures for VR use at the SHC-C. Finally, following the next step of the VR-CORE methodological framework, a randomized controlled VR3 trial will be conducted to definitely test the clinical efficacy of VR distraction in reducing procedural pain and anxiety.

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