Original Clinical Article

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The use of virtual reality in reducing anxiety during cast removal: a randomized controlled trial

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Abstract

Purpose While virtual reality (VR) has been shown to be an effective distractor in children across a range of procedures, no studies have looked at its use within paediatric orthopaedics. The purpose of this study was to look at the use of VR in reducing anxiety levels in children during cast removal. In addition, the study aimed to find ways to enhance the efficiency of future VR trials in paediatrics.

Methods A non-blinded randomized control trial took place in children aged four to 18 years. Intraprocedural anxiety was measured using the Children's Emotional Manifestation Scale (CEMS), while pre- and post-procedural anxiety was measured using the Short State Anxiety Inventory Scale. Additional data was collected on trait anxiety, nausea levels, desire for future VR use and areas of improvement for future VR studies.

Results A total of 90 subjects were included in the study (control n = 45, intervention n = 45) with a mean age of 10.25 years (SD 3.35). Post-procedural anxiety and intraprocedural anxiety were 18% (p = 0.03) and 24% (p = 0.01) lower in the VR group, respectively, with the CEMS facial component showing a 31% (p < 0.001) reduction in the VR group. In all, 99% (n = 89) of subjects experienced no nausea, with one patient experiencing mild nausea that may have been present prior to VR use. Finally, 90% (n = 81) of subjects said they would like to use VR again, 1% (n = 1) said 'no' and 9% (n = 8) said 'maybe'.

Conclusion VR appears to be an effective distraction technique in reducing anxiety levels in children during cast removal.

Level of evidence: II

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Keywords: virtual reality; orthopaedics; distraction; paediatrics

Introduction

Background

Gamification is the use of a gaming design in a non-game context; one example that has been gaining popularly is the use of virtual reality (VR) as a distraction technique in healthcare.[1,2] Due to its immersive abilities,[3] VR serves as a distractor by drawing participants' attention away from real world stimuli and into an interactive virtual world.[4] VR has been shown to be effective in reducing pain and anxiety in several clinical settings including but not limited to: dressing changes, dental care, lumbar punctures and intravenous administration of contrast for a MRI CT scan,[2,4] as well as being an alternative to pharmacological sedation, being an effective adjunct in medical rehabilitation and an effective preparation tool for paediatric patients undergoing surgery.[5,6]

While large effect sizes have indicated that the use of VR as a distraction technique in paediatrics is effective at reducing pain and anxiety in a wide range of medical procedures,[7] to our knowledge there have been no studies assessing its use within paediatric orthopaedics. As the procedures commonly performed within a paediatric orthopaedic clinic are different from the procedures looked at within the literature to date, data from this study may help further delineate which procedures may benefit from the concurrent use of VR as a distraction technique. It is also important to note that early works in VR used older technologies and, therefore, there is a growing need for

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additional randomized control trials (RCTs) looking at the use of VR in reducing pain and/or anxiety within paediatrics across a spectrum of procedures.[4]

Previous papers[8-11] in paediatric orthopaedics have, however, assessed other distraction techniques, including the use of iPads, child life specialists, noise reduction headphones and music therapy.

Common outpatient procedures in paediatric orthopaedics, such as pin removal or the injection of Botox for conditions such as cerebral palsy and clubfoot, can be a painful experience. Pin removal for instance has been reported to be painful by as many as 90% of children and adults, with up to 2% requiring general anaesthesia.[12] Moreover, even painless procedures, such as cast removal and application, can often also lead to distress in a child. The injury itself, combined with the unfamiliar environment and equipment, can provoke fear in children of all ages.[8] Furthermore, patient anxiety often makes it difficult to perform the procedure, reducing parental satisfaction for the care provided.[8] Improperly managed anxiety may then worsen, possibly with depression, thereby reducing overall quality of life.[13] In addition, while pain during an outpatient procedure is often short-lived, the long-term consequences of such exposures in childhood can range from increased pain and analgesia requirements in subsequent procedures, to healthcare avoidance and needle phobias.[12]

Notably, reduction in patient anxiety and pain levels can also increase the overall satisfaction of healthcare providers, thereby minimizing burnout and turnover, while improving overall patient outcomes.[4] It is, therefore, of great importance to find a way to minimize anxiety and pain within the paediatric population to benefit not only patients but also care providers. Furthermore, as the number of VR studies continue to rise and show promise as an effective distractor, it is also important for researchers to be aware of what VR interactions work best and what the potential pitfalls are.

Study objectives

The primary objective of the study was to evaluate the use of VR in managing anxiety levels during cast removal in the paediatric population. Additional objectives included measuring the presence of nausea and subjects' desire to use VR again in the future. Furthermore, this study aimed to determine areas of improvement and special considerations for future VR studies within paediatrics.

Patients and methods

Trial design

The study was a non-blinded parallel RCT with equal randomization between arms (1:1 ratio). The study was approved by the research ethics board at the participating site and registered at the US National Institutes of Health (Clinicaltrials.gov, #NCT03784352). No changes were made to the methods after trial commencement.

Patients

The trial took place in the orthopaedic department at British Columbia Children's Hospital in Vancouver, Canada between 4th February 2019 and 3rd May 2019. Children and their accompanying guardians who were present in the orthopaedic department for cast removal were approached in the waiting area to assess interest and eligibility. A total of 96 children were approached, with a final recruitment of 90 participants. Eligibility included being between four and 18 years of age, with no symptoms of respiratory or gastrointestinal infection, visual, auditory or cognitive impairment, developmental delay or history of seizures or epilepsy. The researcher, BAJ spoke with the families to describe the study (including risks, benefits, voluntary participation, ability to withdraw at any time and description of the procedure). Families were provided with enough time to reflect on the information and had any questions appropriately answered. Written informed consent and assent were obtained from the accompanying guardian and study subject, respectively. As children of different ages are in a different stage of psychosocial development, children were stratified according to their age groups: four to seven years, eight to 12 years and 13 to 18 years.

Control group

The control group received standard of care (SOC) only. SOC involved the technician or care provider explaining the procedure in a comforting and supportive manner once in the procedure room and the parent or guardians being allowed to console and distract the patient.

Intervention

The intervention consisted of SOC in addition to the use of VR, interacting with the Oculus Go (headset and controller (manufacturer's suggested retail price (MSRP) approximately $149 USD to $199 USD; manufactured by Facebook Technologies in Menlo Park, California, USA) while playing the game Snowthrow VR, which is freely available to download through the Oculus Store. A foam replacement set was applied to the Oculus Go (MSRP approximately $29 USD) and Cowin E7 Active Noise Cancelling Bluetooth Headphones (MSRP approximately $50 USD; manufactured by Cowin Audio in Industry, California, USA) were plugged into the device for added immersion. In order to maintain hygiene, universal disposable hygiene covers were applied to the foam cover (MSRP approximately $0.29 USD per cover; manufactured by VR Cover in Bangkok, Thailand) between uses and the foam cover

and headphones were wiped using VR hygiene solutions (MSRP approximately $0.17 USD per wipe; manufactured by VR Cover in Bangkok, Thailand). The foam cover, disposable hygiene covers and hygiene solutions were purchased from VR Cover and manufactured in Bangkok, Thailand.

Snowthrow VR takes place in a winter setting where participants must aim snowballs at presents which are hidden behind blocks of snow. Depending on where the snowballs hit the blocks of snow changes how they topple over to reveal the presents which must then be aimed at by the remaining snowballs. Each level gets progressively more difficult with only a limited number of snowballs, varying configurations of snow blocks and certain number of presents. The game was chosen due to its ease of use, minimal learning curve, comfort level during playing and suitability for a wide range of participants.

VR was administered once patients were in the procedure room. The game was explained to the patient and their accompanying guardian after completion of the Short State Anxiety Inventory Scale (SAIS).[14] Once the patient was familiar with the game, the cast technician would explain the procedure. Following completion of explaining, but prior to commencement of the procedure, the patient would resume interacting with the VR headset. On completion of the procedure, the research coordinator would inform the patient it was time to stop interacting with the VR headset.

Procedure

Demographic data and disease-related information were collected through self- and guardian-report while in the waiting area. Subjects then completed the Penn State Worry Questionnaire for Children (PSWQ-C)[15] to collect data on tendency to worry using a parallel group design, subjects were stratified by age, gender, site of application and procedure reason (trauma *versus* a pre-existing orthopaedic condition such as cerebral palsy). After randomization through research electronic data capture (REDCap, hosted/managed by BCCH Research Institute, Vancouver, Canada), subjects were taken into the procedure room where they completed the Short SAIS to collect pre-procedural state anxiety measurements. Following this, control group subjects received SOC while intervention group subjects received SOC with VR interaction a few minutes before and lasting until the end of the procedure. During the procedure, the researcher completed the Children's Emotional Manifestation Scale (CEMS)[16] to assess procedural state anxiety. Upon procedure completion, both groups were asked to complete the Short SAIS to collect post-procedural anxiety levels. The subject was asked if they experienced any nausea; if yes, they were then asked to complete the Baxter Retching Faces Scale (BARF) questionnaire to measure nausea.[17] Following completion of questionnaires, subjects in the control group were invited to interact with the VR simulation for a total of five minutes to gauge interest in VR use. Upon completion, a final question asked if the subject would like to use VR again at a future hospital visit, with possible answers being 'yes', 'no' or 'maybe'. All data was collected using REDCap.

Primary outcome measures: anxiety

The Short SAIS was used to collect data on pre- and post-procedural state anxiety. State anxiety refers to the anxiety levels at a particular moment in time. This contrasts with trait anxiety which measures tendency to experience anxiety. The Short SAIS has been used and validated in children aged five to 16 years and is a six-item questionnaire with four possible responses for each item.[18] The total score ranges from 6 points to 24 points, with 6 points indicating no anxiety and 24 points indicating the highest level of anxiety.

Pre-procedural SAIS was completed after randomization through REDCap, once subjects were in the procedure room to collect pre-procedural state anxiety data and then administered again immediately after completion of the procedure to collect post-procedural SAIS.

Primary outcome measures: CEMS

The CEMS is an objective method of documenting children's emotional behaviour during stressful medical procedures.[16] It consists of five categories that include: facial expression, vocalization, activity, interaction and level of cooperation. A score is obtained by reviewing five descriptions in each category and selecting the number that most clearly represents the observed behaviour. Each category is given a score from 1 to 5 for a total score of 5 to 25. A higher score corresponds to a more distressed child. Once the procedure commenced, the researcher, BAJ completed the CEMS to assess procedural state anxiety.

Secondary outcome measures: demographic data

Demographic data and disease-related information were collected through self- and guardian-report following completion of providing study consent and assent. Data collected included: age, gender, type of procedure, previous visits for the same procedure, reason for procedure (trauma or underlying orthopaedic condition), previous video gaming experience and previous use of VR (Table 1).

Secondary outcome measures: trait anxiety

Trait anxiety was measured using the PSWQ-C which is a screening tool for assessing generalized anxiety in children aged seven to 17 years. It consists of a 14-item self-reported questionnaire. Respondents indicate how often

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Table 1 Patient demographics

	Control (n = 45)	Virtual reality (VR) (n = 45)
Sex, female (%)	15 (*33.3*)	15 (*33.3*)
Mean age, yrs (SD)	10.3 (3.2)	10.2 (3.5)
Age 4 to 7 yrs (%)	11 (*24.4*)	14 (*31.1*)
Age 8 to 12 yrs (%)	23 (*51.1*)	20 (*44.4*)
Age 13 to 18 yrs (%)	11 (*24.4*)	11 (*24.4*)
Previous VR experience, n (%)	*27* (*60.0*)	*24* (*53.3*)
Previous videogame experience, n (%)	40 (*88.9*)	*29* (*75.6*)
First time having procedure, n (%)	30 (*66.7*)	*27* (*60.0*)
Cast type, n (%)		
Arm long	12 (*26.7*)	10 (*22.2*)
Arm short	17 (*37.8*)	*24* (*53.3*)
Leg long	4 (*8.9*)	3 (*6.7*)
Leg short	12 (*26.7*)	8 (*17.8*)
Reason for procedure due to an underlying orthopaedic condition, n (%)	5 (*11.1*)	3 (*6.7*)

each item applies to them, choosing from the following responses: 'never', 'sometimes', 'often' and 'always', with points ranging from 0 to 3 for each item. The total score ranges from 0 to 42, with higher scores indicating a greater tendency to worry. Individuals with generalized anxiety tend to have a score of around 27; those with other anxiety disorders score around 21, with scores of 16 to 18 representing at-risk groups.[19] The PSWQ-C was completed immediately following collection of demographic data.

Secondary outcome measures: nausea

After completion of interacting with the VR system, subjects were asked if they experienced any nausea. If yes, they were asked to rate the nausea using the BARF, a validated tool for measuring nausea in children using a scale of 0 to 10 with six faces, representing 'no nausea' to 'experiencing vomiting'.[17]

Secondary outcome measures: future VR use

Following the assessment of nausea, subjects in the control group were invited to interact with the VR simulation for a total of five minutes to gauge interest in VR use. A final question was then asked to all subjects asking if they would like to use VR again in future hospital visits, with choices being: 'yes', 'no' or 'maybe'.

Secondary outcome measures: areas for improvement

Throughout the study, notes were made on possible areas to improve following subject observations and subject feedback after completion of the final measurement (future VR use).

Sample size

Sample size was based on the following: 1) a mean score of 15 in the Short State Anxiety Iventory Scale (SAIS) score; 2) a 20% (3 point) reduction due to the VR arm; 3) an assumed standard deviation of 4; 4) 80% power; and 5) a 5% level of significance. Based on a two-sample *t*-test, this required 28 patients to power the study with an achieved final sample size of 90 patients.

Randomization

Participants were randomly assigned in a 1:1 manner to either be in the intervention arm or control arm for their respective procedures. Using a parallel group design, subjects were stratified by age, sex, site of procedure and procedure reason (trauma *versus* a pre-existing orthopaedic condition such as cerebral palsy). A full randomization schedule was calculated using R statistical software (R Foundation for Statistical Computing, Vienna, Austria) and was only known by the trial statistician. After randomization through REDCap, subjects were taken into the procedure room where they completed the Short SAIS to collect pre-procedural state anxiety measurements.

Statistical analysis

Demographic and baseline data were summarized between arms using counts and frequencies for continuous variables and means and SD for continuous variables. Average pre-treatment anxiety measures (SAIS and PSQW-C) are reported with 95% confidence intervals (CIs). The primary analysis of all anxiety measures (pre- and post-procedure SAIS, CEMS and facial component of CEMS) were compared between arms via two sample *t*-tests. Sensitivity analyses were based on the inclusion of covariates thought to be predictive of outcome. These included baseline PSQW-C score, age, VR experience and whether it was a subject's first visit. Analyses to determine possible treatment by age differences were conducted by including an interaction term in the primary model. The overall significance of this interaction term was assessed via the likelihood ratio test. All regression results are reported as mean differences between arms with 95% CIs and p-values. Procedure times were compared between arms in patients with this measurement available via a two-sample *t*-test. There were no interim analyses or stopping rules. A significance level of 0.05 was used for all analyses and no adjustment was made for multiple comparisons.

Results

Recruitment took place between 4th February 2019 and 3rd May 2019. In all, 90 subjects were included in the study (control n = 45, intervention n = 45) with a mean age of 10.25 years (SD 3.35) in both the control and intervention arm, with 60% and 53% having experienced VR at some point in their lives, respectively (Table 1). No patients were excluded from the study.

Table 2 Pre-procedural anxiety and trait anxiety

	Control (n = 45)	Virtual reality (n = 45)
Pre SAIS, mean (95% CI)	10.8 (9.7 to 11.9)	10.4 (9.2 to 11.6)
PSWQ-C, mean (95% CI)	15.0 (13.0 to 17.0)	15.0 (12.8 to 17.2)

SAIS, State Anxiety Inventory Scale; CI, confidence interval; PSWQ-C, Penn State Worry Questionnaire for Children

Table 3 Overall differences in procedural anxiety and pain. State Anxiety Inventory Scale (SAIS) score ranges from 6 to 24; Children's Emotional Manifestation Scale (CEMS) score ranges from 5 to 25; CEMS facial component score ranges from 1 to 5

Variable	Control (n = 45)	Virtual reality (n = 45)	Mean difference* (95% CI); p-value
SAIS, post procedure, mean	11.0	9.0	-2.00 (-3.70 to -0.16); 0.03
Total CEMS, mean	8.6	6.5	-2.10 (-3.80 to -0.55); 0.01
CEMS facial component, mean	2.9	2.0	-0.90 (-1.30 to -0.49); < 0.001

*result from unadjusted linear regression model. All differences are intervention – control.
CI, confidence interval

The mean pre-procedural anxiety measured by the pre-SAIS in the control group was 10.8 (95% CI 9.7 to 11.9) and 10.4 (95% CI 9.2 to 11.6) in the VR group while trait anxiety measured by the PSWQ-C scores were 15.0 (95% CI 13.0 to 17.0) and 15.0 (95% CI 12.8 to 17.2) in the control and VR groups, respectively (Table 2).

Mean post-procedural anxiety measured by post-SAIS was 11.0 in the control group and 9.0 in the VR group, a mean difference of -2.0 points (95% CI -3.7 to -0.16) or 18% reduction (p = 0.03). Mean intraprocedural anxiety measured by total CEMS was 8.6 and 6.5 in the control and VR groups, respectively, a mean difference of -2.1 points (95% CI -3.8 to -0.55) or 24% reduction (p = 0.01). The facial component of the CEMS demonstrated a mean score of 2.9 (95% CI = 2.57 to 3.19) in the control and 2.0 (95% CI = 1.76 to 2.24) in the VR group, a mean difference of -0.9 points (95% CI -1.3 to -0.49) or 31% reduction (p < 0.001). These results are recorded in Table 3. Differences in these measurements adjusted for baseline scores are available in Table 4 while subgroup differences between age groups are available in Table 5.

The presence of nausea was minimal with 99% (n = 89) of subjects experiencing no nausea, with only one subject scoring a 2 out of 10 on the BARF scale but indicated they may have been dizzy beforehand. Finally, 90% (n = 81) said they would like to use VR again at their next hospital visit, while 1% (n = 1) said 'no' and 9% (n = 8) said 'maybe' (Table 6). No unintended effects were observed.

Discussion

Similar to a literature review by Won et al,[20] our study has shown VR to have the potential to be an effective means of reducing anxiety levels during hospital procedures in children across a range of ages. However, this is the first study that examined the use of VR in a paediatric orthopedic outpatient setting, with the results being in line with other VR studies in the areas of general anesthesia,[1] venepuncture,[4,21] and preoperative preparation.[6]

While most children in the study demonstrated some baseline anxiety, with older subjects experiencing less baseline anxiety, it is interesting to note that these subjects still requested the use of VR. This is likely due to the novelty of VR but also demonstrates that it is not only the younger paediatric patients who may benefit from the use of VR as a distraction technique. Moreover, given

Table 4 Overall adjusted analysis for baseline scores

Variable	Mean difference* (95% CI); p-value adjusted for baseline variables*	Mean difference* (95% CI); p-value adjusted for baseline and pre-SAIS score	p-value from Fisher exact test
Mean SAIS post-procedure	-1.60 (-3.10 to -0.14); 0.03	-2.00 (-3.70 to -0.24); 0.03	-
Mean total CEMS	-2.2 (-3.80 to -0.74); < 0.001	-	-
Mean CEMS facial component	-0.92 (-1.30 to -0.53); < 0.001	-	< 0.001

*baseline variables include: age (continuous), previous experience with virtual reality (yes/no), first visit (yes/no) and baseline Penn State Worry Questionnaire for Children (continuous)
CI, confidence interval; SAIS, State Anxiety Inventory Scale; CEMS, Children's Emotional Manifestation Scale

Table 5 Subgroup differences in anxiety and pain between age groups. Confidence limits exceeded scale limits, and thus have been replaced by minimum/maximum difference in score between groups

	Variable	4 to 7 yrs, mean (95% CI)	8 to 12 yrs, mean (95% CI)	13 to 18 yrs, mean (95% CI)	p-value for difference across age groups*
VR	CEMS facial	2.29 (1.69 to 2.88)	1.85 (1.56 to 2.14)	1.91 (1.59 to 2.23)	0.94
Control	CEMS facial	3.27 (2.39 to 4.15)	2.70 (2.32 to 3.07)	2.91 (2.42 to 3.4)	
VR	SAIS	9.36 (6.79 to 11.93)	8.80 (7.42 to 10.18)	8.82 (7.28 to 10.36)	0.28
Control	SAIS	13.64 (10.27 to 17)	9.78 (8.22 to 11.35)	10.45 (7.79 to 13.12)	
VR	CEMS overall	7.43 (5.16 to 9.7)	6.00 (5.57 to 6.43)	6.09 (5.77 to 6.41)	0.17
Control	CEMS overall	12.09 (7.31 to 16.87)	7.61 (6.56 to 8.66)	7.27 (6.57 to 7.98)	

CI, confidence interval; VR, virtual reality; CEMS, Children's Emotional Manifestation Scale; SAIS, State Anxiety Inventory Scale
*Computed from comparing models with and without age by treatment interaction via likelihood ratio test.

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Table 6 Additional outcomes

	Control (n = 45)	Virtual reality (VR) (n = 45)
Presence of nausea, n (%)		
Yes	0 (*0.0*)	1 (*2.2*)
No	45 (*100*)	44 (*97.8*)
Desire for VR use again at next visit, n (%)		
Yes	42 (*93.3*)	39 (*86.7*)
No	0 (*0.0*)	1 (*2.2*)
Maybe	3 (*6.6*)	5 (*11.1*)

that most subjects responded positively to wanting to use VR in the future, this may contribute to VR becoming a preferred distraction technique of both parents and patients.

Although other VR studies[6,22] have included subjects as young as four years of age, we found that there was significant variability in the time it took for patients aged four to seven years to become comfortable with the VR controls, despite SnowThrow VR being selected for its user-friendliness and minimal learning curve. Instead, we recommend that it may be better to offer an immersive video for children aged four to seven years. To further help streamline future studies, we recommend that only the facial component of the CEMS or a Visual Analogue Scale (VAS) be used for intraprocedural anxiety measures. While the CEMS is a validated tool for measuring intraprocedural anxiety, we found it to be cumbersome to administer in a busy clinic. In addition, other VR studies[4,6,21] describe using the VAS as the primary measure in collecting anxiety data. Moreover, while the PSWQ-C is a useful measure for assessing trait anxiety, it proved time-consuming to administer to parents and subjects, taking on average five to 15 minutes to complete. Given the mean PSWQ-C scores of 15.0 for both the VR and control groups, and scores of 16 to 18 representing at-risk groups of having an anxiety disorder,[19] it does, however, raise the question of whether children should be screened more regularly for anxiety by their primary care providers and supports the need for finding more effective ways of reducing anxiety during medical procedures.

Although a theoretical risk of nausea during VR experience is possible,[17] only one subject in our study experienced nausea, who on further questioning thought they may have felt dizzy beforehand, therefore, demonstrating that there are VR games available where nausea risk is marginal. This is an important consideration as patients who did not want to partake in using the VR system cited previous nausea experience, a general bad experience and lack of time as the most common reasons for not wanting to participate. However, it is also worth mentioning that most subjects who were approached were very enthusiastic in wanting to try the VR system, which helped facilitate the high recruitment rate in this study.

Limitations and future directions

While this RCT was non-blinded, it is important for readers to be made aware that this was due to the nature of VR and as such, to our knowledge, there have been no blinded RCTs that have been completed in the assessment of VR as a distraction technique.

While most children enjoyed VR use, the overall experience between different subjects may have differed depending on subject position as the chosen game was unable to calibrate for patients lying down flat in the supine position. However, no patients during cast removal were in this position and there were no patients who criticized the gameplay calibration. Nonetheless, future VR studies in paediatric orthopaedics should consider this potential issue when evaluating the use of VR during other commonly performed in office procedures such as Botox injections.

Future studies should aim for the following improvements: use of a game that is able to calibrate to patient position and the use of VAS for of anxiety to simplify data collection. Moreover, for patients younger than six years of age we recommend the use of a virtual short movie rather than the use of a game due to some patients in this age group requiring significantly more time to understand the controls of the game compared with their older peers.

Conclusion

VR appears to be an effective and easy to set up distractor during cast removal across a wide range of ages within the paediatric population with minimal to no side effects. Therefore, VR as a distraction technique continues to show promise in an ever-growing list of settings.

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COMPLIANCE WITH ETHICAL STANDARDS

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ETHICAL STATEMENT

Ethical approval: The study has been approved by an institutional research ethics board. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: This research involves human participants who have all given informed consent.

ICMJE CONFLICT OF INTEREST STATEMENT

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The other authors declare no conflict of interest relevant to this work.

AUTHOR CONTRIBUTIONS

BAJ: Wrote the protocol, Collected and analyzed the data, Wrote the manuscript.
ES: Oversaw study completion and data interpretation, Advised on the writing of the manuscript.
JB: Statistically analyzed the results.
CS: Aided in writing the protocol and reviewing current literature on the topic.
EH: Developed the study originally.
JJ: Developed the study originally.
KM: Oversaw study completion and data interpretation, Advised on the writing of the manuscript.

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