Effect of Virtual Reality on Adolescent Pain During Burn Wound Care

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The objective of this study was to compare the effect of virtual reality to passive distraction and standard care on burn treatment pain in adolescents.
This single-blinded, randomized controlled study enrolled 30 adolescents who were 10 to 17 years of age from the burn clinic of a large children's hospital. After providing informed consent/assent, these participants were randomly assigned to one of three groups during wound care: standard care, passive distraction watching a movie, or virtual reality (VR) using a tripod-arm device rather than an immersive helmet. Before wound care, participants completed the Spielberger's State-Trait Anxiety Inventory for Children and Pre-Procedure Questionnaire while blinded to group assignment. A total of 28 participants completed the study and rated treatment pain after wound care by using the Adolescent Pediatric Pain Tool and completed a Post-Procedure Questionnaire. The VR group reported less pain during wound care than either the passive distraction or standard care group as determined by multivariable linear regression adjusted for age, sex, preprocedure pain, state anxiety, opiate use, and treatment length. The VR group was the only group to have an estimated decrease in pain perception from baseline preprocedure pain to procedural pain reported. Adolescents pretreated with opiate analgesics and female adolescents reported more pain during wound care.
This between-subjects clinical study provides further support for VR, even without requiring wearing of an immersive helmet, in lessening burn wound care pain in adolescents. Passive distraction by watching a movie may be less effective in reducing treatment pain. Additional between-subjects randomized controlled trials with larger samples of children and during other healthcare treatments may further support VR's effectiveness in pediatric procedural pain management. (J Burn Care Res 2014;35:395–408)

Burn wound care pain subsequent to burn injuries is one of the most intense, severe types of pain.[1–4] Burn wound care pain adds to the trauma pediatric patients already experience from the burn itself and may reduce quality of life[2] by resulting in behavioral and maladaptive responses, such as agitation, anger, anxiety, uncooperativeness, aggression, hyperactivity, and dissociation.[5] Pain management associated with burn wound care is challenging and complex related to several factors. The severe episodic pain during burn treatments is often unrelieved by opioid and nonopioid analgesics alone.[6–8] Further, opioid analgesics have untoward side effects including nausea, constipation, drowsiness, and lethargy.[2,4] While sedation may be effective for pain relief, it is not always available or realistic, especially in the outpatient setting. Additionally, anxiety in anticipation of the repeated painful nature of the procedure and transmission of healthcare provider distress associated with inflicting procedural pain contribute to the pain perceived.[1–3] As a result, undertreatment of burn wound care pain persists.[8] Unique, effective, nonpharmacologic methods of pain reduction are

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needed to augment pharmacologic interventions to reduce burn treatment pain, especially in the pediatric population.

Distraction is one nonpharmacologic intervention often recommended for use in children and adolescents in managing acute procedural pain including burn wound care pain. While evidence exists for using distraction to reduce pain associated with various procedures by using a variety of approaches, such as bubble blowing, counting, interactive toys, listening to stories, music, reading, singing, and television or movie watching, some findings remain equivocal.[2,9–21] Additionally, certain variables, such as anxiety, fear, age, sex, race and ethnicity, medical diagnosis, previous experience with medical procedures, temperament, coping styles, and types of medical procedure, may affect the efficacy of distraction in reducing procedural pain.[22,23] The specific influence of the interrelationship of other factors, such as patient choice, desire for distraction, and belief in distraction's efficacy requires continued investigation.[10,23]

Several theories purport mechanisms related to cognitive processing of attention, distraction, and pain.[24] One theoretical framework for distraction suggests that distraction's effectiveness occurs through controlled processing of attention that focuses on internal or external stimuli rather than on the painful stimulus.[23,25] Engagement in an attentionally demanding task presumably leaves less capacity for the processing of pain. Focused attention is desirable to promote sustained engagement with the task throughout the painful procedure. These theories suggest that distraction that is engaging and interactive will be effective in lessening pain through the role of central processing of attention in limiting the processing of incoming nociceptive stimuli.

Virtual reality (VR) shows great promise as an engaging, interactive, effective distraction intervention for children and adults during painful healthcare procedures including burn wound care treatments.[2,9,10,26–39] While few studies have focused on the relationship between engagement in distraction and effectiveness of distraction in reducing procedural pain, research has begun to explore the role of VR engagement in pain relief.[24,39,40] VR is purported to reduce attention available to process the painful stimulus by redirecting attention toward a more pleasant experience through presence in the virtual world of a highly immersive VR system, thus lessening perceived pain intensity during the pain-inducing procedure.[4,7,41–43] Laboratory studies of immersion in the virtual environment have shown significant reductions in induced pain intensity through perceived presence in a highly immersive VR environment.[41,42] However, one distraction study examining engagement found that engagement was greater and distress associated with venipuncture was lower in a *passive* distraction (PD) group compared with an interactive but non-VR distraction group.[44] In contrast, two laboratory cold-pressor pain studies found that engaging in interactive VR rather than passively viewing VR was more effective.[24,45] A clinical study using nonimmersive VR compared with no VR during venipuncture or port access in children with cancer found few differences in pain between the two groups.[46] These studies suggest more research is needed to determine the relationship between engagement and distraction's effectiveness in reducing procedural pain by comparing an interactive, immersive VR distraction with a more PD during which engagement with the distraction might vary throughout the painful procedure.

While VR studies have shown positive results in lessening procedural pain, methodological issues may limit generalizability.[47,48] Randomized controlled clinical studies of nonpharmacologic interventions including VR for burn wound care pain in children and adolescents, are few.[6,39] The designs of most studies of VR for burn wound care pain in children and adolescents have primarily been case studies or are carefully controlled within-subject designs; sample sizes have been small.[2,9,26] One study using VR during the entire burn dressing change compared VR with other distractions but included only six children.[34] Reviews have called for more randomized controlled clinical studies using VR throughout the procedure, between-subjects designs comparing VR with other distraction interventions, and larger sample sizes to provide additional support for widespread use of VR.[39,47]

Studies have found relationships between anxiety and pain during a variety of healthcare procedures including burn care.[23,49–54] Further, anxiety and pain can occur in anticipation of the burn wound care.[55] In adults having repeated burn dressing changes, increased anxiety was associated with increased pain, and preprocedural anxiety increased after the first dressing change.[56] Anxiety may interfere with ability to engage in the distraction and subsequently reduce distraction's effectiveness, leading to increased procedural pain perception. Through interactivity and immersion in the virtual environment, VR may be more effective than a PD in reducing procedure-related anxiety associated with burn care.[57] VR may be especially helpful with individual children and adolescents who have high trait and state anxiety. A novel, interactive VR experience

may help in reducing procedure-related anxiety and lessen pain perception. However, findings to date are equivocal. While clinical trials may have different outcomes, in a laboratory study, children's anxiety did not moderate cold-pressor pain tolerance or threshold.[58]

The developmental level of children requires consideration when implementing nonpharmacologic interventions. Little is known about the influence of distraction on adolescents' pain perception.[10] Adolescence, as a gradual transition from childhood to adulthood, divided into early (10–13 years), middle (14–17 years), and late (18–21 years) adolescence,[59] may require unique strategies for procedural pain management.[23] Adolescents desire control and autonomy and strive to maintain internal control over thoughts and behaviors in the face of pain through thought stopping, distraction, positive thinking, sleep, and staying calm.[60,61] The severity of burn wound care pain can reduce ability to cope and maintain control.[55] Through its interactive and immersive features, VR might be effective in assisting adolescents to maintain autonomy and sense of internal control during painful procedures, especially those that are very painful, such as burn wound care.

To fulfill research on the aforementioned gaps in the literature, the specific aims of this study were to:

1. Evaluate the effect of VR as an interactive distraction compared with PD and standard care (SC) on acute pain perception among adolescents undergoing a burn wound care treatment in the outpatient burn clinic setting.
2. Determine the relationship and interaction among anxiety, desire for distraction, belief in distraction's efficacy, and engagement with distraction on adolescents' acute pain perception during burn wound care.

METHODS

Design

For this randomized controlled clinical trial, a single-blinded, three-arm, experimental design during one burn wound care procedure performed in the outpatient setting was used. The single-blinded design was used by collecting all key outcome data using study team members who had no knowledge of the group assignment. Given the nature of the interventions, the blinding of study participants was broken after all prewound care assessments were complete. Of notable exception, treatment fidelity was the last outcome to be assessed and required the study team blind to be broken.

Participants were randomly assigned to one of three groups: SC, PD, or interactive VR distraction throughout the entire burn wound care procedure. SC was the typical care and communication provided by the staff nurses during the procedure; nurses did not receive scripting or prompting in advance, and no experimental intervention was provided to participants. Nurses were instructed to provide the care they usually provide to any patient receiving wound care in the outpatient clinic. The PD intervention group watched an age-appropriate movie entitled "Cloudy with a Chance of Meatballs," produced by Columbia Pictures and Sony Animations, on a small, arm-mounted, movable television at the bedside and listened through high-quality, external sound-cancelling Bose Quiet Comfort 3 headphones (Bose Corporation, Framingham, MA). The VR intervention was delivered using SnowWorld, a three-dimensional, computer-generated, interactive VR software program developed collaboratively by the University of Washington (www.vrpain.com), Harborview Burn Center, and Firsthand Technology, Inc. (www.firsthand.com) in Seattle, Washington, and designed specifically for patients receiving burn wound care. The SnowWorld pain control virtual environment was delivered through a Kaiser Optics SR80a VR helmet with SXGA resolution (1280-1024) 80-degree field-of-view mounted on a custom-built, articulated-arm tripod device and via a desktop VR analgesia workstation Falcon NW Fragbox, with interactivity using a Kensington orbit trackball and music through Bose Quiet Comfort 3 headphones. Providing the VR through the mounted device rather than requiring adolescents to wear a head-mounted display (HMD) helmet avoided exclusion of adolescents with burns to the head (Figure 1). The VR was delivered throughout the entire burn wound care procedure. During the two distraction interventions, VR and PD, several minutes of distraction were implemented before beginning the wound care procedure and continued throughout the wound care unless interruptions occurred.

Sample

Participants were recruited from the outpatient burn clinic of a large academic children's hospital located in mid-south United States. The clinic is part of a verified burn center and serves as the only burn center in the state, with the nearest burn centers located in the surrounding states. The outpatient burn clinic treats patients with large thermal, chemical, and

Figure 1. Example of adolescent using virtual reality intervention. Photo copyright © Debra Jeffs.

electrical burn injuries after acute care hospitalization and additional patients with smaller burns who do not require inpatient hospitalization and are referred from emergency departments, physician offices, and other outpatient clinics. Comprehensive burn care is provided by an experienced team of burn specialists including surgeons; nurses; respiratory, occupational, and physical therapists; social workers; nutritionists; and child life specialists. Burn rehabilitation is provided to assist patients with returning to school or work and resuming activities of daily living.

Participants were invited to participate in the study if they met all of the following criteria: were undergoing burn wound care as a first-time visit to the outpatient burn clinic or first clinic visit without conscious sedation; were aged between 10 and 17 years; and were English speaking. Exclusion criteria included burns that would interfere with study procedures; history of motion sickness or seizure disorder because prolonged immersion in VR may lead to seizures and vertigo in individuals with seizure disorders[62]; incarcerated minors; minors in foster care; presence of a cognitive developmental disability, which was determined during prescreening by presence of a Section 504 accommodation plan or Title VIII individualized educational plan in school. If the parent identified the nature of the individualized educational plan or 504 plan as unrelated to a cognitive delay, then the adolescent was included in the study. Presence of concomitant physical pain related to another source was evaluated on a case-by-case basis. No exemptions were made based on sex or race and ethnicity. A $10 gift card to a drive-through fast-food eatery was offered to each study participant as an incentive and in appreciation for participating in the study. A total of 41 adolescents were screened for possible study inclusion, resulting in a convenience sample of 30 adolescents who met eligibility criteria and were enrolled in the study between June 2010 and April 2012. Of those enrolled, 28 adolescents completed the study and were included in the data analysis, and 2 participants who enrolled, completed preprocedural data collection, and were randomly assigned (n = 1 VR and n = 1 PD) either withdrew before the wound care procedure began or had treatment rescheduled. The reasons for patients not meeting eligibility criteria included parent not present to consent (n = 1), parent refused to consent (n = 1), wound healed and no treatment needed (n = 1), history of seizure disorder (n = 2), history of motion sickness (n = 1), possibility that burn location would interfere with study procedure (n = 2), no interest in enrolling in study (n = 1), and presence of developmental delays (n = 2).

Measurements

Adolescent Pediatric Pain Tool. The Adolescent Pediatric Pain Tool (APPT) word graphic rating scale (WGRS) was used to measure baseline preprocedural pain and pain intensity associated with the burn wound care procedure measured after the burn treatment. The APPT is a multidimensional, one-page, two-sided, self-report pain measure for children and adolescents aged 8 to 17 years that includes three components: a body outline to determine pain location, a 100-mm line word graphic rating scale to rate pain intensity (APPT-WGRS), and a word descriptor list to describe the sensory, affective, and evaluative qualities of pain.[63–67] Support for reliability and validity of the APPT components has been demonstrated in several studies.[64–67] Convergent and construct validity of the word graphic rating scale was demonstrated by significant correlations between five scales tested ($r = .66–.84$, $P < .001$) and among pairs of scores ($r = .68–.97$, $P < .001$) along with significant decreases in pain ratings over consecutive postoperative days.[66] Study participants marked the point on the APPT-WGRS that best described the pain intensity of the burn wound care procedure. Pain intensity was scored by measuring the distance in millimeters from the left side of the APPT-WGRS to the point marked by the study participant; pain scores range from 0 (no pain) to 100 (worst pain).

Spielberger State-Trait Anxiety Inventory for Children. The Spielberger State-Trait Anxiety Inventory for Children was used to assess participants' preprocedural state and trait anxiety. Both scales have been used successfully to measure anxiety in research and clinical practice, and support for reliability and validity has been demonstrated.[68] Each measure includes a list of 20 statements with

responses provided on a three-point rating scale. Total scores on each scale range from 20 to 60. The instructions ask participants to respond to each item in the Trait anxiety scale by checking the one frequency choice ("hardly ever, sometimes, or often") that best describes how the person usually feels. The State anxiety scale measures transitory feelings of anxiety and consists of 20 statements about how the individual feels at the present moment. Children with higher Trait anxiety may perceive stressful situations as more threatening and respond with higher State anxiety scores than children with lower Trait anxiety.

Pre-Procedure Questionnaire. The investigator-developed Pre-Procedure Questionnaire consists of open- and closed-ended items and was used to collect demographic data, data about the burn injury (including type of burn, total body surface area burned, and depth of the burn), number and type of burn treatments before the outpatient burn clinic treatment, preprocedural analgesics taken on the day of treatment, and expectations of the procedure at baseline before the wound care procedure. Data were collected through patient and parent interview by asking open-ended questions and including checklist items. A section completed during the current burn treatment consisted of items about the site, extent, and depth of the burn wound; wound care treatments provided; length of time of the burn wound care procedure; and any pharmacologic interventions received during the wound care procedure.

Post-Procedure Questionnaire. The investigator-developed Post-Procedure Questionnaire consists of open- and closed-ended items and was used to collect data related to anxiety associated with the burn wound care, desire for distraction, belief in distraction's efficacy, and perceived level of engagement with the distraction during the wound care procedure. Perceived ability to pay attention to the distraction technique served as a proxy for measuring engagement in distraction. The Post-Procedure Questionnaire includes items to be rated by participants, for example, "How nervous did you feel during the procedure?" (1 = Not nervous at all; 5 = Most nervous I could feel); "I wanted to be distracted during the procedure." (Agree/Disagree); "I believe that the distraction lessened my pain during the procedure." (1 = Distraction did not help to lessen my pain at all; 5 = Distraction completely helped to lessen my pain at all times); "Were you able to pay attention to the DVD or to the VR during your burn treatment?" (1 = Could not pay attention at all; 5 = Totally absorbed at all times). Three separate versions of the Post-Procedure Questionnaire were used, one for each study group, and were completed after the wound care procedure.

Procedure

Human subjects' protection through Institutional Review Board approval was obtained. Additionally a nonsignificant risk investigational device exemption was granted. The principal investigator (PI) was blinded to the participants' random group assignment and responses to the Spielberger State-Trait Anxiety Inventory for Children, APPT, and Pre- and Post-Procedure Questionnaires during the adolescents' participation in the study. In an effort to blind participants and research assistants to the participant's group assignment until just before the burn wound care treatment, a clerical assistant prepared in advance a sealed envelope containing each participant's group assignment from a computer-generated, random numbers table created by the biostatistician (C.J.S.) on the research team. Other than the biostatistician and the clerical assistant, the only other members of the team with advanced knowledge of the group assignment were the two technical assistants who set up the VR equipment in the designated clinic exam room on the day of the patient's scheduled appointment.

Two research assistants collected all data for each participant enrolled. At the time of the patient's scheduled appointment, the first research assistant approached the patient and parent outside of the clinic area to avoid heightening any anxiety related to the burn treatment, determined interest in the study and the adolescent's eligibility criteria, and obtained informed consent through parental permission and adolescent assent. After the participant completed preprocedure data collection, a sealed envelope with the group assignment was given to the participant. The first research assistant initiated the distraction interventions if assigned, and remained with the patient throughout the wound care procedure, collecting data about the procedure and participant response to the study intervention. The PI provided guidance to the first research assistant only if questions arose about a participant's meeting enrollment criteria and if there were questions about the equipment during set up. The staff nurses of the outpatient burn clinic provided all preparatory information about the burn treatment itself and completed all wound care. Instructions to avoid interrupting the distraction interventions during wound care were given to all staff. Immediately after the wound care procedure, the first research assistant handed-off the patient and parent to a second research assistant

who was blinded to the group assignment, all preprocedure data collection information, and the burn treatment itself. The second research assistant asked participants to complete the APPT and rate the pain intensity perceived during the wound care procedure by using the APPT-WGRS. After this measurement was completed, the second research assistant was then informed of the participant's study group and asked the participant to complete the designated Post-Procedure Questionnaire. After all data collection, the second research assistant gave participants a gift card and thanked patients and parents for participating in the study.

Statistical Analysis

Demographic, anxiety, burn injury, preprocedural analgesic use, treatment length, pain ratings, and factors related to engagement with distraction were summarized by the study treatment groups. Continuous measures were summarized as means and standard deviations, whereas categorical data were summarized as frequencies and percentages. Unadjusted differences between groups were estimated using Kruskal–Wallis test for continuous and ordinal measures; Fisher's exact test was used for nominal categorical data. To evaluate the effect of VR as an interactive distraction compared with PD and SC on acute pain intensity among adolescents undergoing burn wound care treatment, differences in reported procedural pain between groups was estimated using ordinary linear regression adjusting for preprocedural pain, state anxiety, current opioid analgesic use, sex, age, and treatment length. To evaluate the association between desire for distraction, belief in distraction's efficacy, and engagement with distraction on anxiety and acute pain intensity during burn wound care, semipartial correlations were estimated adjusting for age, sex, treatment group, and opioid analgesic use; preprocedure pain was also adjusted for in estimating correlations with pain during the procedure. All statistical tests were evaluated for significance using the $P < .05$ criterion. All statistical analysis was completed using Stata v12.1 (College Station, TX), with model overfit assessed using R v2.15.1 (Vienna, Austria). Cursory power analysis based on the study findings was conducted using nQuery Advisor 7.0 (Seagus, MA).

RESULTS

Sample Characteristics

The 28 participants who completed the study were included in the data analysis; two participants failed to complete the study because of protocol violations (one withdrew from study before wound care treatment and one was ineligible because of medically required sedation). Participant ages ranged from 10 to 17 years with a mean age of 13.5 years; 9 (32%) of the participants were female. The study cohort included 8 African-Americans (28%), 17 Caucasians (61%), and 3 from other racial groups (11%). Demographic data, burn characteristics, preprocedural analgesic use, wound care procedure length, and pain and anxiety ratings are summarized in Table 1. While not statistically significant, more females were in the VR group, and more males in each of the other two groups ($P = .12$). Moreover, the PD group had less full-depth burns than the other two groups; while clinically relevant, this difference was not statistically significant ($P = .06$). The VR group had greater body surface area burned than the other two groups, although not statistically significant ($P = .81$). Preprocedure oral opioid analgesics including primarily acetaminophen with codeine or oxycodone for pain management during the current wound care procedure was equal among all three groups. Preprocedure pain was significantly different between the three groups, with VR participants reporting the highest, and PD participants reporting the lowest pain ($P = .041$). Adjusting for age and sex, the partial correlation of state anxiety with preprocedural pain is .557 ($P = .003$); the partial correlation of trait anxiety with preprocedural pain is .242 ($P = .23$).

The VR distraction intervention was used throughout the entire burn wound care treatment procedure. The time period during which VR was used ranged from 5 to 100 minutes. During the VR distraction, no participants reported nausea or light-headedness and none experienced any seizure activity. Of note, procedure length was not adversely affected by the usage of either distraction methods; conversely, both distraction groups had lower average wound care procedure times than the SC group, although not statistically significant ($P = .11$).

Aim 1. The first objective of this study was to evaluate the effect of VR as an interactive distraction compared with PD and SC on acute pain perception among adolescents undergoing burn wound care treatment in the outpatient burn clinic setting.

All participants' APPT-WGRS pain scores ranged from 0 to 115 mm, reflecting individual variation in self-report pain perception. Although the WGRS is a 0- to 100-mm scale, we chose to retain one participant's score of 115 mm because we believed it was an important reflection of this individual's perception of the pain during wound care. Individual variation was also captured using the pain words from the APPT descriptive word list. More

Table 1. Demographics, clinical features, and self-reported pain and anxiety by study group

	Standard Care	Passive Distraction	Virtual Reality	Total	*P*
N	10	10	8	28	
Age (years)**	13.9 (2.8)	12.6 (2.1)	14.3 (2.0)	13.5 (2.3)	.21
Sex					.12*
Female	2 (20%)	2 (20%)	5 (62%)	9 (32%)	
Male	8 (80%)	8 (80%)	3 (38%)	19 (68%)	
Race					.18*
African-American	5 (50%)	1 (10%)	2 (25%)	8 (28%)	
Caucasian	5 (50%)	8 (80%)	4 (50%)	17 (61%)	
Other	0	1 (10%)	2 (25%)	3 (11%)	
Cause of burn injury					.56*
Fire	5 (55%)	4 (40%)	3 (38%)	12 (44%)	
Scald	1 (11%)	3 (30%)	4 (50%)	8 (30%)	
Hot object	3 (33%)	3 (30%)	1 (12%)	7 (26%)	
Full-depth burn					.06*
No	4 (40%)	9 (90%)	4 (50%)	17 (61%)	
Yes	6 (60%)	1 (10%)	4 (50%)	11 (39%)	
Original burn surface area (%)**	4.7 (6.9)	3.4 (3.3)	7.4 (8.5)	5.0 (6.2)	.81
Time from injury to treatment (days)	10.0 (9.0)	6.1 (4.3)	11.9 (13.9)	9.1 (9.4)	0.72
Preprocedure opioid analgesic					.99*
No	2 (20%)	3 (30%)	2 (25%)	7 (25%)	
Yes	8 (80%)	7 (70%)	6 (75%)	21 (75%)	
Previous wound care treatments					.34†
None	2 (20%)	1 (10%)	0	3 (11%)	
One	4 (40%)	3 (30%)	3 (38%)	10 (36%)	
Two	1 (10%)	1 (10%)	0	2 (7%)	
Three or More	3 (30%)	5 (50%)	5 (62%)	13 (46%)	
Desire for distraction					.37*
No	3 (30%)	2 (22%)	0	5 (19%)	
Yes	7 (70%)	7 (78%)	7 (100%)	21 (81%)	
Expectation of pleasant experience					.06*
No	8 (80%)	5 (50%)	8 (100%)	21 (75%)	
Yes	2 (20%)	5 (50%)	0	7 (25%)	
Procedure length (minutes)**	49.0 (27.4)	31.6 (11.0)	31.6 (30.8)	37.8 (24.7)	.11
Pre-Procedure Pain Questionnaire [0–100]**	22.9 (26.0)	8.7 (14.5)	40.1 (30.9)	22.8 (26.6)	**.041**
STAIC State Anxiety Scale**	33.6 (10.6)	27.0 (4.0)	34.4 (9.1)	31.5 (8.7)	.06
STAIC Trait Anxiety Scale**	34.1 (7.1)	33.5 (7.5)	34.6 (5.0)	34.0 (6.5)	.71

STAIC, Spielberger State-Trait Anxiety Inventory for Children.
Boldface indicates statistical significance.
*N (column %) and Fisher's exact test reported. Otherwise,
**mean (SD) and Kruskal–Wallis test reported.
†N (column %) and Kruskal–Wallis reported for ordinal measure.

than a third of participants selected the following pain words to describe their burn wound care pain: "hurting," "sore," "burning," "throbbing," "itching," "uncomfortable," "tight," "off and on," and "comes and goes."

Summarizing the multivariable linear regression, males reported significantly less mean burn wound care procedural pain than females (32.6 mm, 95% confidence interval [CI]: 14.9–50.2, $P < .001$). No difference in state or trait anxiety existed between sex ($P = .96$ and $P = .43$, respectively). Males were more likely to have burns caused by fire (61% males vs 11% females), while females were more likely to have scald burns (67% females vs 11% males) ($P = .007$). There was no sex difference in burn size ($P = .74$). Age-related differences in procedural pain scores were not statistically significant as pain increased 2.8 mm on average with 1-year increase in age (95% CI: –0.2 to 5.8, $P = .07$).

Adolescents pretreated with opioid analgesics reported 22.1 mm more mean procedural pain than those not pretreated with opioid analgesics (95% CI: 7.0–37.1, $P = .004$). No difference in state or trait anxiety was estimated between those who received

or did not receive preprocedural opioid analgesics (P = .18 and P = .81, respectively). Although not statistically significant, participants who received opioid analgesics pretreatment were more likely to have burns caused by fire (55% opioid vs 14% no opioids), while participants who did not premedicate with opioid analgesics were more likely to have scald burns (57% no opioids vs 20% opioid analgesics) (P = .13). There was no difference in burn size between those who did and did not premedicate with opioid analgesics (P= .10). For every unit mm increase in preprocedure pain, an associated increase of 0.9 mm was associated in procedural pain (95% CI: 0.5–1.3, P < .001). State anxiety and treatment length were not associated with procedural pain in the multivariable model.

On average, the VR group reported less pain during the burn wound care procedure than either the PD or SC group, as determined by multivariable linear regression adjusted for age, sex, preprocedure pain, state anxiety, preprocedure opioid analgesic use, and treatment length. The overall model variation explained by the covariates was 81.2% (R^2 = .812), with an estimated optimism (ie, overfit) of 19.1% points. The overall model variation explained by the covariates adjusting for overfit was 62.1% (R^2 = .621). Group assignment accounted for 5.1% of the variance explained in the procedural pain scores in the multivariable regression model. Between group differences in burn wound care pain scores are displayed in Figure 2. Participants in the VR group reported significantly less procedural pain than the PD group (difference = 23.7 mm, 95% CI: 2.4–45.0, P = .029) and, while not statistically significant, less procedural pain compared with the SC group (difference = 9.7 mm, 95% CI: –9.5 to 28.9, P = .32). Pair-wise effect sizes were estimated between treatment groups. The estimated effect size between VR and SC groups was 0.535, between SC and PD effect size was 0.79, and between VR and PD effect size was 1.25. Finally, the VR group was the only group to have a decrease in pain perception from preprocedure pain reported to wound care procedural pain reported.

Aim 2. The second aim of this study was to determine the relationship and interaction among anxiety, desire for distraction, belief in distraction's efficacy, and engagement with distraction on adolescents' acute pain perception during burn wound care.

The estimated semipartial correlations are summarized in Table 2. Both desire for distraction and belief in the distraction's efficacy were estimated to not have statistically significant correlations with state anxiety, trait anxiety, or procedural pain. Engagement with distraction was significantly associated with a negative correlation for both trait anxiety and procedural pain reduction, adjusting for the effects of the other covariates, that is, preprocedural pain, sex, treatment group, and preprocedural opioid analgesic use, on the correlation between distraction engagement and the outcome measures. Trait anxiety was negatively correlated with distraction engagement, indicating that as trait anxiety increased, engagement with distraction decreased independent of the adjusting covariates. Trait anxiety accounted for 39% of the variation in engagement with distraction after adjusting for the covariates. Procedural pain accounted for 6% of the variation in distraction engagement after adjusting for the covariates. While engagement with distraction was assessed qualitatively during the procedure by the first research assistant who remained with the patient throughout the wound care procedure, the quantitative score used for the correlation was obtained through self-report from the Post-Procedure Questionnaire item.

DISCUSSION

The results of this study contribute to the growing body of evidence supporting interactive, high-technology VR as an effective method for reducing procedural pain in patients during burn wound care. Further, our study indicates that type of technology may matter in VR pain control. The first randomized controlled clinical trial of adolescent pain reduction during burn wound care compared off-the-shelf interactive VR to

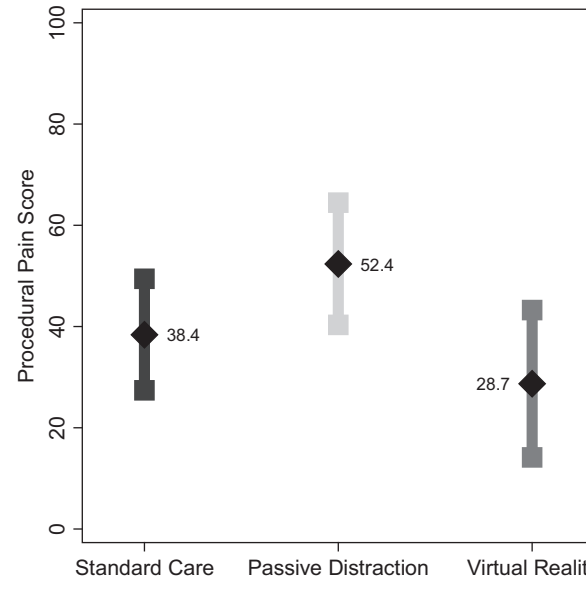

Figure 2. Estimated procedural pain scores by group adjusting for age, sex, state anxiety, opioid analgesic use, treatment length, and preprocedural pain.

Table 2. Estimated semipartial correlations of distraction attitudes to anxiety and pain

	Desire for Distraction (n = 28)		Belief in Distraction's Efficacy (n = 18)		Engagement with Distraction (n = 18)	
	Semipartial Correlation	*P*	Semipartial Correlation	*P*	Semipartial Correlation	*P*
STAIC State Anxiety*	.223	.26	−.276	.15	−.102	.61
STAIC Trait Anxiety*	.119	.59	−.347	.18	−.622	**.007**
Procedural Pain†	−.059	.60	.210	.054	−.217	**.045**

Boldface indicates statistical significance.

*Semipartial correlation estimated adjusting for age, sex, pretreatment opioid analgesic use, and treatment group.

†Semipartial correlation estimated adjusting for age, sex, pretreatment opioid analgesic use, preprocedural pain, and treatment group.

STAIC, Spielberger State-Trait Anxiety Inventory for Children.

a standard distraction group that had access to television, stories, music, caregivers, or no distraction and found lower but not statistically significant self-report pain in the VR group.[69] Our study adds support for use of a *high-technology*, customized VR device that can be implemented without wearing the heavy HMD VR helmet that may interfere with burns to the head. We believe our study is the first known randomized controlled clinical trial to use the VR technology in this way with an adolescent population. We used a similar device and found consistent results with another study of adults using SnowWorld and the first arm-mounted VR system not requiring participants to wear the helmet, which found positive results along with increased patient comfort, more patients who could use VR such as those with head burns, and reduced contact between the patient and the VR equipment.[70] As a result of the newer, articulated-arm device to hold the VR hardware, participants in our study were able to engage in the virtual environment by interacting through manipulation of the trackball rather than through head movements. No participants of the VR group in our study experienced any seizures or reported any nausea or adverse motion effects associated with the use of the VR technology even during the longer usage times. This benefit may have been related to lack of a fully immersive virtual environment. Despite lack of a fully immersive experience and ability of participants to move their view away from the virtual environment, participants reported engaging and interacting in the virtual environment. Participants of the VR group and their parents commented on how much they appreciated use of a high-technology method of pain management during the wound care procedure. All the VR group participants indicated they liked the VR and would recommend it to others.

While the interactive, more engaging VR distraction is supported by the findings in our study, PD provided by watching an age-appropriate movie and listening through noise-cancelling headphones was not as effective as VR or even as effective as standard care. The mean adjusted pain rating was highest for the PD group. While all but one participant in the PD group indicated they liked the movie, procedural pain was highest in this group. The significant correlation estimated between engagement and procedural pain lends support to the theories of attention and distraction that suggest that with more engaging distraction, less procedural pain is experienced, but also that less engagement with distraction is possible with more severe pain.[23] Because engagement in the distraction and procedural pain were negatively related, the higher pain in the PD group suggests this group was less engaged in the distraction. The VR group was the only group that included action as part of the experience. Engagement in an activity may be related to action or a sense of control associated with the action itself or may be associated with immersion into the distracting virtual world. Studies comparing other active distraction techniques using less-expensive and sophisticated technology to PD techniques may add to theoretical understandings of distraction and suggest practical interventions for clinical practice.

Engagement with distraction was also significantly, negatively correlated with trait anxiety. This suggests that those individuals with a tendency toward anxiety proneness may be less engaged with distraction as a method of reducing procedural anxiety and pain. Further, state anxiety and preprocedural pain were positively related. These findings lend support for consideration of both anxiety and pain reduction when selecting interventions to be implemented before and during procedures. Patients who present with a tendency toward higher anxiety proneness and preprocedural pain and anxiety may need unique preprocedural interventions to lessen the pain

experienced during the procedure. Further research on strategies to reduce anxiety and pain before and during burn wound care and the effectiveness of VR on both are recommended.[38,54]

Overall, most but not all participants in the study wanted to be distracted and believed in its efficacy to reduce procedural pain. Yet, similar to findings in a previous study of distraction interventions compared with SC provided by the nurses performing the procedure, less pain was reported in the SC group compared with a more PD intervention, although not statistically different in either study.[23] The question of the influence of the nurse as a powerful "intervention" in the patient–nurse relationship to lessen procedural pain warrants further investigation and may require a qualitative-methods approach. Additionally, future studies comparing the distraction intervention with SC may consider scripting the approach nurses take with patients in the SC group to minimize variations among nurses providing the wound care. This would provide for a more consistent approach to SC. Further, another study found that not all participants desired distraction.[46] Future research to address matching nonpharmacologic interventions with coping styles and preferences is needed to enhance tailoring interventions for patients in clinical practice. Perhaps some patients who want to "attend" to the procedure may do better by actively participating in the wound care procedure, while others may want to be fully immersed in the distraction and not participate in the procedure at all because participating in the wound care may represent a mismatch with coping style by drawing attention back to the painful procedure.

Sex differences in this study are consistent with another study finding similar results with females reporting higher pain scores than males.[23] However, in another study sex did not explain any of the variances in postoperative pain ratings in adolescents undergoing spinal fusion surgery.[71] These findings suggest additional study of sex and pain including preferences of males and females for procedural pain management interventions. Specific to VR distraction, developing a wider range of VR programming choices and more advanced technical equipment might enlarge the success of VR pain distraction within sex and various age groups.

This clinical study is one of the few studies to use the between-subjects design rather than the often-used within-subjects designs of other VR studies. This permitted a comparison of the VR intervention with other intervention groups. The singled-blinded procedure used in this study offers an advantage over previously unblinded studies. Participant blinding to the study group until just before the wound care procedure and after preprocedural data collection, PI blinding to the assigned study group, and the blinded research assistants during study enrollment, consent and data collection, especially with regard to the outcomes measures, limited bias and enhanced the internal validity of the study.

The use of the APPT as a multidimensional pain measure permitted a more comprehensive understanding of burn wound care pain. Variability in adolescents' pain ratings and choice of pain words to describe burn wound care pain reflect individual perception of pain and remind healthcare providers that each individual's procedural pain experience is unique. The pain words chosen by the adolescents add a new contribution to our understanding of burn wound care pain. This is the first known study to include words that adolescents use to describe the burn wound care experience.

The effect size of 1.25, a large effect, may explain the ability to detect a significant difference between the VR and PD groups despite the small sample size. This has implications for future research, suggesting that a two-group, between-subjects design would require only 13 participants per group to detect a significant difference with an effect of 1.25. Anticipating a more moderate effect of 0.5, 65 participants would be needed per group in a two-group design.

Implications for Practice

Subjectively, nurses report that burn wound care pain is often underassessed and therefore remains undertreated. Premedication with oral opioid analgesics before wound care is not enough to prevent severe episodic pain during the procedure. Results of this study suggest the safe, nonpharmacological, noninvasive use of VR during wound care can be an invaluable resource to healthcare professionals. VR as an adjuvant to pharmacologic interventions can result in a decrease of opioid analgesic use, which is widely known to have undesirable side effects.

Currently, routine use of VR in a clinical setting has several limitations: size and cost of the equipment, technical resource limitations, hardware/software malfunctions, and concerns regarding infection control. These limitations can affect the success of a VR program. Other considerations include an increased time necessary to set up, remove, and disinfect the VR equipment. Patient exclusion criteria including burn mapping distribution and history of motion sickness or seizure disorders may also limit use by some patients. Clinical application

of high-end technology VR is a concern especially because of the expense and availability of hardware equipment. Increased availability and lower cost of high-technology equipment are needed for full widespread implementation in the clinical setting.

Limitations

The small, convenience sample of one burn center site is a limitation of this study despite being one of the larger sample size clinical studies on the use of VR for procedural pain management, especially in the pediatric population. Given the small sample size for a three-group, between-subjects study, accounting for key covariates in the statistical analysis to answer the first study aim led to an overfit regression model. Yet, the multivariable linear regression model allowed for these key clinical, demographic, and psychological covariates to be taken into account in order to elucidate the treatment effect. Other variables may have affected the outcome analysis, such as the time from the original burn injury to the wound care treatment under study. While no statistically significant differences were found between the groups on time from injury, the fewer mean number of days since injury in the PD group could be a factor in that group's higher mean pain score. Variation in days from the original burn injury and the individual's experience with previous wound care episodes may affect individual perception of pain and anxiety. Thus, this study's results should be interpreted with caution; generalizability of the study findings is limited. Replication of this study, consideration of other key variables, and conducting other randomized controlled comparative studies using high-technology, interactive VR without the HMD helmet including larger sample sizes are recommended.

Because this study's design included only one burn wound care treatment in an ambulatory clinic setting, results may not be applicable to an inpatient setting where more extensive burns may be encountered. Furthermore, effective results related to the VR intervention may not persist over repeated burn wound care procedures. However one recent study has demonstrated beginning support for repeat use of VR over several burn wound care treatments to lessen procedural pain.[37]

Two technical problems experienced with the VR hardware and software early in the study forced one subject to withdraw from the study just before burn wound care was initiated and another subject to be reassigned to another study group after enrollment but before randomization. Ongoing improvements with the VR technology should lessen unfortunate technical occurrences but technical problems seem inherent in any type of technology product.

Another limitation of this study relates to the self-report method used for evaluation of procedural pain measurement. To avoid interrupting the distraction intervention and thus engagement, the measurement of procedural pain took place after the burn wound care procedure was completed. The element of memory is always in place when self-report measurement takes place after the procedure. Yet self-report is considered the definitive standard for pain assessment. Combining self-report with other measures, such as behavioral observation and physiological measures, for example, vital signs, pulse oximetry, and salivary cortisol, during the procedure may provide a more comprehensive measurement of the procedural experience. Refinement of procedural anxiety measurement would be important to determine the effect of the distraction intervention on anxiety as well as on pain. Improving the measurement of engagement with distraction also needs consideration.

CONCLUSION

Despite its limitations, this study provides several contributions to the literature; foremost being a partially blinded, between-subjects, randomized controlled clinical trial evaluating the effect of VR compared with another more PD and SC during a burn wound care procedure in an adolescent population in an outpatient clinic setting. Further, the use of the VR intervention throughout the burn wound care procedure without any side effects and ability to interact and engage with the VR without wearing the HMD helmet offer additional support. In conclusion, interactive, high-technology VR is a powerful, engaging distraction in lessening pain perception during burn wound care in the adolescent population in the ambulatory setting even without requiring wearing of the HMD helmet. Further studies with larger sample sizes are warranted to replicate findings and extend to other populations including inpatient settings and other types of procedures. With further empirical support for the benefits of VR and improvement in and reduced cost of VR technology, routine use of VR in clinical settings may become more feasible and commonplace.

Less support for PD was demonstrated in this study, but additional comparative effectiveness studies are needed to better understand cognitive and behavioral mechanisms of distraction in lessening procedural pain. A beginning exploration of factors promoting efficacy of distraction

for lessening acute procedural pain in adolescents experiencing burn wound care pain is offered by this study. The interrelationships of anxiety, sex, engagement in distraction, and pain warrant additional study. Similar calls for research on nonpharmacologic interventions include consideration of child temperament, ages, and preferred coping strategies.[10,47,72] Studies tailoring nonpharmacologic interventions matched to the individual's choices, coping styles, and preferences for procedural pain management may demonstrate improved procedural pain control. Treating burn wound care pain in children and adolescents by using novel nonpharmacologic approaches is essential in mitigating the severe pain and emotional trauma associated with this procedure.

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