ORIGINAL ARTICLE

Factors Influencing the Efficacy of Virtual Reality Distraction Analgesia During Postburn Physical Therapy: Preliminary Results from 3 Ongoing Studies

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ABSTRACT. Sharar SR, Carrougher GJ, Nakamura D, Hoffman HG, Blough DK, Patterson DR. Factors influencing the efficacy of virtual reality distraction analgesia during postburn physical therapy: preliminary results from 3 ongoing studies. Arch Phys Med Rehabil 2007;88(12 Suppl 2):S43-9.

Objective: To assess the efficacy and side effects of immersive virtual reality (VR) distraction analgesia, as well as patient factors associated with VR analgesic efficacy in burn patients who require passive range-of-motion (ROM) physical therapy (PT).

Design: Prospective, randomized, controlled, within-subject trials.

Setting: Regional level I burn center in a university-affiliated urban hospital.

Participants: Patients (age range, 6−65y) who required passive ROM PT in sessions lasting 3 to 15 minutes after cutaneous burn injury.

Interventions: Standard analgesic (opioid and/or benzodiazepine) care and standard analgesic care plus immersive VR distraction.

Main Outcome Measure: Self-reported subjective pain ratings (0 to 100 graphic rating scale).

Results: A total of 146 treatment comparisons were made in 88 subjects, 75% of whom were children ages 6 to 18 years. Compared with standard analgesic treatment alone, the addition of VR distraction resulted in significant reductions in subjective pain ratings for worst pain intensity (20% reduction), pain unpleasantness (26% reduction), and time spent thinking about pain (37% reduction). Subjects' age, sex, ethnicity, size of initial burn injury, or duration of therapy session did not affect the analgesic effects of VR distraction. Nausea with the standard care plus VR distraction condition was infrequent (15%) and mild, with 85% of the subjects reporting no nausea. Children provided higher subjective reports of "presence" in the virtual environment and "realness" of the virtual environment than did adults, but age did not affect the analgesic effects of VR distraction.

Conclusions: When added to standard analgesic therapy, VR distraction provides a clinically meaningful degree of pain relief to burn patients undergoing passive ROM PT. Multiple patient factors do not appear to affect the analgesic effect. Immersive VR distraction is a safe and effective nonpharmacologic technique with which to provide adjunctive analgesia to facilitate patient participation in rehabilitation activities.

Key Words: Analgesia; Burns; Pain; Physical therapy techniques; Rehabilitation; Virtual systems.

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PATIENTS WITH SEVERE cutaneous burn injuries require comprehensive care, including daily wound care, surgical skin grafting, nutritional support, and coordinated rehabilitation therapy. Aggressive physical therapy (PT) is of particular value to victims of significant extremity burns in efforts to increase the flexibility and elasticity of healing skin (native or grafted), and to help maintain normal extremity range of motion (ROM) and function. Without daily PT, the normal healing process in burn-injured skin may result in contractures and reduced joint ROM secondary to hypertrophic scarring.[1,2] Thus, successful participation in such rehabilitation activities is often crucial to minimizing long-term disability. Unfortunately, the pain and anxiety associated with PT can discourage burn patients from participation[3] and can lead to such additional morbidity as permanent reduction in limb mobility, or to a need for further surgery. Because procedural pain often cannot be adequately managed with pharmacologic analgesics alone (eg, opioids), in large part because of intolerable side effects (eg, opioid-induced sedation and respiratory depression),[4] these patients are aggressively treated with both pharmacologic and nonpharmacologic analgesic techniques.[5] Several nonpharmacologic, psychologic techniques have been used alone or as adjuncts to opioid analgesics[6] to reduce pain during brief procedures such as postburn PT. Cognitive distraction (eg, listening to music, watching a movie) is one psychologic technique that favorably alters pain perception.[7]

Immersive virtual reality (VR) is a particularly attention-grabbing distraction technique that is designed to give users the illusion of going inside a computer-generated virtual environment. VR appears to provide significant cognitive distraction because it is interactive, it utilizes a head-mounted display that blocks from the user visual and aural input from the immediate medical care environment, and it places significant cognitive demand on patients through the provision of multisensory input (visual, aural, and sometimes tactile). Thus, VR commands the user's attention and may exert its analgesic effect by diverting conscious attention away from concurrent nociceptive stimulation, resulting in an attenuated subjective pain experience. Adjunctive, immersive VR distraction has provided clinically meaningful pain relief (at least 33% reductions in subjective pain scores[8]) compared with standard care (eg, opioid analgesia alone, with or without lesser forms of cognitive distraction) in

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Table 1: Summary of 3 Study Protocols Utilized for Data Collection

Protocol Component	Study Protocol 1	2	3
Within-subject design	Yes	Yes	Yes
Control condition	Standard care	Standard care	Standard care
Intervention condition	Standard care + VR	Standard care + VR	Standard care + VR
0 to 100 GRS scores for pain, nausea, VR realness, and VR presence	Yes	Yes	Yes
Patient age range (y)	21–66	6–18	6–19
Study days	2	1	≥2
Condition duration (min)	10–15	3–15	3–15

Abbreviation: GRS, graphic rating scale.

different clinical procedural pain settings, including burn wound débridement,[9-11] postoperative PT,[12] prostate thermosurgery,[13] and dental procedure pain.[14] Similarly, VR distraction has been reported to reduce pain and nausea, and enhance comfort in patients undergoing brief cancer-related procedures,[15,16] and in cancer chemotherapy.[17-19]

Specific to the setting of postburn PT, immersive VR distraction has been an effective analgesic in 2 preliminary studies exploring single therapy sessions[20] and multiple, serial therapy sessions.[21] Both studies, however, were constrained by the small numbers of subjects (a total of 19 subjects), which limits the generalizability of VR analgesic efficacy and side effects to larger populations of burn patients, and also limits the ability to determine potential associations between efficacy and patient age, sex, race, or other factors. Our goal in this study was to assess the efficacy and side effects of VR distraction analgesia, and to determine what patient factors, if any, are associated with VR analgesic efficacy, in a larger sample of burn patients who require passive ROM (PROM) PT.

METHODS

Participants

Study patients were recruited from the daily inpatient census of the regional level I burn center for the 5-state Pacific Northwest region of the United States, located in Seattle. Eligible patients were between 6 to 65 years of age and who required postburn PT consisting of PROM exercises on at least 1 occasion during their hospital stay. Participation was voluntary and subjects were not reimbursed for their participation. Informed written consent (and parent/guardian assent for children) was obtained using protocols reviewed and approved by the institutional human subjects review board.

Study Design

To maximize the number of participants in order to meet the study's goal, we pooled data from 3 ongoing, separate studies of the application of immersive VR distraction analgesia for postburn PT. None of the 3 studies has been completed, summarized, or submitted for publication. Taken individually, none will have sufficient sample size to meet this study's goal, but by combining their data our goal will be met. No patient was enrolled in more than 1 study.

The protocols for the 3 studies were identical in the following ways: (1) each subject was assigned the same therapist for all exercise sessions, (2) the maximum duration of the therapy session was 15 minutes, and (3) all studies used a within-subject design that compared subjective pain ratings between "standard care" and the "standard care plus VR distraction," thereby controlling for each subject's pre-procedure pharmacologic analgesic therapy (not controlled by the investigators). The protocols differed slightly, however, in the age range of the study populations and the number of PT sessions. Details of each study protocol are provided below and summarized in table 1.

Study 1. Subjects were ages 21 to 65 years who required PROM exercises of 1 or more joints during 1 daily PT session that was repeated in an identical fashion on 2 consecutive days. Subjects received standard analgesic care (systemic opioid and/or benzodiazepine medication) on 1 day, and identical standard analgesic care plus VR distraction on the other day, with the order of treatments randomized by a random number generator. Self-reported subjective assessments of pain, nausea (VR condition only), "realness" of the virtual environment (VR condition only), and sense of "presence" in the virtual environment (VR condition only) were recorded immediately after each treatment session with 100-mm graphic rating scales (GRSs) (see below).

Study 2. Subjects were ages 6 to 18 years who required PROM exercises of 1 or more joints during a single PT session performed on 1 day. Subjects received standard analgesic care (systemic opioid and/or benzodiazepine medication) before the session, which was divided into 2 components corresponding to the intervention conditions of standard analgesic care with or without VR distraction that were identical in both duration and content. VR was not administered during 1 of the session components but was during the second component, with the order of treatments randomized, again by random number generator. Self-reported subjective assessments were identical to those described for study 1.

Study 3. Subjects were ages 6 to 19 years who required PROM exercises daily of 1 or more joints in 2 or more consecutive PT sessions. Subjects received standard analgesic care (systemic opioid and/or benzodiazepine medication) before each session, with the session divided into 2 components identical in both duration and content. VR was not administered during 1 of the components but was during the other component, with the order of treatments randomized, also by random number generator, and counterbalanced. Subjective assessments were identical to those described for study 1.

Although standard analgesic care was individualized and often differed among the subjects, the within-subject study design provided for pharmacologic analgesia that was identical (drug and dose) for each subject in both the control (no VR)

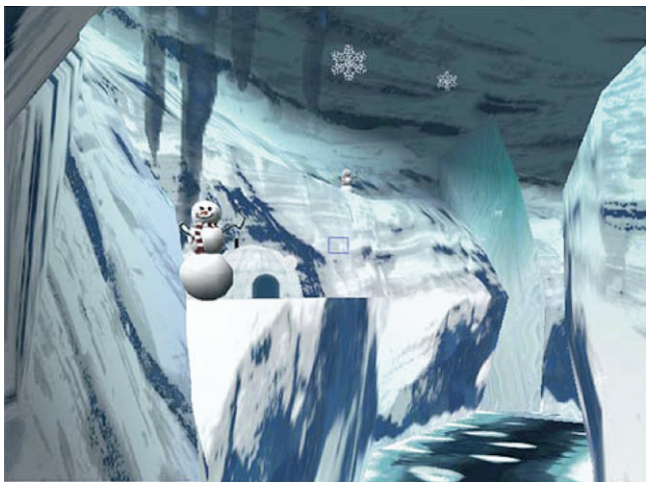

Fig 1. User's view of SnowWorld, the 3-dimensional virtual environment experienced by subjects when in immersive VR. Reprinted with permission. Image by Stephen Dagadakis. ©Hunter Hoffman, University of Washington.

and VR distraction conditions. Because the standard analgesic care was controlled, and because the PT sessions were identical (in both content and therapist) under both study conditions, the dependent outcomes assessed reflect the specific effect of the VR distraction intervention.

Study Protocol

The typical PT session consisted of slow, gentle stretching of the selected extremity to end range of the affected joint in all possible planes of movement. When more than 1 joint was involved, the proximal joint was ranged first, followed by the distal joint(s). The same assisted PROM exercises were performed during both experimental conditions for each patient (ie, same exercises performed in the same plane[s], same number of repetitions, and same duration of stretch time). Treatment sessions in both study conditions were timed (maximum, 15min) to ensure that both sessions were of equal duration for a given patient. Although the order of the 2 interventions was randomized (ie, each treatment condition had an equal chance of occurring first or second for each patient), joint ranging in the VR condition was always preceded by helmet placement and a brief (1−2min) orientation period to familiarize the patient with how to navigate the virtual environment.

The VR system consisted of a personal computer workstation with dual 2GHz central processing units, 2GB of RAM, a GeForce 6800 video card running the VR software SnowWorld[a] on the Windows 2000 operating system. We used a Polhemus Fastrak position tracking system[b] to monitor the position of the user's head. While in immersive VR SnowWorld, subjects followed a predetermined path, "gliding" through an icy 3-dimensional virtual canyon. Subjects aimed with their gaze direction (head orientation) and pushed a keyboard button to shoot virtual snowballs at virtual snowmen, igloos, robots, and penguins (fig 1).

The VR condition included head tracking (eg, subjects saw the sky when they looked up, a canyon wall when they looked to the left or right, a river when they looked down), sound effects (eg, a splash when a snowball hit the river), and animated green, blue, or white colored explosions. Subjects wore the nVisor SX[c] high-resolution, head-mounted display, which completely blocked their view of the immediate, real world, medical care environment. This helmet has a 60° diagonal field of view for each of the 2 eyepieces, and a resolution of 1280×1024 pixels per eye (2 eyes = 2,621,440 pixels total). The head-mounted display included stereophonic sound consisting of background music, intermittently joined by sounds of snowball shooting, snow splashing in the virtual river, and other sound effects.

Immediately after each therapy session (study 1) or component session (studies 2 and 3), subjects were asked to provide subjective ratings of 3 separate pain outcomes, as well as the "fun" they had during the session (studies 2 and 3 only), using the 0- to-100-labeled GRSs. Specifically, subjects rated the amount of time spent thinking about pain (cognitive pain dimension), pain unpleasantness (affective pain dimension), and worst pain intensity (sensory pain dimension) they experienced during the preceding therapy session. Such pain rating scales are valid through their strong associations with other measures of pain intensity, as well as their ability to detect treatment effects.[22,23] Cognitive, affective, and sensory pain are separately measurable and are often differentially influenced components of the pain experience, and such ratio scale measures have reliably assessed these subjective pain outcomes.[24] Figure 2 shows an example of one such labeled GRS. In addition, after every therapy session performed in the VR condition, subjects were asked to provide subjective ratings (using GRSs) of any nausea they experienced (to assess for potential simulator sickness), the perceived "realness" of the virtual environment, and the degree to which they felt "present" in that environment. VR presence is a subjective illusion created by sensory input in the user's mind and can be assessed by 1-dimensional or multidimensional rating scales.[25,26]

Data Analysis

To take advantage of the within-subjects study design (each subject serving as his/her own control), we used regression models that accounted for the longitudinal nature of the data to assess all outcomes. Specifically, to account for correlations among repeated measures on the subjects, generalized estimating equations were used to obtain valid standard errors of model parameter estimates. We used separate regression models for each of the dependent variables (time spent thinking about pain, pain unpleasantness, worst pain intensity, nausea, fun, VR realness, VR presence). The independent variables were categorical in nature and included the primary intervention (standard care, standard care plus VR distraction), and the demographic variables of sex, age (6−18y, 19−65y), and ethnicity (white, nonwhite). We used dummy variables to represent these in the regression models. Interaction terms were included as products of the dummy variable for VR and the demographic dummy variables. We assessed potential effect modification (interaction) of patient factors on VR analgesia

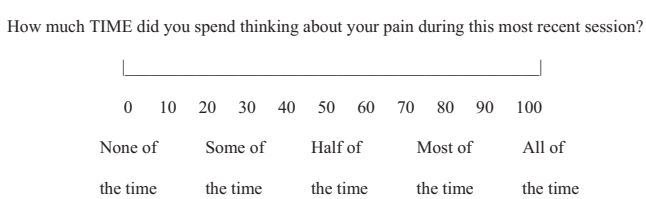

Fig 2. Example of a GRS used for subjective pain assessment by subjects; in this example, the subject is assessing the cognitive dimension of the pain experience (time spent thinking about pain).

Table 2: Demographics of Study Population

Demographics	Study Population	
	Subjects (n=88)	Comparisons (n=146)
Males	74 (84)	120 (82)
Females	14 (16)	26 (18)
Ages 6−18y	52 (59)	110 (75)
Ages 19−65y	36 (41)	36 (25)
Ethnicity: white	68 (77)	110 (75)
Ethnicity: nonwhite	20 (23)	36 (25)

NOTE. Values are n (%). Because the study protocol for study 3 allowed subjects to be evaluated in both treatment conditions (standard care, standard care plus VR distraction) on more than 1 study day, 26 subjects were studied on multiple occasions (range, 2−7d), resulting in a total of 146 treatment comparisons among the 88 study subjects.

using the same models. We also used linear regression models for outcomes measured only in the VR distraction condition (nausea, VR realness, VR presence).

All statistical analyses were performed using SAS,[d] and comparisons differing at the level of *P* less than .05 were considered significant.

RESULTS

Eighty-eight subjects (74 males, 14 females) aged 6 to 65 years completed the study. Because 26 subjects in study 3 were studied under both treatment conditions (standard care, standard care plus VR) on more than 1 day (range, 2−7d), the final dataset included a total of 146 within-subjects comparisons between the standard care and the standard care plus the VR distraction conditions. Table 2 shows the demographics of the study population and the population of comparisons. The majority of subjects (84%) and comparisons (82%) were male, a sex predominance in the study population that reflects burn injury survivor demographics in the United States in general (70%[27]) as well as among all patients admitted to the burn center where the study was performed (71%[28]). With respect to age, 75% of comparisons were performed in children ages 6 to 18 years and 25% were performed in adults 19 to 65 years of age. Of the 20 nonwhite subjects, 8 were African Americans, 2 were Asian/Pacific Islanders, 6 were Hispanics, and 4 were American Indians. Initial burn injury size ranged from 1.5% to 60% of total body surface area.

The subjective pain and fun scores for the entire cohort of comparisons are summarized in table 3. The addition of VR distraction to standard analgesic care resulted in significant improvements in pain reports, including a mean reduction of 20% across the entire comparison group for worst pain intensity, 26% for pain unpleasantness, and 37% for time spent thinking about pain. The amount of fun that subjects reported experiencing during the therapy session increased 4-fold with the addition of VR distraction. Of the significant improvements observed in all 3 pain outcome measures with the addition of VR distraction to standard care, none were affected by age (≤18y vs ≥19y), sex, ethnicity (white vs nonwhite), initial burn size, or duration of therapy session (3−5min vs 6−15min).

Table 3: Summary of Subjective Pain and Fun Ratings (0 to 100 GRS assessment) Between Treatment Conditions (n=146 comparisons)

Outcome	Treatment Condition		*P*
	Standard Care	Standard Care Plus VR	
Worst pain intensity	54.2±3.1	43.5±3.5	.003
Pain unpleasantness	41.0±3.6	30.3±3.0	.01
Time spent thinking about pain	47.1±3.5	29.5±3.0	<.001
Fun	18.7±3.1	73.7±3.1	<.001

NOTE. Values are mean ± standard error (SE).

Table 4: Summary of Age-Dependent Outcomes (0 to 100 GRS assessment) in the VR Distraction Condition (n=146 comparisons)

Outcome	Age Subgroup		*P*
	6−18 Years	19−65 Years	
VR realness	47.0±4.7	31.2±3.9	.02
VR presence	53.5±5.3	35.9±3.9	.01
Worst pain intensity	42.2±4.3	47.4±4.9	.43
Pain unpleasantness	31.7±3.9	26.3±4.0	.33
Time spent thinking about pain	30.2±3.8	27.5±3.7	.60

NOTE. Values are mean ± SE.

The 3 outcomes assessed only in the VR distraction condition (nausea, user assessment of realness of the virtual environment, user assessment of presence in the virtual environment) are summarized in table 4. User assessments of both realness of, and presence in, the virtual environment were affected only by age of subjects, with younger subjects (6−18y) reporting significantly higher ratings for SnowWorld realness and presence than adult subjects (19−65y). Despite these age-dependent differences in the virtual environment experience, however, there were no age-dependent differences in subjective pain ratings in the VR distraction condition. Eighty-five percent of participants rated nausea in the standard care plus VR condition as zero. The remaining 15% reported only mild nausea, with a mean subjective magnitude of 15 (0−100 GRS assessment). Nausea ratings were not affected by age, sex, ethnicity, initial burn size, or duration of therapy session.

DISCUSSION

Rehabilitation activities, including PT and occupational therapy, are integral components of today's comprehensive treatment approach to patients with major burn injuries. Specifically, PROM PT, by maintaining skin elasticity and flexibility, is beneficial in preventing hypertrophic scarring, contractures, and reduced joint mobility that are often secondary complications resulting from normal healing mechanisms in burn-injured skin. Such therapy sessions begin as soon as possible after the initial injury and require daily repetition for periods of weeks to months to prevent complications of immobility. The pain that patients experience during these therapy sessions is significant, repeated, challenging to treat, and is also a determinant of how patients will cooperate and participate in the rehabilitation plan.[2]

Early analgesic interventions in the inpatient burn care setting usually involve systemic opioids and/or anxiolytics[5]; however, unintended side effects of these medications, as well as a desire to minimize such agents before hospital discharge, may limit their use. As a result, nonpharmacologic behavioral interventions such as cognitive distraction and behavioral modification, are valuable analgesic adjuncts in the treatment of burn-related rehabilitation pain.[3,29] Preliminary reports suggest

that distraction with immersive VR may have both analgesic and functional outcome benefits in this specific setting,[20,21] as well as in nonburn settings, such as postoperative PT.[12] Published reports of VR distraction analgesia in these and other medical care settings have been severely limited by their small sample sizes. As a result, little is known about the generalizability of these preliminary results, or of the potential interaction effects of various patient factors such as age, sex, and ethnicity on the reported analgesia.

We conducted this study to address these shortcomings by assessing the analgesic efficacy and other factors associated with VR distraction in a significantly larger population, including a wider range of subjects, than previously reported. A within-subjects design permitted the specific assessment of VR distraction analgesia while controlling for individualized and varying pharmacologic analgesic dosing that necessarily occurs in the clinical setting. Our principal finding was that VR distraction, when added to standard analgesic care, resulted in statistically significant and/or clinically significant (defined as at least 33% or greater[8]) reductions in subjective pain reports for 3 complementary dimensions of the pain experience (sensory, emotional, and cognitive pain). The magnitude and direction of the VR analgesic effect were consistent with those reported in previous pilot studies in the same burn PT setting.[20,21]

Regarding the potential application of VR analgesic techniques to varying patient populations, we found the analgesic effect of VR distraction to be maintained irrespective of patient age, sex, and ethnicity. These findings of potential wide applicability are consistent with VR analgesia investigations in experimental pain settings, including the independence of analgesic effect on sex[30] and on hypnotizability.[31] In addition, patients in this study reported a 4-fold greater sense of fun when engaged in ROM exercises during VR distraction than without it. This is an important finding in that anticipatory anxiety and an increased pain experience can result from the performance of repeated, painful medical procedures,[32] and may be attenuated with behavioral interventions.[33,34] Although we did not assess it, one might speculate that the fun associated with VR distraction during painful PT may be a valuable incentive for patients to be more cooperative with, and more consistent in, their therapy, potentially enhancing rehabilitation success, as well as pain reduction. Together, these observations provide increasing evidence that VR distraction is of potential widespread benefit in treating the pain associated with rehabilitation activities.

VR "presence" is a subjective illusion created in the user's mind, a psychologic state of consciousness that is determined by the sensory input delivered to the user, and is distinguished from VR "immersiveness."[25] VR immersiveness is an objective quality determined by the hardware and software components of the VR system,[25] and is an important determinant of VR presence. For example, enhancing VR immersiveness by increasing the field-of-view size in the VR helmet,[35] adding or improving the quality of sound input,[24] and adding electromagnetic head-tracking[24] have all increased the user's subjective illusion of VR presence.

One interesting finding of our study is that patient assessments of the VR experience differed with age, with children and adolescents (≤18y) reporting a greater sense of realness of the virtual environment and a greater feeling of presence in that environment compared with adults (≥19y). Such age dependence of user impression of virtual environments has been previously reported,[36] and may seem predictable, given the more regular exposure that children have to similar audiovisual experiences (eg, videogame entertainment). Relevant to the issue of pain relief, however, the age-dependent difference in VR experience we found did not translate into an age-dependent difference in VR analgesic effect. This observation suggests that under the conditions of the current study, the magnitude of VR presence may not correlate with the magnitude of analgesic effect. This relationship has been explored in experimental pain studies with VR distraction using manipulations of immersiveness designed to affect both presence and analgesic effect. Increasing immersiveness by changing VR helmet characteristics, sound exposure, and user interactivity results in both increased user presence and analgesic effect,[9,37] whereas increasing immersiveness by changing helmet characteristics alone does not affect user presence, but does affect analgesia.[38] This is an important topic for further study because it would be useful to determine the optimal VR hardware and software system configurations that produce maximal distraction analgesia at the lowest cost. For example, the cost of a maximally immersive VR distraction system (such as the one we used) is currently about $30,000. Consumer-level audiovisual distraction systems (eg, handheld videogames) cost significantly less, but appear to provide significantly inferior distraction analgesia.[9] The cost-benefit balance of VR analgesia technology will become more clear as additional studies determine the potential reduction in hospital costs associated with VR analgesia (eg, shorter procedure times, more effective therapy procedures resulting from less pain), and hardware development and marketing trends lead to less expensive VR system components.

Study Limitations

This study had several limitations. First, in an effort to maximize the sample size, we combined data from 3, yet-to-be-completed studies. We described the rationale for this strategy above, but a single study protocol would be a more preferable study design. Second, the conditions of the standard care control group were based on the standard clinical care provided at our institution. It did not, however, provide any form of attentional control to adjust for potential bias of the subject or the therapist during the VR distraction condition. Nonetheless, objective neural correlates of VR analgesia have been reported using functional brain imaging, demonstrating reductions in pain-related brain activity during VR distraction (compared with no VR) in healthy volunteers experiencing thermal pain stimulation.[39] Third, although our study population was significantly larger than that of any previously reported clinical trial of VR distraction analgesia, the limited numbers of female and nonwhite subjects do not completely exclude the possibility of a type 2 error in concluding that VR analgesic effect is independent of sex and ethnicity. Fourth, our outcome measures were limited to subjective pain ratings and assessments of the VR experience and did not include measures of functional therapeutic outcome (eg, maximal PROM) of significant clinical importance. Last, nausea assessments were only obtained in the standard (pharmacologic) analgesic care plus VR distraction condition, and therefore do not specifically reflect the incidence of simulator sickness associated with VR distraction alone. In fact, opioids—well known for their nauseating side effects—were used in the standard care regimen in the majority of the subjects, and may have been responsible for an unknown portion of the reported nausea.

CONCLUSIONS

Our results indicate that VR distraction is an effective adjunctive pharmacologic analgesic technique for burn-related rehabilitation activities. Compared with standard an-

algesic care alone, this intervention resulted in significant reductions in complementary subjective patient pain ratings and did not appear to be affected by patient age, sex, or ethnicity. Future investigations should explore its effects on pain reduction and potential enhancement of functional outcome in other painful rehabilitation settings.

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Suppliers

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b. Polhemus, 40 Hercules Dr, PO Box 560, Colchester, VT 05446.
c. NVIS Inc, 11495 Sunset Hills Rd, Ste 202, Reston, VA 20190.
d. Version 9; SAS Institute Inc, 100 SAS Campus Dr, Cary, NC 27513.