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Virtual Reality in Surgery: Double Blind, Randomized Clinical Trial of Pain Control and Augmented Satisfaction

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Abstract

Introduction: Virtual reality (VR) utilizing a head-mounted display allows viewers to immerse themselves in a virtual environment. This technology may be useful in attenuating pain and anxiety and reducing patient subjective stress as well as objective physiological increase in heart rate and blood pressure. Aside from the improved experience, physiological stress is reduced which results in improved patient outcomes. **Patients and methods:** Eligible participants were all adults aged 18 or over who had non craniofacial lesions requiring minor surgery. A total of 99 adult patients who were capable of independent consent were randomized to receive a virtual reality experience (VR) or standard music distraction (no VR). Patients were recruited for the study during their office visit when scheduling minor procedure surgery. This was a single center, double-blind, controlled study conducted at Guthrie Clinic Robert Packer Hospital in Sayre, Pennsylvania between March 2019 to January 2020 (pre-pandemic). Ethics approval for this study was obtained from the Institutional Review Board of the Guthrie Clinic. **Results:** The change in systolic blood pressure (SBP), diastolic blood pressure (DBP) and heart rate (HR) significantly decreased from pre-procedure to mid-procedure in the VR group compared with standard. Herein our results are presented. **Conclusions:** Reductions in intraprocedural SBP, DBP and HR can be achieved when using VR. Although subjective reporting of pain and anxiety were not different between groups, VR significantly improves patient satisfaction compared with non VR standards.

Keywords

Virtual Reality, Plastic Surgery, Pain Control

1. Introduction

Virtual reality (VR) is a new technology that enables individuals to immerse themselves in a virtual world. VR has been studied in the treatment of medical and psychiatric conditions. Some researchers focused on VR as a form of pain and anxiety attenuation using the term VR analgesia [1] [2] [3] [4] [5].

360-degree video VR is created by filming with multiple high definition cameras carefully arranged to capture all angles in a 360-degree area of a live action event. These angles are stitched together post-production into a 360-degree texture sphere, and the sphere is then mapped to the head tracker on the user's head mounted display (HMD). When users turn their heads, their views of the live action video footage turn with them in real time, thus allowing the user to look around anywhere in the 360 degrees of filmed footage of the live action event. In advanced models, head tracking systems are built into the HMD enabling the VR system to track the motion creating the illusion of being completely surrounded by the virtual world.

Surgical procedures of the skin such as removal of benign or malignant skin lesions are amongst the most common interventions in the practice of surgeons. Although typically performed under local anesthesia, these are often associated with anxiety and fear of pain and discomfort. Adjunct distractive measures to decrease the level of anxiety may be able to help with pain perception and stress and improve overall patient experience.

Hoffman *et al.* [6] published a crossover study comparing VR with a video game (Nintendo 64) in two male adolescent patients attempting pain control during burn wound care and found declines in pain intensity, anxiety and time spent thinking about pain in both patients when using VR.

Simple forms of distraction that have been attempted for pain control in the past include imagery, relaxation and positive thinking [7] [8] [9]. More technology driven distracters include video games, 2D videos, and music [10]. VR distraction builds on these as it is immersive, engaging and integrates many sensory experiences resulting in more significant attention distracting.

Several theories regarding how distraction inhibits or decreases pain perception have been proposed. The gate control theory of Melzack and Wall [11] proposes that the central nervous system activities (*i.e.* attention, emotion, memory) play a role in sensory perception. When pain signals travel through the body, they must pass through "nerve gates" before the body can determine the level of awareness. In other words, the level of attention paid to the pain, the emotion associated with the pain, and past experience with pain all play a role in how that pain is individually interpreted. McCaul and Malott [12] expanded on gate theory suggesting that attention to pain is crucial to how pain is perceived concluding that if the individual is distracted, the perception of pain will be decreased.

Wickens [13] proposed the Multiple Resources Theory, which states that resources in different sensory systems function independently and multisensory

distraction such as used in VR technology adds to better pain control.

Bantick *et al.* [14] tested the effect of distraction on pain perception using functional magnetic resonance imaging (fMRI). During the distraction task (an adapted Stroop task), subjective reports of pain intensity decreased, and fMRI showed an overall decrease in activation in the pain matrix and an increase in activity in the anterior cingulate cortex and orbitofrontal regions of the brain. VR, arguably a more powerful distracter, could potentially utilize these or other brain regions to attenuate perception of pain.

Gold *et al.* [15] showed that VR was superior to topical anesthetic with regard to pain control in children requiring intravenous placement of contrast for an MRI or computed tomography (CT) scan. Of note, children, care givers and nurses were more satisfied with the use of VR for pain management. Furman *et al.* [16] compared VR with watching movies as alternative forms of analgesia in 38 patients during painful dental procedures. Pain scores were significantly lower in the VR group compared with the movie group and controls.

The present study analyzes the effect of VR compared to standard non-VR distraction using music in patients undergoing non-cranial skin procedures under local anesthesia.

2. Patients and Methods

2.1. Inclusion Criteria

Eligible participants were all adults aged 18 or over who had non craniofacial lesions requiring minor surgery. A total of 99 adult patients who were capable of independent consent were randomized to receive a virtual reality experience (VR) or standard music distraction (no VR). Patients were recruited for the study during their office visit when scheduling minor procedure surgery. This was a single center, double-blind, controlled study conducted at Guthrie Clinic Robert Packer Hospital in Sayre, Pennsylvania between March 2019 to January 2020. Ethics approval for this study was obtained from the Institutional Review Board of the Guthrie Clinic (3/21/2019; approval # 1903-09).

2.2. Exclusion Criteria

Exclusion criteria were conditions that may prohibit participation or evaluation of the procedure such as developmental delay, cognitive, visual or hearing impairment. Patients with lesions of the head or face that would prohibit them from wearing the Oculus Go headset were not considered. Severe vertigo or related symptoms such as chronic nausea/vomiting or motion sickness, history of stroke and seizure disorder/epilepsy were exclusion criteria. Finally, patients in isolation precautions for drug-resistant infection (e.g. methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant Enterococcus (VRE)) were excluded. The data accrual was completed prior to the COVID-19 pandemic with no cross use of VR headsets after January 2020.

2.3. Distraction Technique

Participants in the VR group wore an Oculus Go VR headset and were standardized to "Guided Meditation VR - ocean meditation". The device was sterilized after every application using standard alcohol-based techniques. Patients in the non VR group were asked to choose music according to their preference which was played through a speaker system.

2.4. Data Accrual

Presence of nausea, vomiting, dizziness, or seizures during or after the case was recorded for every patient. Systolic blood pressure (SBP), diastolic blood pressure (DBP) and heart rate (HR) were taken at the start of the procedure, at the procedural mid-point and one minute post-procedure. Subjective pain perception was measured using the 11-point Numeric Rating Scale (NRS) [17] and anxiety levels were determined using an 11-point Numeric Rating Scale (NRS) at the halfway point and 1 minute after completion of the procedure. Patient satisfaction was evaluated by the Global Rating Scale (1 = poor, 2 = borderline, 3 = satisfactory, 4 = good, 5 = outstanding). Patients were interviewed after the procedure about their VR experience and specifically asked "will you use VR in the future for similar procedures?"

2.5. Analysis

Descriptive statistics were calculated for key demographic and clinical characteristics between groups, including age, sex, race and ethnicity, primary reason for hospitalization, and baseline pain scores. Bivariate analysis was performed to evaluate for significant differences between groups, including two-sample t tests for continuous parametric variable sand chi-square tests for categorical variables. Pre-and post-intervention pain scores were compared within subjects (using paired t tests) and then differences-in-difference (DID) pain scores were compared between cohorts (using the rank sum test given non parametric DID distributions). Each individual patient was classified as a responder or non-responder using the criterion standard of achieving an effect size of >−0.5 standard deviation on the pain scale, a medium effect size using the rule of Cohen, and a value corresponding to the minimum clinically important difference (MCID) using the rule of Norman. The proportion responding between groups were compared using chi-square test and the number needed to treat (NNT) was calculated between groups. Because the study uses a mixed factorial design, a repeated-measures analysis of variance (ANOVA) was used, which incorporated both a between-subjects and a within-subject factor (Pretest-posttest). The F ratio of interest in the analysis was the interaction between the 2 factors, representing the treatment main effect. After estimation, eta squared (n2) was calculated. To adjust for potential differences in patient characteristics a multivariable linear regression analysis was performed to test the independent effect of VR on pain reduction, adjusting for demographic and clinical variables. Data are given as

percent of the collective for discrete parameters and median with range for continuous variables. Statistical analysis was done using SPSS with Chi-square and Fishers exact test for continuous and ANOVA and non parametric Kruskal Wallis for continuous parameters as applicable. A p-value of 0.05 was considered statistically significant.

2.6. Sample Size

Previous published data demonstrated an effect difference of 0.8 on a 10 point pain and anxiety scale between standard and VR methods. Treating the trial as two separate independent comparisons of each arm to the standard with $\alpha = 0.05$ for each comparison, we estimated aggregate 2 arm sample size with a target power of 0.80 and performed the following sensitivity analysis. Powering the study at 80% and assuming a loss-to-follow-up rate of 10%, we anticipated the need to enroll at least 40 patients per arm. To support a regression model with 5 covariates, and assuming at least 20 subjects per covariate, we required a total sample size of at least 80 patients.

3. Results

A total of 99 patients who fit our inclusion and exclusion criteria could be recruited and were randomized to VR group (49) and no VR group (50). Groups were well matched with regard to age, gender, beta blocker use, history of pacemaker, use of VR in the past, or location of surgery (upper extremity, torso, or lower extremity) and Charlson comorbidity score (Table 1). Surgery time averaged 28.5 minutes for the no VR group and 24 minutes for the VR group (p = 0.659). During and after the procedure, small percentages of each group experienced nausea and dizziness with no difference between the two groups. No major side effects such as vomiting or seizures occurred in any patient.

3.1. Hemodynamics

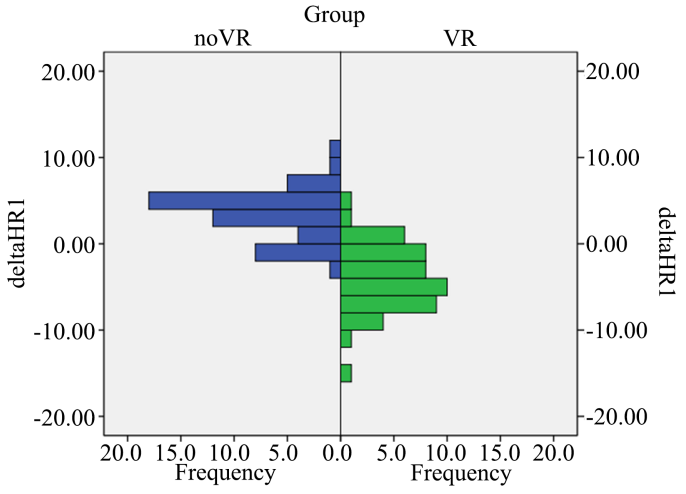
The percentage of patients using betablockers (28% no VR versus 26.5% VR) and having a pacemaker (14% no VR versus 14.3% VR) did not significantly differ between the two groups.

Pre-procedure average HRs were 76 beats per minute (bpm) (VR) and 74 bmp (no VR) p = 0.588. Mid-procedure average HR of the VR group was significantly lower than that of the no VR group (70 bpm versus 78 bpm, p = 0.003). The VR group had an average −6 bpm change in HR from pre-procedure to mid-point compared with an average +4 bpm for the no VR group, p < 0.0001. Average HRs at end of the procedure were 69 bpm (VR) and 76 bpm (no VR), respectively p = 0.071 (Table 1, Figure 1(a)).

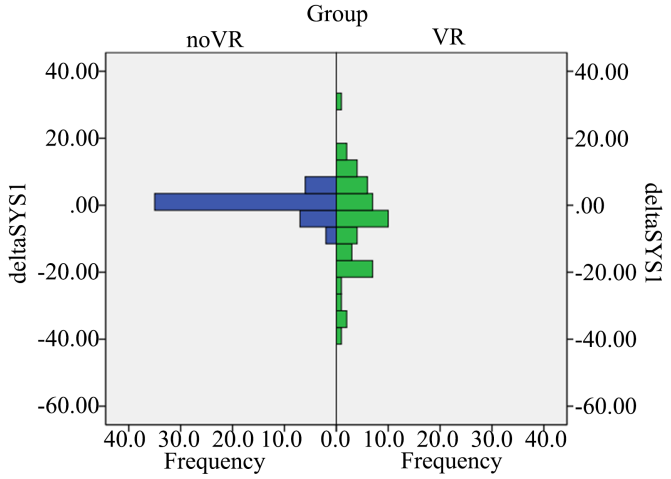
Pre-procedure average SBPs were 143 mm Hg (VR) and 130 mm Hg (no VR) p < 0.0001. Mid-procedure average SBPs were still higher in the VR group (136 mm Hg) as compared to the no VR (130 mm Hg) (p = 0.001). The VR group had an average −7 mm Hg change in SBP from pre-procedure to mid-point compared with an average 0 mm Hg for the no VR group, p < 0.0003. Average SBPs at the

Table 1. Demographics and clinical data.

	no VR	VR	p-value
n	50	49	
% female	54%	49%	0.383
Beta blocker	28%	26.50%	0.525
Pacemaker	14%	14.30%	0.597
Used VR in the past	18%	16.30%	0.518
Type surgery			0.251
upper extremity	34%	41%	
torso	26%	35%	
lower extremity	40%	24.50%	
Nausea	2%	4%	0.492
Vomiting	0%	0%	NA
Dizziness	4%	6%	0.49
Seizures	0%	0%	NA
will VR use again	14%	96%	*<0.0001
Satisfaction			*<0.0001
1	0%	2%	
2	2%	0%	
3	10%	4%	
4	56%	8%	
5	32%	86%	
age	43 (range 18 - 86)	48 (range 19 - 87)	0.165
Charlson	3 (range 0 - 20)	3 (range 0 - 10)	0.581
Surgery time	28.5 (range 17 - 43)	24 (range 17 - 57)	0.659
Pre pain	0 (range (0 - 5)	0 (range (0 - 5)	0.818
Pre anxiety	4 (range 0 - 10)	5 (range 0 - 10)	0.535
Pre systolic BP	130 (range 110 - 150)	143 (range 112 - 173)	*<0.0001
Pre diastolic BP	76 (range 54 - 90)	79 (range 56 - 92)	0.242
Pre HR	74 (range 50 - 92)	76 (range 56 - 93)	0.588
half pain	0 (range (0 - 1)	0 (range (0 - 2)	0.69
half anxiety	0 (range (0 - 2)	0 (range (0 - 2)	*0.02
half systolic BP	130 (range 114 - 155)	136 (range 120 - 156)	*0.001
half diastolic BP	79 (range 55 - 90)	75 (range 58 - 88)	*0.047
half HR	78 (range 54 - 98)	70 (range 55 - 88)	*0.003
End pain	0	0	NA
End anxiety	0	0	NA
End systolic BP	127 (range 109 - 148)	132 (range 112 - 155)	*<0.0001
End diastolic BP	72 (range 55 - 88)	72 (range 57 - 85)	0.459
End HR	76 (range 52 - 90)	69 (range 54 - 86)	*0.071



(a)



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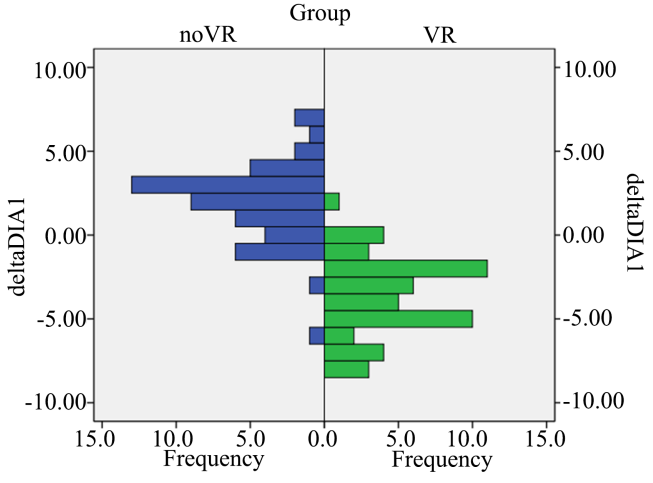

(c)

Figure 1. Timeline of changes in heart rate and diastolic and systolic blood pressure according to the two groups. (a) Change in Heart Rate from start to mid procedure; (b) Change in SBP from start to mid procedure; (c) Change in DBP from start to mid procedure.

end of the procedure were 127 mm Hg (VR) versus 132 mm Hg (no VR), $p < 0.0001$. Overall, patients in the VR group had higher initial SBPs, which dropped significantly more than in the no VR group (Table 1, Figure 1(b)).

Pre-procedure average DBPs were 79 mm Hg (VR) and 76 mm Hg (no VR), $p = 0.242$. Mid-procedure average DBPs were lower in the VR group (75 mm Hg) compared with the no VR group (79 mm Hg) $p = 0.047$. The VR group had an average −4 mm Hg change in DBP compared with an average +3 mm Hg change in DBP in the no VR group, $p = 0.0001$. The endpoint average DBPs were 72 mm Hg in both groups, $p = 0.47$ (Table 1, Figure 1(c)).

3.2. Pain, Anxiety, Patient Satisfaction

Pre-procedure average pain scores for both VR and no VR groups was 0/11 points ($p = 0.818$) with less than 20% of patients reporting only mild pre-procedure pain (range 0 - 2 points). Mid-procedure, both groups again averaged 0/11 pain points (rage 0 - 2 points) $p = 0.69$. Finally, at the end of the procedure, none of the patients reported pain (Table 1, Figure 2).

The pre-procedure average anxiety score was 4/11 points for the no VR group compared with 5/11 points for the VR group ($p = 0.535$). In the VR group more responders exhibited mild anxiety compared with the no VR group (Table 1, Figure 3). At the mid-procedure point, the average anxiety score was 0/11 points

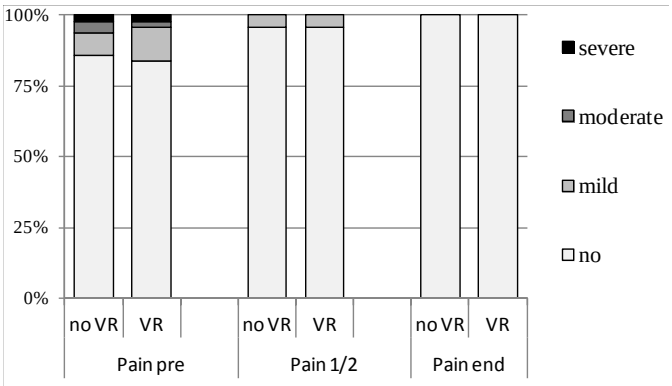

Figure 2. Timeline of pain.

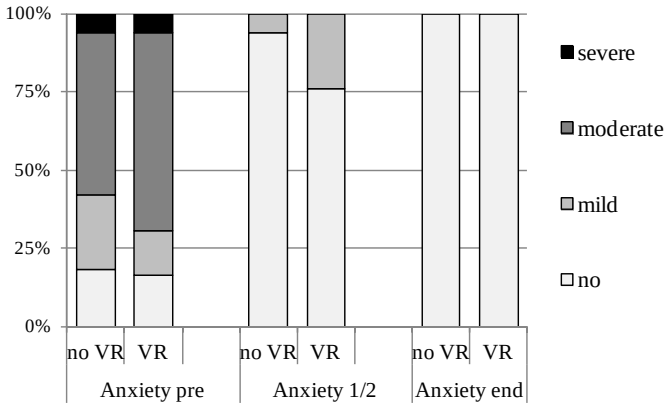

Figure 3. Timeline of anxiety.

for both groups ($p = 0.02$). End procedure average anxiety scores were 0/11 for both VR and no-VR groups.

Patient satisfaction was significantly higher for the VR group, with 86% ranking 5 out of 5 on the global rating scale while only 32% of subjects in the noVR group gave this rating ($p < 0.0001$).

4. Discussion

This study suggests that VR may be able to lower systolic and diastolic blood pressures as well as HRs in patients undergoing skin procedures under local anesthesia. Patient satisfaction with VR was high in this study. However, we were not able to demonstrate that anxiety levels and subjective pain perception were influenced by the technique. A larger randomized controlled study may have to be performed to understand these differences further.

VR has shown to decrease pain perception and other negative aspects of painful medical and experimental procedures in several studies, however, results should be interpreted cautiously in light of some basic scientific limitations. Sample sizes of published series continue to be small and methodology used to test the technology has been widely variable. Concern has also been raised that VR may be effective primarily due to its ability to impede the patient's view of the painful procedure. In a study by Gershon *et al.* [18], the participants reported increased levels of anxiety while immersed in VR. The investigators hypothesized that this effect may be due to patient's inability to view the procedure and fear of the unknown. In our cohort, average pre procedural anxiety scores were similar between our no VR and VR groups; however, our VR group had a mild non-significant trend towards more anxiety at the mid-procedure point. By the end of the procedures, both modalities demonstrated parity. By contrast, Gold *et al.* [19] designed a study controlling for visual occlusion and demonstrated that VR remained superior. Still others, like Lambert *et al.* [20], have not demonstrated significant improvement in pain or perception of pain, as it is difficult to fully control end-point data.

VR is a more expensive mode of distraction compared to other traditionally used techniques such as television, music or videogames that have proven effective. Costs associated with VR have significantly declined, but superior pain control with VR has yet to be demonstrated. In our study, we found no difference in reported pain perception before, during, or after the procedure. Thus, health systems may be reluctant to spend extra money on a pain control modality that appears non superior to simpler modes. Although all of our patient accrual occurred pre-COVID Pandemic, there is a significant viral transfer risk with VR headset transfer between patients. We minimized bacterial and viral transmission with alcohol-based sterilization of the device between patients. However, the headset does sit on and above the nasal and oral orifices with significant chance for viral contamination. Although the amount of viral contamination with these devices has not been studied, this may be an area worth investigating in the future.

While subjective measures of pain and anxiety were not found to be superior in our VR group, objective measures of pain and anxiety: SBP, DBP and HR, were significantly influenced by VR. Subjective pain reporting is intimately linked with a number of difficult to control variables. Pain threshold, personality traits, and rapport with staff are among many factors that change the way people may perceive and report pain. Much larger cohorts than ours may be able to better control for these factors.

The average pre-procedural SBP was significantly higher in our VR group compared with the no VR group. This difference may be attributed to anxiety, stress or excitement related to being randomized to the VR headset as the SBP was taken after randomization was complete. The average SBP decreased significantly more in the VR group by mid-procedure compared with the no VR group (−7 mmHg for VR vs 0 mmHg for no VR; $p < 0.0003$). The average DBP decreased significantly more in the VR group by mid-procedure compared with the no VR group (−4 mmHg vs +3 mmHg; $p < 0.0001$). The average HR decreased significantly more in the VR group by mid-procedure compared with the no VR group (−6 bpm vs +4 bpm; $p < 0.0001$).

Our study has multiple limitations as it is a single center study and the sample size is low. We believe, skin procedures under local anesthesia are an excellent model to study the effects of VR. Although we did not find convincing evidence that VR improves patient reported subjective markers of pain and anxiety, we did show that our VR group showed statistically significant favorable effects on objective markers of pain and anxiety such as procedural hemodynamic status. Whether or not these effects are a sufficient objective surrogate for pain and anxiety warrants further study.

5. Conclusion

VR use for pain control is in its infancy. Investigations have demonstrated initial promise with specific populations and acute medical procedures. VR studies like ours have demonstrated potential benefits for acute pain as well as chronic pain [21]. However, findings of superiority to less immersive distraction therapies have not been consistent. Our study employed a randomized, controlled trial of 99 patients and demonstrated significant reductions in intraprocedural HR, DBP, and SBP in our VR group. However, subjective reporting of pain and anxiety were not improved in the VR group. As VR technology decreases in cost and increases in availability, new integrated VR technology will enable clinicians to further investigate usability of VR. Future studies in VR require greater scientific rigor, increased sample sizes, sounds methodology and increased attention to individual user characteristics in order for there to be more significant findings.

Conflicts of Interest

None of the authors has a financial interest in any of the products, devices, or

drugs mentioned in this manuscript. The work is not under review at any other journal.

Declaration

Patient data related to this study was protected and secured in compliance with our Institutional IRB standards in accordance with the Declaration of Helsinki. (IRB # 1903-09; approval date 3/21/2019). Fund support for this study was obtained by successful institutional micro-grant for the purchase of materials relevant to this study.

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