

Influence of distraction factors on performance in laparoscopic Surgery in immersive Virtual Reality - a study protocol of a cross-over trial in medical students and residents - DisLapVR.

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Abstract

Background: Working in an operating room (OR) is physically and mentally challenging: the operation itself demands the surgeon's full attention, while owing to time and cost efficiency constraints daily planning and emergency care keep interfering on different levels. Thus, multitasking becomes an integral surgical competence.

Objective: This study aims to examine the effect of disruptions during surgery in highly immersive virtual reality (IVR) operation environment combined with a VR laparoscopy simulator.

Methods: An IVR environment was created using a high resolution, stereoscopic 360° video of the OR. Different distractions were identified, classified as auditory, visual or audio-visual and recorded accordingly. The surrounding was combined with a VR laparoscopic simulator. Participants - medical students and surgical residents - receive proficiency-based training in basic laparoscopic skills and are blinded to the aim of the experiment. Following a cross-over design, each participant receives a unique order of virtual distraction factors while performing tasks on the laparoscopic simulator. During the experiment, subjective passing of time, stress, heart rate and visually induced motion sickness are recorded. After the experiment, validated questionnaires for usability, immersion and stress are completed, as well as subjective evaluation of the distractions. Performance in the laparoscopic tasks in relation to the distractions will be evaluated. Subgroup analyses in regard of age, gender and expertise (medical students vs. surgical residents) are planned.

Results: We present a protocol for a study aiming to identify the impact of different disruptions in the OR during laparoscopic training in immersive VR. Hence, it may lead to an improved awareness of distractions and facilitate accommodations towards an improved work environment. Prior research leads to the hypothesis that the performance of a more experienced surgeon is less impacted by distractions, than the performance of inexperienced surgeons and medical students. Furthermore, we investigate which type of distraction has the largest impact on performance.

Conclusions: With this knowledge, specific multitasking training can be devised, which may be particularly useful in medical education, for which VR might play a leading role. Clinical Trial: This trial has been prospectively registered in the German Clinical Trials register with the registration number DRKS 00030033, registration confirmed 18th of August 2022, https://www.drks.de/drks_web/

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Original Manuscript

Influence of distraction factors on performance in laparoscopic Surgery in immersive Virtual Reality – a study protocol of a cross-over trial in medical students and residents - DisLapVR.

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Key Words

Immersive virtual reality, laparoscopic surgery, work environment, distractions in surgery, laparoscopy simulation, laparoscopy training

Abstract

Background

Working in an operating room (OR) is physically and mentally challenging: the operation itself demands the surgeon's full attention, while owing to time and cost efficiency constraints daily planning and emergency care keep interfering on different levels. Thus, multitasking becomes an integral surgical competence. This study aims to examine the effect of disruptions during surgery in highly immersive virtual reality (IVR) operation environment combined with a VR laparoscopy simulator.

Objective

This study aims to identify distractions in the OR and their importance in the clinical setting.

Methods

An IVR environment was created using a high resolution, stereoscopic 360° video of the OR. Different distractions were identified, classified as auditory, visual or audio-visual and recorded accordingly. The surrounding was combined with a VR laparoscopic simulator. Participants - medical students and surgical residents - receive proficiency-based training in basic laparoscopic skills and are blinded to the aim of the experiment. Following a cross-over design, each participant receives a unique order of virtual distraction factors while performing tasks on the laparoscopic simulator. During the experiment, subjective passing of time, stress, heart rate and visually induced motion sickness are recorded. After the experiment, validated questionnaires for usability, immersion and stress are completed, as well as subjective evaluation of the distractions. The questionnaires used included SUS (System Usability Scale), SAM Score (Self Assessment Manikin), NASA-TLX (Nasa Task Load Index) and the immersion rating scale as described by Nichols. Performance in the laparoscopic tasks in relation to the distractions will be evaluated by Wilcoxon test and ANOVA for continuous variables. Subgroup analyses in regard of age, gender and expertise (medical students vs. surgical residents) are planned.

Results

The described trial has started in August of 2022 and is ongoing in July 2024. By July 2024 30 medical students and 9 surgeons have completed the study.

Discussion

We present a protocol for a study aiming to identify the impact of different disruptions in the OR during laparoscopic training in immersive VR. Hence, it may lead to an improved awareness of distractions and facilitate accommodations towards an improved work environment. Prior research leads to the hypothesis that the performance of a more experienced surgeon is less impacted by distractions, than the performance of inexperienced surgeons and medical students. Furthermore, we investigate which type of distraction has the largest impact on performance in. With this knowledge, specific multitasking training can be devised, which may be particularly useful in medical education, for which VR might play a leading role. Additionally workplace surroundings in the operating room can be optimized with this knowledge.

Trial registration

This trial has been prospectively registered in the German Clinical Trials register with the registration number DRKS 00030033, registration confirmed 18th of August 2022, https://www.drks.de/drks_web/



Background

Laparoscopic simulation has been shown to be beneficial in the training of surgical residents [1-3] and has been a mandatory part of surgical education in different countries. Following this example, an obligatory laparoscopic simulation curriculum consisting of six tasks was implemented in the Department of General, Visceral and Transplant Surgery, University Medical Center Mainz, Germany.

Surgery requires different professions to cooperate closely and efficiently to facilitate a smooth workflow while maintaining high levels of concentration on the procedure itself. Patient safety and cost efficiency demand swift procedures, which are regularly impaired or interrupted by various factors: emergency care, organizational tasks and management of complications cannot be postponed in many cases; thus multitasking becomes a surgical key competence. Moreover, teaching of residents and medical students remains an integral part of working in an operation room (OR). In combination, these circumstances turn the OR into a bustling workplace with high physical and mental demands, rendering the ability to multitask a key surgical competence. Prior studies have identified and quantified distractions in the OR and examined their influence on surgeons [4-6]. Experienced surgeons were found to be more adept at handling distractions and were less impaired by them [7], suggesting this to be an ability, which can be trained.

Laparoscopic simulation training usually takes place away from the hustle of everyday clinical work, yet a structured training for multitasking or stress resilience has not been developed so far.

To test laparoscopic simulation in more realistic conditions, the institute designed a highly immersive virtual reality (IVR) application using high resolution, stereoscopic 360° videos of the operation room and displaying them on a head-mounted display (HMD) (Vive™ Pro, HTC Corporation, Taoyuan, Taiwan) [8, 9]. This application includes to the surgery unrelated background work in the OR including typical background noises and movements. In a prior study of our group, an immersive VR setting using 360° videos was deemed more realistic and was preferred by participants over an artificial VR setting [10]. Furthermore, it has been previously shown that 360° video-based VR experiences enhanced memory recall, compared to conventional two-dimensional videos [11], suggesting facilitated learning.

Prior studies could show that training in immersive laparoscopy induces a higher cognitive load, making this method already more demanding than conventional laparoscopy training [12]. Sankaranarayanan et al have presented a simulated immersive virtual reality program with similar goals and were able to show a significant

difference in performance with or without distraction [13]. As mentioned, our group was able to show in the past, that immersive virtual reality using real video material is preferred by users over simulated environments [10, 14]. We aimed to create a realistic environment with realistic distractions, i.e. phone calls or presentations of the next case, in contrast other studies in the past have employed unrelated distractions like music or other noises [13]. To achieve a realistic environment different distractions were identified and classified as auditory (i.e., a phone call), visual (i.e., somebody walking through the field of vision) and audio-visual (i.e., somebody presenting an emergency case including a CT-scan) and can be inserted into the simulation at any time. Participants can immerse themselves into this realistic environment and perform tasks on a laparoscopic simulator including haptic feedback (LapSim ©, Surgical Science, Gothenborg Sweden, software version LapSim 2020.2). The simulator detects numerous parameters such as completion time for a task, tissue handling, amount of bimanual work and instrument path length to calculate a performance score. Laparoscopy tasks are designed to train numerous abilities and competences.

We present a protocol to a study aiming to identify the impact of different distractions during laparoscopic simulation in IVR. This study aims to identify distractions in the OR and their importance in the clinical setting.

Methods

Aims

The current study aims to examine the influence of distractions on laparoscopic surgery in immersive VR. Therefore, a unique presentation sequence was created for each participant repeating the six tasks combined with five different distractions and without distractions. Each task will be performed with each distraction once and without distraction twice following a cross-over design. Figure 1 depicts one of the distractions in VR.

After completing the proficiency-based curriculum and passing the final tests, all surgical residents as well as residents in gynecology are eligible to participate in the study. As a second group, medical students, who complete the same curriculum with lower thresholds, are eligible to participate in the study. These thresholds were introduced to eliminate the influence of the learning curve during the experiment.

Participants are blinded towards the aim of the study. They are instructed to test the familiar curriculum in an immersive VR environment but are unaware of possible distractions. Prior research has shown simulation to be a useful tool not only for training practical skills, but also regarding communication, stress and handling of difficult situations [15].

The results may suggest how to improve the work environment in the OR by identifying distractions, classifying and reducing them, wherever possible. As mentioned however, a complete elimination is nearly impossible but reduction especially during critical steps of the operation should be attempted. Different surgeons react differently to stress and distractions [16] and experienced surgeons appear to be less impaired by them [7]. This suggests that the individual reaction to stress may be a subject to training, which could be conducted in VR.

Objectives

The primary objective of this study is to examine the influence of simulated distractions in immersive VR on the performance in laparoscopic surgery. The LapSim © (LapSim © with haptic feedback, Surgical Science, Gothenborg Sweden, software version LapSim 2020.2) is able to evaluate laparoscopic performance using time required for an exercise, tissue handling, amount of bimanual work and instrument path length. Secondary objectives are to collect participant-specific data, such as grade of immersion, subjective perception of the passing of time, subjective perception of stress in form of NASA TLX questionnaire, system usability index (SUS), visually induced motion sickness (VIMS), eye strain, heart rate and eye tracking behavior.

Trial design

The trial is designed as a cross-over trial. Each participant trains in six exercises on the simulator until a proficiency cut-off level is reached. After the training phase, participants enroll into the experiment. They complete the exercises wearing an HMD in IVR in a 360° video of the operation room while five different auditory, visual and audio-visual distractions are played. Each exercise is completed once combined with all five distractions and twice without distractions, amounting to 42 exercises in total. The order of exercises and distractions is determined by a Latin squares design, which minimizes potential order effects as each participant has an individual order of exercises and distractions [17]. The sequences are prepared with control for neighboring exercises and distractions, ensuring that there is no clustering of same exercises and / or distractions.

Study setting

The study will be conducted as a single center study in the University Medical Center Mainz, Germany. The Department of General Visceral and Transplant Surgery is a high volume center for minimally invasive surgery

and has implemented a mandatory laparoscopy training for all residents, facilities for training are available. The Department conducts mandatory laparoscopy training for all medical students and offers an elective about minimally invasive surgery.

Eligibility, inclusion and exclusion criteria

Eligible are volunteer medical students of the University Medical Center Mainz, who have completed the training of the six laparoscopic exercises to a predetermined proficiency level as well as residents in visceral surgery and gynecology after completion of the department-specific laparoscopy training.

Since the presented program is a novelty design there is no effect size known. Due to prior experience, a sample size of 30 medical students and 20 residents in visceral surgery and gynecology was chosen. Medical students are recruited through announcements via posters and flyers in the University Medical Center Mainz, as well as during classes in Visceral Surgery. Surgical and gynecological residents are informed about the study on a personal basis and recruited if interested. To improve adherence to the experiment, breaks are offered after each exercise and can be taken at the liberty of the participants. The experiment can be paused or discontinued at any time if the participant wishes to, number and duration of additional pauses will be recorded.

Exclusion criteria are impacted sight or hearing, which are tested before inclusion using standardized tests. All participants must be able to stand for 120 minutes upright to work on the laparoscopy simulator and are excluded if this is not possible. Furthermore, all participants have to complete a laparoscopy curriculum and reach a threshold to rule out the learning curve as an effect on the study. Not passing of the threshold is an exclusion criterion.

Data collection and management

Data is collected immediately after the experiment using LimeSurvey © (LimeSurvey GmbH, Hamburg, Germany, licensed by the Johannes Gutenberg-University Mainz) and later transferred to SPSS ©, Version 27 (IBM, NY, USA).

Data are checked manually for correct transfer. Data is going to be stored in anonymized fashion on password-protected computers of the study group in locked rooms, to which only members of the study group have access to.

Ethics approval and consent to participate

The trial including all information material and the consent form has been reviewed and approved by the local ethics committee (Ethik-Kommission der Landesärztekammer Rheinland-Pfalz, application number: 2022-16528-andere Forschung erstvotierend). Each eligible participant will be informed concisely about the studies potential and risks. If participation is desired, written consent is obtained by a member of the study group before inclusion into the trial.

Interventions

Performance in laparoscopic exercises will be evaluated with and without different distractions. A cross-over design was chosen to allow a within-subject-control for each participant. Primary comparators are performance in laparoscopic surgery during different distractions. This will be assessed by the parameters of the laparoscopic simulator. Prior studies have shown more experienced surgeons to be less impacted by distractions [7], deeming the two eligible groups – medical students and surgical residents – an interesting contrast. Further comparators are subjective passing of time, subjective stress levels and heart rate [18-20], as well as usability, visually induced motion sickness (VIMS), eye strain and immersion, which are key comparators in newly developed VR programming [21-23]. Furthermore, the Self-Assessment Manikin (SAM) Score is assessed to employ a measurement for psychological stress and emotion [24]. Most of the afore mentioned parameters are assessed by validated questionnaires, which have been used in similar experiments for years. Eye Tracking is performed using the head-mounted display (Vive™ Pro, HTC Coporation, Taoyuan, Taiwan), to examine, whether participants look at distractions without consciously perceiving them.

Each participant is going to complete each of the six laparoscopic exercises with all five distractions and twice without distraction. This amounts to 42 exercises, breaks will be taken after exercise 14 and 28. Mandatory breaks are ten minutes long, but can be extended as needed. Additional breaks will be offered after each exercise and can be taken at the freedom of the participant. The order of exercises and distractions is determined by a Latin squares design. After each exercise participants are asked for their subjective stress levels using NASA TLX score, subjective passage of time, VIMS (measured by the Fast Motion Sickness (FMS)-Scale (17)) and eye strain. After the experiment, participants are questioned about usability, immersion and are asked if they have noticed any distractions and, if yes, of which kind and how disrupting they were

perceived to be. The trial design is depicted schematically in **Table 1** with all data collected at different time points.

Table 1

	Study period				
	Enrolment	Post-allocation			Close-out
TIMEPOINT	-1 day -0	+ 1 – 2 weeks	Warm up	Experiment	After experiment
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
INTERVENTIONS:					
Training					
Experiment				X	
ASSESSMENTS:					
Participants' characteristics	X				
NASA TLX			X	X	X
FMS		X		X	
Eye Strain			X	X	
SAM Score				X	
Heart rate			X	X	
Eye Tracking				X	
SUS					X
Subjective passing of time				X	
Noticed distractions					X

Table 1:

The table depicts the course of the study with its different phases and the data collected at different time

points. Before enrolling into the study participants complete a mandatory laparoscopy curriculum. Right before the experiment a warm-up phase is conducted. During the experiment data about performance on the laparoscopy simulator as well as heart rate and the items of multiple questionnaires are collected. After completion of the experiment participants evaluate the distractions as well as usability of the system.

Statistical methods

Statistical analysis of the primary outcome, perceived passage of time and perceived stress will be conducted using Wilcoxon Test, since it consists of a connected sample. Participant related data, usability, immersion and visually induced motion sickness are analyzed using repeated-measures ANOVA and t-Tests. Eye Tracking is analyzed qualitatively (i.e., participant looked away from the laparoscopy monitor yes / no). Students' and residents' performance, subjective passing of time and NASA TLX variance over different time points and exercises will be analyzed using ANOVA.

The trial has started recruitment on 31st of August 2022 and is still in July of 2024.

Results

By July of 2024 the trial has recruited 30 medical students and 9 surgeons and is still recruiting. Recruitment of surgeons has been progressing slowly because of high demand and workload in the department, thus inclusion has been prolonged.

Discussion

This study aims to explore the effect of different distractions during laparoscopic surgery using laparoscopic simulation in highly immersive VR. The OR can be a demanding and at times stressful workplace. Distractions during surgery are often triggered by necessary communication and urgently incoming demands [4], which cannot be eliminated even with utmost consideration and thoughtfulness. Furthermore, teaching, organizational tasks and care for emergencies and complications disrupt the workflow, without the option for delay.

This trial is a first evaluation of distractions in the operating room using highly immersive VR and may be able to assist in possible improvement of working conditions and environments as well as development of specific training. A group of 50 participants is sufficient for the exploratory aim of the study and according to

experience attainable. Novel technologies like VR using head-mounted displays usually spark the interest of possible participants and others alike, but have not found extensive everyday application, yet. Simulation has been known to be a useful resource for years not only in laparoscopy [1, 15]. If a laparoscopic curriculum extended by highly immersive VR can be tested successfully, an implementation as a set curriculum for improvement of more than only manual skills could be possible.

Limitations of this trial include the usability of VR head-mounted displays, which can be distracting and exhausting to wear to some participants, while performing complex tasks. This might reduce the immersion during training. However, we have not experienced any difficulties with this yet.

Prior research suggests, that more experienced surgeons are able to handle demanding situations more easily and are able to multitask [7]. This knowledge offers an opportunity for targeted training of stress resistance and multitasking. A future use of this program could include standardized training of medical students and surgical residents. Furthermore a future extension of the program could facilitate an even more high stress environment simulating an unstable patient and including different distractions that are common in an emergency situation. This would make the program interesting for more advanced surgeons as well.

Declarations

Consent for publication

Not applicable.

Availability of data and materials

The data acquired during the trial will be kept strictly confidential and only be accessible by members of the research group. Personal information of participants will not be released and their personal privacy will be protected. The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request in a condensed and thus not trackable manner.

Conflicts of Interest

The authors declare that they have no competing interests.

Funding

The application for this study was prepared as part of the project AVATAR (FKZ: 16SV0857), which received funding from the Federal Ministry of Education and Research, Germany. The project itself was not peer reviewed, but part of a cluster of projects within the funding.

The used laparoscopic simulator was funded by the Alexander Karl Foundation Mainz.

Authors' contributions

LH and TH are the chief investigators. The study protocol was developed by TH, LH, CB and FH under the consultation of HH, CC and MW (conceptualization). LH and RS are conducting the study, preparing the questionnaires, and managing and analyzing data (investigation). The crossover sequence was prepared by MW, CC and HH (resources). The programming of the virtual reality application was performed by PS and VC under the supervision of CH (resources, software). HL as head of the department oversaw the development and will oversee the conduction of the trial (supervision). The manuscript was prepared by LH (writing); all authors read and approved the final manuscript.

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There are no further acknowledgements, all researchers participating are listed as authors.

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List of Abbreviations

AE: adverse event

CT-scan: computed tomography scan

CRF: case report form

FMS: Fast Motion Sickness Scale

IVR: immersive virtual reality

NASA TLX: National Aeronautics and Space Administration Task Load Index

OR: operating room

SAE: serious adverse event

SUSAR: suspected unexpected serious adverse reaction

SUS: System Usability Scale

VR: virtual reality

VIMS: visually induced motion sickness



Figure 1: Part of the view of the participant in immersive virtual reality is shown. The scrub nurse is standing beside the participant. On the left edge of the picture, the laparoscopy monitor with an exercise is shown. In the background, a colleague is demonstrating a CT scan of the next emergency patient with a bowel obstruction (audio-visual distraction)


Supplementary Files

Figures

Part of the view of the participant in immersive virtual reality is shown. The scrub nurse is standing beside the participant. On the left edge of the picture, the laparoscopy monitor with an exercise is shown. In the background, a colleague is demonstrating a CT scan of the next emergency patient with a bowel obstruction (audio-visual distraction).



Table 1: The table depicts the course of the study with its different phases and the data collected at different time points. Before enrolling into the study participants complete a mandatory laparoscopy curriculum. Right before the experiment a warm-up phase is conducted. During the experiment data about performance on the laparoscopy simulator as well as heart rate and the items of multiple questionnaires are collected. After completion of the experiment participants evaluate the distractions as well as usability of the system.

	Study period				
	Enrolment	Post-allocation			Close-out
TIMEPOINT**	-1 day -0	+ 1 – 2 weeks	Warm up	Experiment	After experiment
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Informed consent	X				
INTERVENTIONS:					
Training					
Experiment				X	
ASSESSMENTS:					
Participants' characteristics	X				
NASA TLX			X	X	X
FMS		X		X	
Eye Strain			X	X	
SAM Score				X	
Heart rate			X	X	
Eye Tracking				X	
SUS					X
Subjective passing of time				X	
Noticed distractions					X