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Learning from the surgeon's real perspective – First-person view versus laparoscopic view in e-learning for training of surgical skills? Study protocol for a randomized controlled trial

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ABSTRACT

Background: Surgical proficiency is highly dependent on continuous and efficient training. However, efficacy of training hinges on questions such as accessibility and how intuitively the training can be translated into reality. Minimally invasive surgery (MIS) in particular relies on adequate training modalities in order to compensate for its additional psychomotor and visuospatial challenges. The increasing demand for MIS procedures longs for further enhancement of training and steep learning curves. We are investigating a nouveau training concept that continuously utilizes the first person view as addendum to laparoscopic view. We hypothesize this approach to be more intuitive thus faster and more naturally to apprehend than a laparoscopic view only and aim to establish a new standard to implement into training curricula.

Methods and analysis: The present study is conducted as a monocentric, two-arm randomized trial. Participants undergo a training curriculum in laparoscopic suturing and knot tying, using e-learning video material with either the first-person perspective of the surgeon or the laparoscopic view only. Primary endpoint is the total training time needed to reach a predefined proficiency level. Participants are evaluated by blinded raters using validated checklists. Number of attempts, procedure and knot quality subscore difference as well as metric parameter analysis from the first and last knots analyzed as secondary endpoints. Furthermore, trainees are assessed with regard to surgical background, basic skills level and spatial awareness. A total sample size of 80 participants for the analysis of the primary endpoint was determined, which will be performed as a two-sided *t*-test.

Ethics and dissemination: Ethical approval was obtained from the Ethics Committee of the Medical Faculty at Heidelberg University (Code S-334/2011). This trial was registered with the German Clinical Trials Register (DRKS) in Freiburg, Germany, on May 6th (DRKS00009997). The results will be published and presented at appropriate conferences.

1. Background

With increasing demand for minimally invasive surgery (MIS) and related approaches replacing numerous yet openly performed procedures, training capacities are needed to ensure each surgeon's skills are adequate prior to patient contact. This training needs to be more efficient and apprehensible as well, since MIS comes with natural obstacles and psychomotor demands additional to those one faces when performing open surgery. Consequently, many centers and universities worldwide provide specific laparoscopic training courses and research is conducted to optimize training [1–4].

E-learning has been shown to be a valuable asset to laparoscopic training; our group continuously conducts research for further evaluation [5–7]. Since computer games are believed to be a commonplace to today's students and their experience potentially

Abbreviations: MIS, minimally invasive surgery; VR, virtual reality; MRT, Mental Rotation Test; PSVT:R, Revised Purdue Spatial Visualization Test.

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enables them to profit from different approaches, the concept of 'Serious Gaming' is subject to training research [8]. Serious games have been evaluated in various situations within the framework of surgery and combining serious gaming with competition in laparoscopy training has recently been shown to improve dexterity [9–11]. Available literature suggests that a certain number of practical repetitions as part of the learning process is required for proficiency in laparoscopic surgery thus restricting usage of e-learning platforms with regards to time efficiency [12–14]. Accordingly, further research seems to be indicated in order to maximize utility during e-learning modules and to safeguard that learning content is properly translated into reality, especially since translation of simulator training to the operating room has been proven to take place. Its described resistance to decay is favorable, but comes with risks, if apprehension during training was flawed [15,16].

Perception and imitation of movement hinges on visual perspective. The human mirror system is an important subject to neuro and cognitive sciences and presumably similarly essential to social interactions and psychomotor cognition [17,18]. We believe that approaches discussed in current research render taking advantage of the mirror system and its fluidity possible in order to enhance psychomotor training. Coherent findings of various investigations indicate the first-person view to be determinative to full-body ownership [19,20]. One might easily surmise that movements already perceived as one's own can be reproduced and implemented more intuitively. We consequently aim to evaluate this conclusion within the framework of a training concept consistently using first-person view as a reference.

2. Methods and analysis

Primary objective of this study is to evaluate whether training outcome of a structured laparoscopy training curriculum is influenced by the visual perspective chosen in e-learning video material. We are comparing the visual perspectives of first-person view showing the surgeon's hands in addition to the laparoscopic view versus laparoscopic view only (Fig. 1).

2.1. Registration

This trial was registered with the German Clinical Trials Register (DRKS) in Freiburg, Germany, a primary registry in the WHO Registry Network, on May 6th, 2016 with the trial registration number DRKS00009997 (https://drks-neu.uniklinik-freiburg.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00009997).

2.2. Study design

This is a registered prospective, single-center, rater-blinded, two-arm, parallel-group randomized trial. A scheme of the study is shown in Fig. 2.

2.3. Setting and participants

This study is carried out in the MIS training center of the Department of General, Visceral, and Transplantation Surgery at Heidelberg University Hospital. This study is conducted in the context of a voluntary laparoscopy training course for medical students during their clinical years at Heidelberg University. Around 2800 medical students study medicine at Heidelberg University, with around 320 new students each year. In their clinical years (3–5) all students (around 1400) are obliged to participate in at least one elective module, such as the course in laparoscopic surgery, which is offered in the training center of the Department of Surgery at Heidelberg University. Every year around 100 medical students participate in this specific elective module, where this study was set.

2.4. Sample size determination

We plan to exceed this group sizes by 10% to account for possible drop outs. Sample size calculations were done according to results of a previously evaluated study [21] with identical primary endpoint and conducted in a similar context. Mean difference between group 1 and group 2 was 785.7 s, standard deviation in group 1 was 1388.0 s, whereas it was 1046.8 s in group 2. This difference can be detected with a two-sided significance level $\alpha = 0.05$ and a power of $1\text{-}\beta = 0.8$, with a group size of at least 40 participants randomized to each group.

2.5. Inclusion and exclusion criteria

The inclusion criterion mandates that participants are medical students in their clinical years (3rd–6th year) at Heidelberg University. Exclusion criteria include students who have already participated in basic laparoscopy training courses for more than 2 h, who have experience in laparoscopic suturing and knot tying, or who have experience assisting in laparoscopic surgeries for more than 2 h, respectively.

2.6. Randomization, allocation and blinding

Blocked randomization stratified by gender is used to randomly assign participants to each group (1:1 ratio) resulting in two intervention groups. Randomization is performed by an independent employee of the statistics department not involved in recruitment, allocation, training, rating, data collection and outcome assessment regarding the present study, by using Research Randomizer [22]. Block size is not revealed until the end of the study. The numbers indicating group assignment are kept in sealed, opaque and sequentially numbered envelopes. Students are allocated by the main coordinator according to their time of application to the elective module, after written informed consent is obtained. Due to the nature of the intervention, participants and main coordinator of the study, granting the participants access to the video interven-

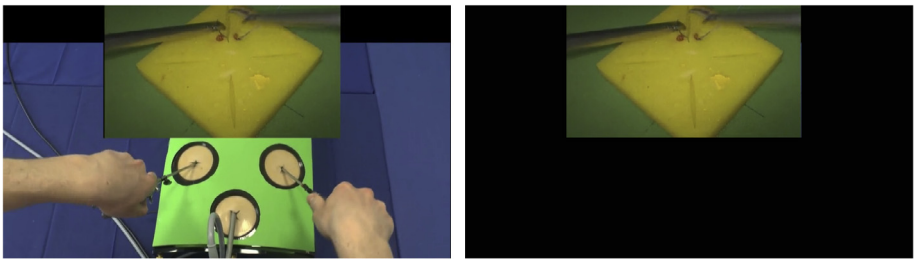


Fig. 1. Screenshot of e-learning material in combined first-person and laparoscopic view (left) vs. laparoscopic-view-only (right).

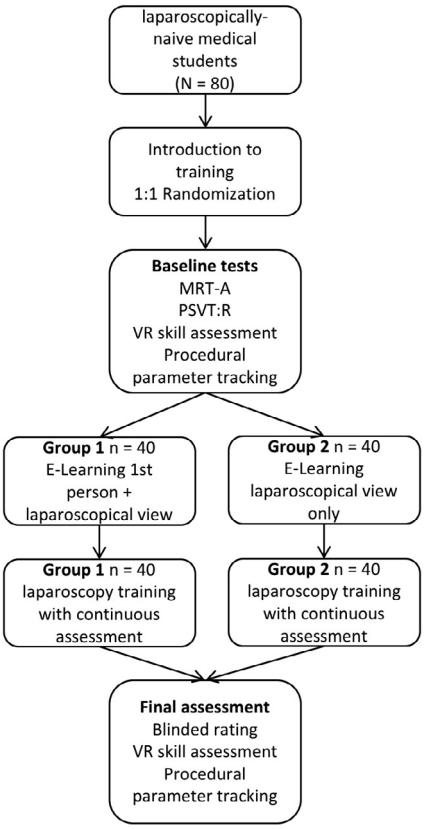


Fig. 2. Study protocol flow chart.

tion in regards to their group allocation, cannot be blinded. But all raters involved in grading and assessing the participants' proficiency level will remain blinded at all times. If, due to any unforeseen event, the group assignment of one tandem is revealed to the rater, he or she will be replaced. To limit this risk the raters are only present in the training room when needed and all students are instructed not to discuss specifics as well as to watch their videos privately at the limited time a rater is present.

2.7. Study process

2.7.1. Introduction to the training modalities in the training center

At the beginning of the study and training course, respectively, all participants attend an introduction to the training center and its modalities. An instruction on how to access the teaching videos is also provided. Students are then allowed to familiarize themselves with box-trainers and virtual reality (VR)-trainers as well as mobile training devices (iPad Air 2®, Apple Inc, Cupertino, USA) and instruments before training commences.

2.7.2. Baseline-test

Prior to training, each participant is asked to perform an initial assessment consisting of a questionnaire, visuospatial tests and a performance task on the VR-trainer. The VR-trainer software allows for the continuous recording of various individual parameters. Based on this data, learning curves can be displayed for all participants and compared between groups. Personal parameters will be collected using pseudonymized questionnaires. The questions will relate to prior laparoscopic experience and surgical background as well as leisure behavior with regards to physical activity, computer games, music, handedness and personal interests.

Participants will also undergo two validated psychometric testing assays to determine spatial awareness and visualization abilities. We will use version A of the Mental Rotation Test (MRT) modified by Peters et al. [23–24] as well as the Revised Purdue Spatial Visualization Test (PSVT:R), published by Yoon et al. [25–26]. Test results and analysis of some suggested critical valuables will be examined in subgroup analysis.

2.7.3. Proficiency

Procedural proficiency assessment is based on a validated modified 23-point implementation checklist (Table 1), originally published by Munz et al. [27]. Knot quality is assessed using a 5-point scale introduced by Muresan et al. and by measuring time needed (Table 2) [28]. Proficiency is stated if one knot is finished in $\leqslant$02:00 (mm:s) and $\geqslant$18 points on the procedural performance checklist as well as $\geqslant$4 points on the knot quality scale are attained. These are performance levels reached by experienced surgeons [29].

2.7.4. Interventions

Before each training session all students will receive a short reminder about the correct use of the e-learning material and the structure of the training session. Each student will be handed their personal iPad, with only their assigned video accessible. No participant will have access to the video material of the other group, nor will they receive the e-learning material outside of the training room. Only students of the same group will be present at the training room simultaneously. At the beginning of each training session, participants of groups 1 and 2 are asked to study the video material, showing a laparoscopic knot, assigned to them three times. They then proceed training on a box-trainer until reaching proficiency according to the predefined criteria outlined below (Tables 1–3; Section 2.7.3). Participants are allowed to refer to their assigned video material at any time during the 2-h training sessions, at least referring to learning videos once every second attempt. The students will work in teams of two, swapping after every second knot and rate their fellow teammate, using the Proce-

Table 1
Procedural proficiency checklist.

Procedure assessment	Y	N
Needle position 1	1	Held at 1/3–2/3 from the tip
	2	Angle 90° ± 20°
	3	Uses tissue or other instrument for stability
	4	Attempts at positioning ($\leqslant$3)
Needle driving 1 (Entry to incision)	5	Entry at 60°–90° to the tissue plane
	6	Driving with one movement
	7	Single point of entry through the tissue
	8	Removes the needle along its curve
Needle position 2	9	Held at 1/2–2/3 from the tip
	10	Angle 90° ± 20°
	11	Uses tissue or other instrument for stability
	12	Attempts at positioning ($\leqslant$3)
Needle driving 2 (Incision to exit)	13	Driving with one movement
	14	Removes the needle along its curve
Pulling the suture	15	Needle on needle holder in view at all times
	16	Uses the pulley concept
Technique of knots	17	Correct C-loop (no S- or O-loops)
	18	Smoothly executed throw, no fumbles
	19	Correct inverse C-loop (no S- or O-loops)
	20	Smoothly executed throw, no fumbles
	21	Knot squared (capsized/reef/surgical)
	22	Correct third C-loop (no S- or O-loops)
	23	Smoothly executed throw, no fumbles
Total points		

Table 2
Knot quality checklist.

Knot quality assessment	Available points
No visible gaps between stacked throws	1
Knot tight at base	1
Only edges are opposed (no extra tissue in knot, e.g. back wall)	1
Knot holds under tension	2
Maximum	5

Table 3
Competency checklist.

Competency assessment	Goal	Y	N
Time (min:s)	⩽02:00		
Procedure	⩾18		
Knot quality	⩾4		
Maximum	5		

dural Checklist by Munz et al. (Section 2.7.3). The Checklist will be available as an online questionnaire and each score will therefore be recorded. All participants will be obliged to keep a personal, handwritten training record, writing down not only their time for each knot but also their time taken to watch the e-learning material. Prior and at the end of each training session performances are video recorded and assessed on site by blinded, trained raters using all checklists required for proficiency (Section 2.7.3), as well as modified OSATS checklist (Table 4) according to Chang et al. [30]. All participants will be asked to refrain from practicing or learning laparoscopic knot tying and suturing outside of the training room. During the training sessions the main coordinator will ensure the adherence to the protocol through personal surveillance and short, standardized introductions. Personal training records will be checked regularly, to recognize non-adherence to the protocol at an early stage. Any problems or difficulties that may occur will be reported and discussed with the corresponding research of this study and solved accordingly.

When using box-trainers, students train with two laparoscopic needle holders (KARL STORZ GmbH & Co. KG, Tuttlingen, Germany) and a standardized silicone suture pad with diagonal incisions and predefined suture entry and exit points (Fig. 2) (Big Bite Medical GmbH, Heidelberg). The suture material is a coated braided polyester suture with a CV-305 Taper 1/2 25 mm needle (Covidien™, Minneapolis, USA).

2.7.5. Post-test

Participants will be asked to perform specific tasks on the VR-trainer, parallel to those measured during baseline assessment, thus rendering comparison of learning curves possible. On top of

Table 4
Objective structured assessment of technical skills (OSATS) for Laparoscopic suturing and intracorporeal knot tying: procedure specific component (PSC) and global rating checklist (GRC) modified according to Chang et al. [29].

Procedure specific component		
Needle Delivery/Load	1	Needle delivered atraumatically to the field (not caught in trocar)
	2	Load needle perpendicular to needle driver
	3	Choke needle 1/2–2/3 from needle tip
Suturing	4	Place needle at 90° angle to tissue
	5	Drive needle with wrist supination
	6	Pull suture through to establish short free end (⩽1 in. tail) (⩽2,54 cm)
	7	Suture placed accurately, on target
Knot tying	9	First throw: a) Surgeon's knot, ie. 2 throws in same direction b) Knot laid flat without air knots c) Short free end maintained
	10	2nd throw: a) Square knot, i.e. Opposite direction from prior throw b) Knot laid flat without air knots
	11	3rd throw: a) Square knot, i.e. Opposite direction from prior throw b) Knot laid flat without air knots
	12	Appropriate tissue re-approximation without strangulation
	13	Good use of both hands to facilitate knot tying
Suture cut and removal	14	Needle cut from suture under direct visualization
	15	Needle safely removed under direct visualization
General	16	Kept needle in view at all times when grasping needle
	17	Non-dominant hand helps dominant hand in suturing
Total points		

Global rating checklist (GRC)				
Tissue and instrument handling				
1 Rough movements; awkward handling of instruments and tissue	2	3 Careful handling of instruments and tissue overall, with occasional awkward movements	4	5 Consistently appropriate and careful handling of instruments and tissue
Depth perception/accuracy				
1 Constantly misses target, slow to correct	2	3 Sometimes misses target, quick to correct	4	5 Accurately directs instrument to target
Dexterity/efficiency				
1 Uncertain, inefficient movements without progress	2	3 Efficient movements overall with some unnecessary moves	4	5 Fluid, efficient movements without wasted time or motion
Autonomy (proficiency)				
1 Unable to complete entire task in time	2	3 Able to perform task safely with some instruction	4	5 Able to perform task safely and independently

that, baseline and final participants' knot tying performances will be analyzed with a previous established system. This system calculates performance metrics such as path length, number of movements, speed and joint angle range with the help of optical tracking devices. A NDI Polaris system is used for instrument tracking with passive sensor spheres attached to the instruments. At the end participants are asked to evaluate the training course with regard to estimated personal proficiency level attained by training, motivation and suitability of training modalities.

2.8. Primary and secondary endpoints

An outline of all data recorded can be found in Fig. 3.

2.8.1. Primary endpoint

Primary outcome is the total training time needed (in seconds) to reach proficiency in the predefined laparoscopic suturing and knot tying technique. The level of proficiency is assessed by independent, blinded raters.

2.8.2. Secondary endpoints

Number of attempts, procedure and knot quality scores and subscore differences as well as metric parameter analysis from the first two and the last knot performed at the self-developed system are examined as secondary endpoints.

2.8.3. Subgroup analysis

Feedback of training motivation and influences of gender, handedness, leisure and physical activities, individual gaming and music experiences as well as performances in the above mentioned spatial awareness tests are analyzed regarding their influence on the laparoscopic performance. We aim to identify character profiles particularly benefiting from the presented training concept [31–36].

2.9. Statistical analysis

Formal hypothesis for primary outcome:

H_0: The total training time needed to reach proficiency is the same in both groups.
H_1: The total training time needed to reach proficiency differs between both groups.

This hypothesis will be tested using a two-sided *t*-test with a level of significance of $\alpha = 0.05$.

All endpoints and subgroup evaluations are analyzed descriptively according to their respective empirical distributions. In line with the scale levels of the variables, means, standard deviations, medians, first and third quartiles and minimum/maximum or absolute and relative frequencies are provided. Descriptive p-values of the corresponding statistical tests are reported in combination with the associated 95% confidence intervals. If found to be appropriate, graphical statistical methods are deployed to illustrate findings.

The study is conducted within a voluntary elective module with interested students. Therefore, we do not expect missing data regarding our primary outcome. Students who will not be able to train to the level of proficiency due to e.g. injuries or time issues are therefore regarded as dropouts and will not be included in statistical analysis.

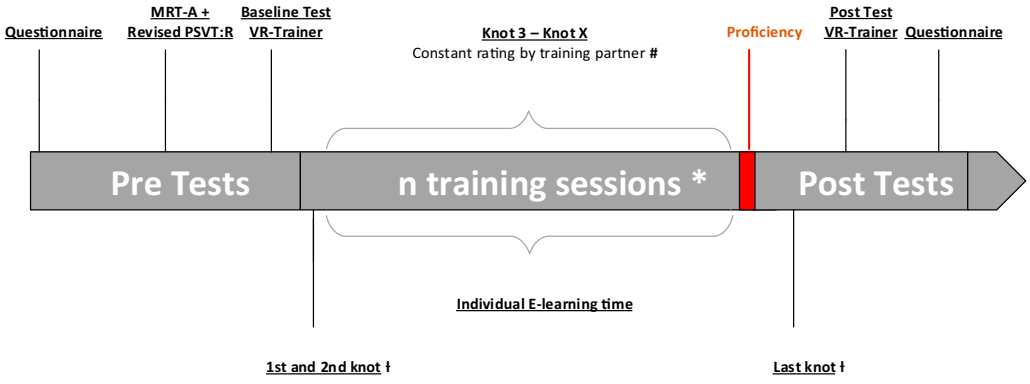
After validating the data, the complete data base is frozen prior to analysis. The statistical analysis will be performed by an independent statistician, who will be blinded during analysis. All authors will have access to a copy of the final dataset.

2.10. Protocol version

This refers to the third version of the full study protocol from May 6th, 2016. All further protocol modifications will be registered with the DRKS, published in the final paper and communicated to the participants.

3. Discussion

In this study, we aim to determine if "learning from the surgeon's real perspective" is superior to training methods currently



Recorded data
* Time + Procedural Checklist + OSATS Knot quality + Video recording Assessed by blinded raters at the beginning and the end of each session
ǂ Time + Procedural Checklist +OSATS Knot quality + Self developed system
Time + Procedural Checklist + Knot quality

Fig. 3. Timeline of data recording.

applied in laparoscopic courses. We hypothesize the first-person view in addition to standard laparoscopic view being a more intuitive means of acquiring surgical basic skills than just standard laparoscopic view alone. Elements of Serious Gaming are embedded in our training modalities as well, with the spatial situation of ego shooter games adapted in the provided teaching videos. We believe these elements to prove additionally beneficial to outcome when teaching today's digitally native medical trainees, especially, if certain personality criteria are met. To identify such susceptible combinations of personality traits is a secondary objective to this investigation. The outlined training curricula will be compared to the current standard of laparoscopy training (control group) benefiting of both repetitive hands-on practice and a motivational partner setting [37]. If results are promising, training standards might be shifted with regard to first-person reference frames as valuable adjunct. Handedness as well as gaming experience could act as specifically interesting factors of influence and will consequently be examined in data analysis as secondary endpoints. Participants are encouraged to study the video material carefully. Nevertheless, possible influences on training outcome resulting of individually different vigilance and training motivations remain. With the present investigation being limited to laparoscopically-naïve medical students and the performance of basic surgical skills, results cannot directly be transferred to more experienced surgeons and more complex procedures without further ado. However, positive results might trigger further investigations, and results of this study will increase the available knowledge about criteria to be met in order to ensure optimal surgical training. Since 'patients' safety prevails over students' training', committed training research is perpetually required [37].

Ethical and dissemination

All data for the study is recorded anonymously, treated confidentially and evaluated by authorized staff for scientific purposes only. Participants' names are kept separate from all study data and are not used for the study. Each participant is assigned a designated code that is used for the entire study documentation and data collection. The study courses are offered in addition to compulsory university courses. Participation in the study is voluntary and may be ended at any time. There are no foreseeable negative consequences for participants related to participation. Due to the relatively short time span of the study and no foreseeable harm to the participants' health a data monitoring committee (DMC) is not needed. The participating staff of the Heidelberg MIS center is experienced in the handling of training devices and in tutoring MIS [38–40]. In the event that a participant's physical or mental health becomes jeopardized due to participation in the present study, the participant will be dismissed immediately and excluded from the study.

Ethical approval was obtained from the Ethics Committee of the Medical Faculty at Heidelberg University prior to the beginning of the study (Code S-334/2011). The CONSORT guidelines for randomized controlled trials [41] and SPIRIT guidelines for implementation of study protocols were followed and the SPIRIT Checklist [42] is attached to the manuscript.

Final results of this study will be published and presented at suitable conferences. Access to the dataset and statistical code will be granted individually upon request.

Authors' contributions

Study conception and design: FN, MWS, MF, BM, KK.
Acquisition of data: MWS, MF, KK, JGH.
Statistical analysis: TB, KK, MWS, FN.
Analysis and interpretation of data: MF, FN, MWS, KK, TB.
Drafting of manuscript: MWS, MF, FN, KK, TB, JGH.
Critical revision: BM, FN.

All authors read and approved the final version of this manuscript.

Authorship eligibility guidelines according to the ICMJE were followed. The use of professional writers is not intended.

Competing interests

The authors hereby declare that they have no competing interests.

Disclosure information

FN reports receiving travel support for conference participation as well as equipment provided for laparoscopic surgery courses by KARL STORZ, Johnson & Johnson, and Medtronic. MWS, MF, KK, JGH, TB, BM have no conflicts of interest or financial ties to disclose.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.isjp.2017.01.001.

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