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# Validation of ELVIS, a virtual simulator for laparoscopic training

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## Abstract

Laparoscopy is the standard approach for many surgeries because of its benefits for the patients. However, being proficient in laparoscopic surgery requires a significant amount of training, exploited by using validated surgical simulators. The goal of this project is to validate ELVIS (Educational Laparoscopy with Virtual Instructive Simulations and robotics), a prototype of a high-tech and low-cost Virtual Reality laparoscopic simulator, that results from the collaboration between high-tech companies in Liguria, Italy and the University of Genoa. To validate the simulator, we collected performance data, subjective feedback on task load and face validity, and heart rate of three groups of subjects: surgeons, surgical residents, and people with extensive videogame experience. All subjects were required to perform exercises with the simulated optics and the grasper. Preliminary data show that the task was more demanding for people with videogame experience, with respect to surgical residents and surgeons. Indeed, surgeons seemed to be faster in completing the hand-eye coordination task. Also, participants found the simulator useful for the acquisition of basic hand-eye coordination skills. Altogether these results suggest that ELVIS is a promising tool for the training and evaluation of laparoscopic skills.

**Keywords:** laparoscopic surgery; surgical training; medical simulation

## 1. Introduction

Laparoscopy is a surgical method used to inspect and operate on the organs inside the abdominal and pelvic cavity, in a less invasive way, as opposed to open surgery (Spaner & Warnock, 1997; Torricelli et al., 2016). Today, laparoscopy is the gold standard for many surgical procedures (Buia et al., 2015). Indeed, it offers significant advantages in terms of post-operative outcomes and quality of life for the patient, including a faster post-operative recovery, and a shorter hospital stay (Bosch et al., 2002; Delaney et al., 2003). However, laparoscopy presents several challenges to the surgeons: they rely on a two-dimensional display to see a tri-dimensional space; the fixed trocars have a limited range of motion; the interaction with the surgical instruments provides limited haptic feedback (Scott et al., 2000; Smith et al., 2001). These limitations can be overcome with training and experience.

With the development of simulators, residents can practice skills such as visual-spatial perception, hand-eye coordination, and manual dexterity, in a riskless and controlled environment (Gaba, 2004). Currently, two groups of laparoscopic simulations exist: box trainers and virtual reality (VR) (Levine et al., 2013). The former consists of a box that mimics the abdominal cavity, a camera projecting on a screen the view of the inward of the box, surgical instruments, and a set of tools for performing manual activities (Levine et al., 2013). Box trainers are inexpensive, portable and provide haptic feedback; however, they do not allow to simulate real surgeries and do not provide performance feedback. VR simulators instead include a physical part and a VR application that can either simulate preparatory exercises or real surgeries, eventually importing real patients' data. Some simulators provide simple haptic feedback, but most of them do not. The main advantages of VR simulators lie on the possibility to simulate different tasks in terms of ability to train or task difficulty. Furthermore, the simulator records performance data, thus allowing objective assessments (Levine et al., 2013). The downside of VR simulators is their cost which can be higher than hundred thousand dollars.

The goal of this work is to validate ELVIS (Educational Laparoscopy with Virtual Instructive Simulations and robotics). In detail, we assessed whether the simulator could effectively measure laparoscopic skills, namely, hand-eye coordination and optics movements. Furthermore, we wanted to ensure that the system does not cause any simulator sickness symptoms, as well as excessive workload. ELVIS is a prototype of a high-tech and low-cost VR laparoscopic simulator that has been designed and developed in Liguria, Italy thanks to the collaboration between high-tech companies and the University of Genoa (Marco Frascio et al., 2022; Gaudina et al., 2013). To perform the validation, we collected performance data of surgeons (refereed to surgeons throughout the manuscript), surgical residents (residents), and people with wide videogame experience, to ensure that videogame ability does not affect the simulation score (Clauser et al., 2008). Other than performance data, we collected subjective feedback about the realism and efficacy of the simulator, task load, and possible occurrence simulation sickness symptoms. Finally, we collected hearth rate during the experiment, as physiological data can gather quantitative and objective measures regarding the user's cognitive and emotional states, such as stress and attention levels (Dzedzickis et al., 2020).

## 2. Material and Methods

A description of the simulator can be found in (M Frascio et al., 2022). Briefly, the system combines a physical structure and a VR application.

The physical part includes a computer, a structure mimicking the abdominal cavity, a monitor and a sensorized surgical instrument (Figure 1). The height and tilt of the simulation box can be adjusted; on the simulation box, there are holes into which the surgical instrument can be inserted to allow for different insertion points (Figure 1). The surgical instrument can be used as a laparoscopic camera or as a grasper, according to the task to perform, as both handlings are integrated into the instrument (Figure 1; see also (M Frascio et al., 2022)). It is sensorized to monitor rotations and translations, to reconstruct the movements in the VR application.

The VR application has been developed in Unity Game Engine; it has an interface allowing the user to access it by entering ID and password. Once logged in, the user can select different exercises (Figure 2; see below); all

**Figure 1.** ELVIS Simulator

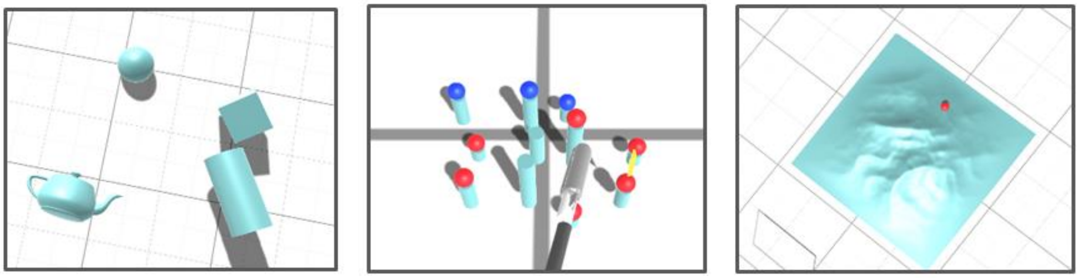

**Figure 2.** VR application. Exercises used for the system validation. Left: the exercise allows users to practice optics movements with a static object; Middle: exercise to practice hand-eye coordination; Right: exercise to train how to move the optics with a moving target

the performance data are stored in a database, to keep track of the user performance. The VR application communicates in real time with the sensors inside the surgical instruments, such that the movement of the virtual instrument replicates those of the real one.

### 2.1. Subjects

We enrolled 27 subjects: 6 expert surgeons (age mean ± STD: 46.0 ± 13.6 years, age range 33-64 years, 1 woman), 11 surgery residents (30.9 ± 4.2 years, age range 27-39 years, 8 women) and 10 gamers (i.e., people with wide gaming experience; 26.2 ± 2.7 years, range: 24-33 years, 4 women). Inclusion criteria were: (i) being enrolled in surgical residency for the residents group; (ii) not having any medical experience (i.e., no healthcare-related studies) and playing videogames at least 3 times a week for the gamers; (iii) being specialized surgeons for the surgeons group.

### 2.2. Experimental Design

The experiment was carried out on two different days.

The protocol followed during the first day lasted about 60 minutes and could be divided into distinct phases (Figure 3):

- Pre-experiment questionnaires
- Familiarization
- Training exercises
- Post-experiment questionnaires

At the beginning of the session, the subject completed two questionnaires: a demographic one, and the Simulation Sickness Questionnaire (SSQ, (Bimberg et al., 2020)). The demographic questionnaire consists of nine multiple-choice questions and was proposed to obtain general information about the subject (gender and age), as well as information about video game use (frequency and platforms), and mobile devices usage. The SSQ questionnaire, instead, is a standard validated questionnaire aimed at measuring the level of discomfort resulting from being exposed to a VR simulation. It indicates 16 symptoms typically associated with "Simulation Sickness" and asks the user to report their intensity on a scale from 0 to 3. This questionnaire was proposed to the subject before and after the experimental phase, to ensure that any discomfort reported was caused by the simulation.

After completing the questionnaires, the participants started the familiarization phase, that consisted in completing one repetition of the exercise with the laparoscopic camera and static objects (see below). At this stage, we encouraged participants to explore the virtual environment, so that they understood how to use the setup. The duration of the familiarization part varied depending on the subject's manual dexterity.

At the end of the familiarization, the subject wore a smart band TICKR FIT device (Wahoo Fitness, USA; sampling frequency 1 Hz) on the wrist of the non-dominant arm, to collect heart rate data during the experiment. Then, he/she started to perform two exercises:

**Laparoscopic camera with static objects**

This task was designed to understand how to move the optics, performing wide and tight movements. Subjects were required to find targets in the virtual scene, by moving and rotating the optics, without touching any virtual object (Figure 2). This exercise included two levels: intermediate with 13 targets to find and 4 objects to avoid; difficult having 5 targets to find and 6 objects to avoid. Each level was repeated twice for a total of four repetitions.

**Hand-eye coordination exercise in fine movements**

In this exercise, the subject handled the surgical instrument like a grasper to touch spheres placed on top of cylinders (Figure 2). The goal of the task was to touch all the spheres in the scene without touching the cylinders supporting them. Once the manipulator touched a sphere, the sphere disappeared. This exercise included three levels: easy, the spheres could be touched in any order; intermediate, the spheres had

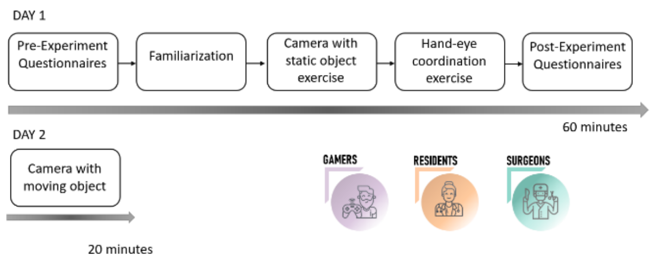


**Figure 3**. Experimental Pipeline

two different colours, and must be touched alternated; difficult, the simulator indicated which sphere to touch. Each level was repeated twice for a total of 6 repetitions.

After completing the exercises, subjects filled up three questionnaires: (i) a Face Validity questionnaire, specifically developed for the experimental session; (ii) SSQ, identical to the one completed at the beginning of the experiment; (iii) and NASA Task Load Index (NASA TLX, (Hart, 2006)). The Face Validity questionnaire consists of 10 statements that the subject must evaluate by assigning a score ranging from 1 (very poor) to 5 (very good; Appendix A). This questionnaire was developed with the aim of collecting data on the degree of realism and efficacy of the simulator. The NASA TLX questionnaire is a validated standard questionnaire proposed with the aim of quantifying the effort required to perform the tasks. It measures mental, physical, and temporal demand, performance, effort, and frustration levels.

The second part of the experiment, run on a separate day, included a single exercise (Figure 3):

**Laparoscopic camera with moving objects**

The exercise involved the use of the optics, with the aim of enhancing the ability to move it in tight spaces with a moving target. Briefly, by moving the laparoscopic camera, the subject needed to follow a target (Figure 2), keeping a constant distance from it. For this exercise, subjects performed two 180-second repetitions for each level (easy, intermediate, difficult). Due to the fact that subjects had to come back to the lab to perform this part on a separate day, we were able to collect data of 14 subjects (3 surgeons, 1 resident, 10 gamers).

### 2.3. Data Analysis

For each item of the questionnaires, we computed: mean, median, range of answers provided and standard deviation.

Performance data recorded by the simulator include: (i) number of collisions, total duration of the exercise and time required to find a single target, for the laparoscopic camera with static objects exercise; (ii) number of collisions during the hand-eye coordination exercise in fine movements; (iii) percentage of focus, computed as the percentage of total time the target is centered by the optics, during the laparoscopic camera with moving target exercise. For each parameter, we computed mean and standard error of the mean for each exercise and each repetition.

Finally, we computed the mean heart rate of each subject and repetition. Subjects with heart rates less than 50 bpm or greater than 100 bmp for the entire experiment were excluded from the analysis, as these values were likely the result of technical problems.

Questionnaire responses, performance data and hearth rates have been compared between the three groups (surgeons, residents, and gamers) using non-parametric t-tests (Mann-Withney test). Before averaging the performance data across repetitions, we have compared them using a paired t-test to ensure that they do not change with practice. All the data have been analyzed using Matlab 2023a.

## 3. Results

For this study, we collected performance data, subjective feedback on experienced workload, simulator fidelity and realism, and occurrence of simulation sickness, and heart rate. Preliminary results are described below.

### 3.1. Questionnaires

Analysis of the SSQ data did not reveal any discomfort resulting from the use of ELVIS, as can be seen in Table 1.

Interestingly, results from the NASA-TLX questionnaire show that gamers found the task significantly more demanding in terms of mental request than residents ($p=0.047$) and surgeons ($p=0.009$; Figure 4). Physical demand was also perceived more by gamers than surgeons ($p=0.047$). These results suggest that surgeons and residents are more familiar with both the instrument and the tasks to perform. Conversely, gamers must pay attention and be focused during the exercise.

Analysis of the Face Validity questionnaire showed that all the participants considered the simulator sufficiently useful for the training and evaluation of basic skills. Experienced surgeons have also reported that the simulator can be useful for the acquisition of basic hand-eye coordination skills (mean ± STD 4.2 ± 0.8). A critical issue concerns the degree of "*realism*" of the movements compared to a real laparoscopic surgery, and the degree of realism in the management of the optics that have obtained sufficient score only by gamers, who do not have experience with laparoscopy.

### 3.2. Heart rate

The average heart rate did not differ between groups (surgeons N = 6: mean ± S.E. 79 ± 5 bpm; residents N = 10: 83 ± 4 bpm; gamers N = 9: 88 ± 3 bpm). Interestingly, we found a slight, albeit not significant,

**Table 1.** Results of the SSQ questionnaire before (pre) and after (post) the experiment for the three groups.

| Symptom | Gamers | | Residents | | Surgeons | |
|---|---|---|---|---|---|---|
| | Pre | Post | Pre | Post | Pre | Post |
| General discomfort | 0 [0 1] | 0 [0 0] | 0 [0 1] | 0 [0 2] | 0 [0 1] | 0 [0 1] |
| Fatigue | 0 [0 1] | 0 [0 1] | 1 [0 2] | 1 [0 1] | 0 [0 0] | 0 [0 0] |
| Headache | 0 [0 2] | 0 [0 2] | 0 [0 1] | 0 [0 0] | 0 [0 1] | 0 [0 1] |
| Eye strain | 0.5 [0 3] | 1 [0 3] | 1 [0 1] | 1 [0 2] | 0 [0 0] | 0 [0 0] |
| Difficulty focusing | 0 [0 1] | 0 [0 1] | 0 [0 1] | 0 [0 1] | 0 [0 0] | 0 [0 0] |
| Salivation Increasing | 0 [0 1] | 0 [0 0] | 0 [0 1] | 0 [0 0] | 0 [0 0] | 0 [0 0] |
| Sweating | 0 [0 1] | 0 [0 1] | 0 [0 1] | 0 [0 1] | 0 [0 0] | 0 [0 0] |
| Nausea | 0 [0 0] | 0 [0 1] | 0 [0 0] | 0 [0 2] | 0 [0 0] | 0 [0 1] |
| Difficulty concentrating | 0 [0 2] | 0 [0 1] | 0 [0 1] | 0 [0 1] | 0 [0 0] | 0 [0 0] |
| Fullness of the head | 0 [0 1] | 0 [0 1] | 0 [0 2] | 0 [0 1] | 0 [0 1] | 0 [0 1] |
| Blurred vision | 0 [0 0] | 0 [0 2] | 0 [0 1] | 0 [0 1] | 0 [0 0] | 0 [0 0] |
| Dizziness with eyes open | 0 [0 2] | 0 [0 2] | 0 [0 2] | 0 [0 2] | 0 [0 0] | 0 [0 0] |
| Dizzines with eyes closed | 0 [0 0] | 0 [0 1] | 0 [0 1] | 0 [0 1] | 0 [0 0] | 0 [0 0] |
| Vertigo | 0 [0 0] | 0 [0 0] | 0 [0 0] | 0 [0 1] | 0 [0 0] | 0 [0 0] |
| Stomach awarness | 0 [0 1] | 0 [0 0] | 0 [0 0] | 0 [0 1] | 0 [0 0] | 0 [0 0] |
| Burping | 0 [0 1] | 0 [0 0] | 0 [0 0] | 0 [0 1] | 0 [0 0] | 0 [0 0] |

heart rate decreases between the first and last repetition of the hand-eye coordination exercise (repetition 1: 93 ± 5 bpm; repetition 6: 85 ± 5 bpm) which might suggest a progressive reduction of stress.

## 3.3. Performance

As a first step, we compared the performance data (collisions, time, and percentage of focus) across repetitions and groups.

For the laparoscopic camera with static objects exercise we did not detect any group difference in terms of collisions (surgeons: mean ± S.E 0.4 ± 0.2; residents: 1.1 ± 0.2; gamers: 0.9 ± 0.3) and time needed to find a target (surgeons: 8.5 ± 1.7 s; residents: 13.6 ± 1.5 s; gamers: 12.7 ± 1.7 s). A possible interpretation of this result, supported by the results of the NASA TLX questionnaire, is that gamers had to pay more effort to complete the exercise, in order to achieve the same performance of surgeons and residents.

In the hand-eye coordination exercise in fine movements we with did not find a group difference in the number of collisions (surgeons: 3.7 ± 0.5; residents: 4.8 ± 1.1; gamers: 4.6 ± 1.4). However, we found that gamers were significantly slower than surgeons, (Figure 5; gamers: 134 ± 18 s; surgeons: 71 ± 9 s, p=0.047), who in turn were slightly faster than residents (86,8±7,5 s). This result, in line with previous considerations suggests that, despite the performance, the task was more complicated and challenging for gamers. Another result to underline concerns the variability between subjects: surgeons took from 43 s to 93 s to complete a repetition; gamers had average values between 43 s and 225 s; residents have intermediate values (50-132 s; Figure 5). Interestingly, the overall duration of each repetition decreased

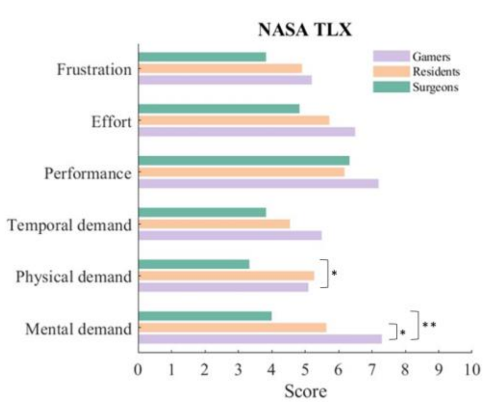


**Figure 4** NASA TLX questionnaire results. Average values per group.
* p< 0.05; **p<0.01

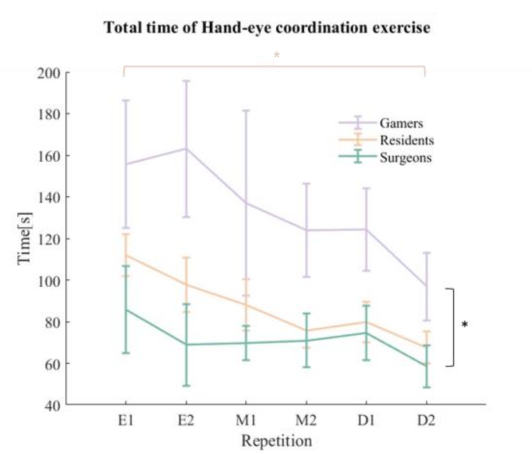


**Figure 5** Total time to perform the hand-eye coordination exercise. The bars indicate the standard error of the mean each repetition.
* p<0.05.

significantly with practice only in the residents' group ($p<0.001$), and slightly in the gamers group (Figure 5). Altogether, these results show that those having less mastery of the instrument can improve with practice. Conversely, expert surgeons are more homogenous and maintain the execution time throughout the experiment.

As the subject sample of the laparoscopic camera with moving objects exercise was limited, we could not carry out any statistical analysis. Visual inspection of the data showed that the percentage of focus in the gamers group was (mean ± S.E) 92 ± 2% during the first repetition and decreased to 81 ± 3% at the end of the session. This trend seemed to be true also for surgeons (first repetition, 95 ± 2%, last repetition 75 ± 6%). This preliminary result leads to two considerations: on one hand, the decrease in the percentage of focus can be the consequence of repetitions having different levels of difficulty (from easy to difficult). On the other hand, it might be possible that participants reduced their attention throughout the repetition, as the exercise is quite repetitive. To discriminate between these two hypotheses, more engaging scenarios should be implemented (e.g., by proposing different scenarios, feedback, or adding a penalty-based scoring system) and tested.

## 4. Conclusions

The aim of this work was to validate ELVIS, a prototype of a high-tech and low-cost VR laparoscopic simulator and assess whether such system could measure laparoscopic skills. To do so, we collected performance data, subjective feedback, and physiologic data of three groups of subjects: residents, surgeons, and gamers. This way, we could ensure that no factors other than the laparoscopic ability (e.g., videogames expertise) affects the results.

Preliminary results of this study suggest that the simulator replicates a realistic situation in terms of movements to perform; indeed, the tasks were more demanding for the gamers group. Residents and surgeons, who are already familiar with laparoscopy found it less demanding. Results from the face validity data report that participants, particularly those belonging to the residents and surgeons' group, found the simulator useful for hand-eye coordination skills training. This further support the idea that the simulator can be a useful educational tool in the field of laparoscopy training.

Collisions data did not reveal any difference between groups in both the laparoscopic camera with static objects exercise and the hand-eye coordination exercise in fine movements. However, surgeons seemed to be faster than gamers, particularly in the hand-eye coordination exercise. These results suggest that additional performance indexes, other than collision, should be considered in the future to better capture performance differences between groups.

Finally, no heart rate differences have been detected. On one hand, this suggest that more advanced physiological data acquisition system should be used (e.g., electroencephalography). On the other hand, the number of subjects involved is limited, also considering that age might affect the proficiency with technology. Therefore, the study should be replicated with a bigger sample size, and age-matching gamers with surgeons and residents. Another factor to consider is that hand-eye coordination task has been performed with a single surgical tool, while usually this is bimanual exercise. Hence, this could have affected the performance of surgeons and residents. However, subjective data, as well as time differences between groups were pretty consistent and suggest that ELVIS is a promising tool for the training and evaluation of laparoscopic skills.

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## Appendix A. Face Validity Questionnaire

**Table A1** Face validity questionnaire. Subjects answer the following sentences with 1=very Insufficient, 2=Insufficient, 3=sufficient, 4=good, 5=very good

| | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| Degree of "realism" of devices | | | | | |
| Degree of realism in the positioning of instruments and actual possibility of triangulation on defined targets | | | | | |
| Image quality | | | | | |
| Degree of realism of the "target" objects | | | | | |
| Degree of "realism" of movements compared to real laparoscopic surgery | | | | | |
| Degree of "realism" of in the management of laparoscopic optics | | | | | |
| Degree of usefulness of simulation in reference to acquiring basic eye-hand coordination skills | | | | | |
| Degree of usefulness of simulation in acquiring skills with the non-dominant hand | | | | | |
| Overall degree of usefulness of the simulator in acquiring basic laparoscopic techniques | | | | | |
| Confidence in the device's ability to measure performance. | | | | | |

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