VALIDATION OF A 4D LOW COST LAPAROSCOPIC TRAINING PLATFORM

M. Sguanci[(a)], F. Mandolfino[(b)] , M. Minuto[(c)] G. Vercelli[(d)] M. Gaudina[(e)] , V. Rumolo [(f)] M. Frascio[(g)]

[(a)]DISC - Department of general surgery
[(b)]DISC - Department of general surgery
[(c)]DISC - Department of general surgery
[(d)]DIBRIS – Department of Informatics, Bioengineering, Robotics and Systems Engineering
[(e)]DIBRIS – Department of Informatics, Bioengineering, Robotics and Systems Engineering
[(f)]DISC - Department of general surgery
[(g)]DISC - Department of general surgery

[(a)]marcosguanci@yahoo.it, [(b)]fcmandolfino@gmail.com [(c)] micheleminuto@hotmail.com
[(d)] gianni.vercelli@unige.it [(e)]marco.gaudina@gmail.com [(f)] valerio.rumolo@gmail.com [(g)]mfrascio@unige.it,

ABSTRACT

The use of simulation in laparoscopic surgery training appears to be qualitatively effective if supported by a suitable evaluation system.

The increasing demand of more complex laparo-scopic simulators has inspired the creation of a 4d simulator which is a physical low-cost laparoscop-ic training platform that reproduces the tactile feedback: eLaparo4d) integrated with a software for virtual anatomical realistic scenarios (Unity3D V 4.1).

The aim of the present project is to show the plat-form validation results using two instruments: the face validity and the construct validity.

The results have been obtained by a 12 items standardized questionnaire focused on the “user's satisfaction” submitted to two 15 users groups .

4 basic skill have been chosen to be analyzed: lap-aroscopic focusing and navigation (2 different ex-ercises), Hand – eye – coordination (HEC) (2 dif-ferent exercises).

Keywords: low cost simulation, face validity, construct validity, training.

1. BACKGROUND

The use of simulation in laparoscopic surgery training appears to be qualitatively effective if supported by a suitable evaluation system.

The continually increasing demand of more complex laparoscopic simulators has inspired the creation of a 4d simulator which is a physical low-cost laparoscopic training platform that reproduces the tactile feedback: eLaparo4d) integrated with a software for virtual anatomical realistic scenarios (Unity3D V 4.1).

The School of Medicine of Genoa and the Biomedical Engineering and robotic department (DIBRIS) have cooperated to create a low-cost model based on existing and brand new software.

Aim of this work is to describe the the platform validation results using two instruments: the face validity and the construct validity.

2. MATERIALS AND METHODS

This study validates eLaparo4D simulator: face and construct validity.

2.1 The simulator system

The system is based on a nodejs (htpp://www.nodjes.org) application server that manages the visualisation system, the communication with hardware interfaces and the database where users' data are stored.

The server technology is indeed a sort of data gateway between the several different elements, regardless they are hardware or software. The following figure (figure 1) shows how communication data are exchanged from the very low part of the system (Hardware Interfaces, bottom) to the user interface (HTML Client,top).

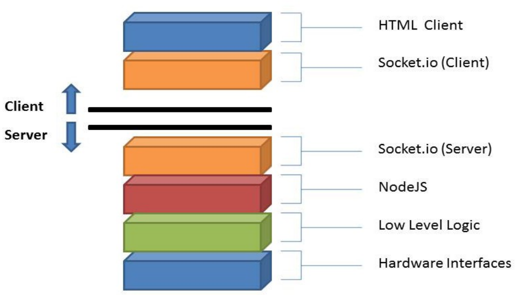


Figure 1: part of the system simulation

The user interface is a simple HTML5 web page running a Unity3D engine (htpp://unity3d.com) plugin. We run several performance tests to compare Unity3D and native WebGL, getting same results. We finally decided to adopt

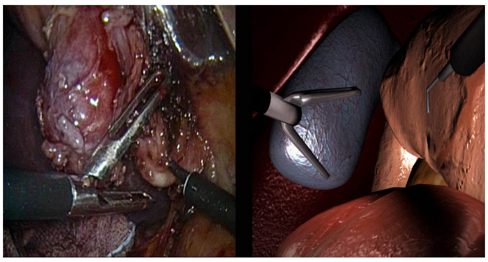
Unity3D engine due to its rapid development time. WebGL is a great technology but still too young to allow us working on a powerful and robust framework. The use of web pages as the main user interface allows us to be more versatile and in the future will give us the possibility, thanks to HTML5 powerful characteristics, to easily share contents in a live way with other systems. An interesting feature is, for example, having the possibility to be guided by an external supervisor, who is monitoring the training phase, while data are quickly exchanged via internet.

2.1.1 Visual and fisical modelling

As previously introduced, visual modelling is a very important aspect of the entire project.

A videolaparoscopic surgery simulator needs a detailed representation of the organs and the tissues inside of the human abdomen. The meshes included in eLaparo4D are developed in Blender 3D Modelling software (htpp://blender.org), and then imported in Unity3D, including textures and UV maps. Eventually, in Unity3D render shader materials are added to the raw meshes, to simulate the specific surface of each of the modelled tissues. In Figure 2, a screenshot of the current virtual environment is shown.

Figure 2: a screenshot from the current aspect of the virtual environment compared to a screenshot of the camera view of a real surgical operation.



As remarked by our colleagues of the Videolaparoscopy Unit of the Department of Clinical Surgery, highly specific training sessions are required to help the operator achieving a proper skill set. In an ideal scenario, medical students should have access to a complete simulator composed of several training scenes, as part of a modular and step-based training process. While the main components and controls of the simulator should be in common, each scene should focus on a very specific surgery operation, differentiating in: the zone and the organs physically manipulated (the target), the particular surgical maneuvers performed (the task), and the type of manipuli used (the means).Considering these remarks, we developed a dynamic parametric physical simulation approach, arbitrary applicable to the rendered meshes in every scene and able to avoid system overloads. Such an approach permits the creation of different scenes starting from the same set of models and interaction algorithms, easily supporting a step-based training. In detail, each 3D object in the scene carries a selectable 3 layer collider component, driving a vertex deformation script. The first layer is a simple box collider; the

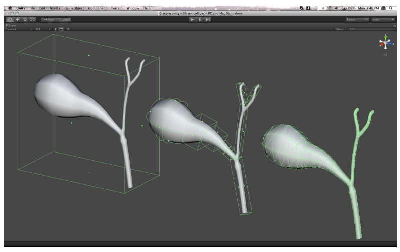


Figure 3: I.e of a collider layer for a gallbladder model

second one is a combination of simple shape colliders which cover, with good approximation, nearly all the volume of the object; the third is a precise mesh collider which exactly coincides with the vertex disposition of the object's mesh. In the foollowing figure (figure 3) is possible to see the 3 different collider layer for a gallbladder model.

2.1.2 Feedback system

Haptic feedback is implemented thanks to the use of three Phantom Omni devices from Sensable (htpp://sensable.com).

The first two are used as manipuli (grasper, hook or scissors) and the third one is used to move the camera within the virtual abdomen, as it happens in a real scenario. The system generates a resultant force when the user puts a manipulus in contact with a mesh, according to the executed task. Phantom devices have been chosen because reasonably low cost although precise enough for the needed level of realism. Furthermore, their stylus-like shape will permit a complete merging of the devices with the physical environment reconstruction; in particular, each stylus will be easily connected to real manipuli. Thanks to an Arduino board connected to a vibrating motor we have also included a vibration feedback. Vibration is used to enhance the realism of operations like tissue shearing (hook) and cutting (scissors).

2.2 The validation system

A valid simulator measures what it is intended to measure.

There are a variety of aspects to validite; subjective approaches are the simplest.
In this sense, we have chosen 2 different kind of validation:

- The Face Validity
- The Construct Validity

Face validity usually is assessed informally by no experts and relates to the realism of the simulator; that is, does the simulator represent what it is supposed to represent?
This kind of validity relates to the realism of the simulator.
A questionnaire validation was created.
In this document 12 closed-ended questions were selected about the following topics:

ergonomics
structure
realism
tactile feedback
quality

For each question must be given a score according to the rating scale "Likert" (Highly inadequate, Insufficient, Sufficient, Good, very good).

Concurrent validity: is the extent to which the simulator, as an assessment tool, correlates with the “gold standard.”
This testing can be achieved by evaluating two groups of subjects, with a different professional experience, with the simulator, comparing the performance scores. This necessitates establishing an objective structured assessment of technical skills (OSATS) evaluation by which the model or “gold standard” performance can be assessed reliably for comparison.(Max V. Wohlauer et al. , 2013)
About this, the simulator must be able to distinguish the experienced from inexperienced surgeons. This is best determined by testing a large number of surgeons with various degrees of training, experience, and frequency of performance of a specific surgical skill or procedure.
For competency assessment, the performance of an individual on a simulator should ideally predict, or at least correlate with, that individual’s performance in the real environment of the operating room. As such, a valid and reliable measure of operating-room performance must be established. This allows differentiation between surgeons assumed to be clinically competent (experienced or expert clinicians) and noncompetent (junior or inexperienced residents). These evaluations are much simpler to perform when a specific task like Hand-eye coordination and laparoscopic navigation and focusing.

2.2.1 Subject

The total number of recruited participants in the study was 24. All participants were included in the face validity study.
A division into two subject groups was made to accomplish the study of construct validity.
The division criterion was the subject experience in laparoscopic surgery.

- Group 1: was composed by 12 novices (5 female, 7 male).
- Group 2: was composed by 12 experts (3 female, 9 male).

The mean age of the groups was years (range years) for novices and years (range years) for experts.
None of the novices had previous experience in virtual reality simulators.

2.2.3 Methodology

For the platform validation, 4 tasks have been selected. These tasks are focused to enhance the most basic skills.

Acquisition of basic skills: exercises related to the acquisition of tasks which allow students to reach basic gestures competences. They could practice using probes that simulate the haptic feedback according to the kind of action.

The 4 selected tasks are:

1. *laparoscopic - focusing - navigation*: This task aims to evaluate the ability to navigate a laparoscopic camera with a 30º optic. This is done by measuring the ability to identify 14 different targets placed at different sites
Two different exercises were chosen:

   Exercise 1: the student, working with a 30° ptic, have to focus different solid targets in a static scenario. This task evaluates the macro – focusing.

   Exercise 2: the student working with a 30° ptic, have to focus a lot of hidden micro- targets, placed in different areas of the scenario.

2. *hand – eye – coordination (HEC):* This task aims to evaluate the ability to work with the non-dominant and dominat hand.
The camera is static.
Two different exercise were chosen:

Exercise 3: the student have to touch a defined point in an “organic scene” with the left and right instrument simultaneously

Exercise 4: the student have to touch a lot of spheres that appear sequentially and in random positions.
There is a time limit to center and touch each sphere with the right and left hand. In this task, the camera is static.

For each of these tasks, a certain number of metrics have been automatically recorded.
Metrics are defined as follows:

– *Total time.* Time that the user needs to accomplish the
Task.
– *Partial time.* Mean time that the user needs to accomplish a partial task.
– *Fulfillment.* Percentage of partial tasks done within the established time.
– *Penality:* number of penality about each task.

Which metrics are recorded for each task is shown in Table 1.

Task	Description	Metrics
Navigation	ability to navigate a laparoscopic camera with a 30º optic	Fulfillment (%) Total time (s) Score penality
Navigation and focusing	the student have to focus different solid targets in a static scenario	Fulfillment (%) Total time (s) Score penality
Coordination (HEC) 1st exercise	the student have to touch a defined point in an “organic scene”	Fulfillment (%) Total time (s) Score penality
Coordination (HEC) 2nd exercise	the student have to touch a lot of spheres that appear sequentially and in random positions.	Fulfillment (%) Total time (s) Score penality

Table 1 “Metrics and Tasks” in the Construct Validity

2.2.4 Questionnaire

All Expert subject were requested to fill a Face validity Questionnaire, referred to characteristics of the eLaparo4D simulator (11 questions).
The questions had to be answered in a 5-point Likert Scale.
The format of Likert item is:

- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly agree

2.2.5 Statistical analysis

Statistical analysis was performed using Excel software and SPSS.
Data are expressed in terms of mean ± standard deviation. The data from the Novice group and expert group are compared with the Mann-Whitney U test; about this, differences were considered significant at $P \leq 0.05$.
In this validation program, we decided to use also the Cronbach’s Alpha Test to measure the “Reliability” of the internal consistency of the simulator.

3. RESULTS AND DISCUSSION

3.1 Results

Face Validity

The questionnaire analysis has shown the following data:

- Excellent degree of usefulness of simulation in reference to 'acquisition of skills, "basic" hand-eye coordination (4,4 ± 0,69)
- A real confidence in the ability of this device to allow an accurate performance measurement (4 ± 0,81)
- A great degree of realism in the management of the optic in the virtual scenario (3,9 ± 0,87)
- An excellent realism of targets (4,1 ± 0,56)
- An excellent degree of realism of the positioning of the instruments (3,9 ± 0,56)
- An high quality of the images (4 ± 0,81)
- A great Haptic feedback (sensation) (3,3 ± 0,67)

The Table 2 show the results of the Face Validity.

Characteristics	Experts (n=12)
Realism	3,6 ± 0,84
Degree of realism of the positioning of the instruments	3,9 ± 0,56
quality of the images	4 ± 0,81
Realism of targets	4,1 ± 0,56
Degree of "realism" movement	3,4 ± 0,96
Haptic feedback (sensation)	3,3 ± 0,67
Degree of realism in the management of the optic	3,9 ± 0,87
Degree of utility of the haptic feedback	3,5 ± 0,70
Degree of usefulness of the simulator about acquisition of "basic" skill (hand-eye coordination)	4,4 ± 0,69
Degree of usefulness of the simulation about acquisition of skills with non-dominant hand	3,9 ± 0,63
Degree of overall usefulness of the simulator about acquisition of basic laparoscopic	3,8 ± 1,03

techniques	
Confidence in the ability of this device to allow an accurate performance measurement	4 ± 0,81

Table 2 Face Validity Questionnaire results
Construct validity

The following table summarize the results of the comparison between the novices group and expert surgeons group.

Task	Metrics	Novice (n=12)	Expert (n=12)	P Value
Navigation Task 1 (First time)	Fulfillment (%)	91.66 ± 28.86	100.00 ± 0.00	0.374
	Total time (s)	53.00 ± 0.00	50.16 ± 10.46	0.171
	Score	11.48 ± 1.12	11.56 ± 1.23	0.488
	penality	1.09 ± 0.69	0.41 ± 0.79	0.472
Navigation Task 1 (Second time)	Fulfillment (%)	100.00 ± 0.00	100.00 ± 0.00	0.086
	Total time (s)	30.08 ± 4.64	31.00 ± 7.21	0.440
	Score	11.00 ± 0.00	10.62 ± 1.06	0.337
	penality	0.00 ± 0.00	0.25 ± 0.70	0.337
Navigation Task 2 (First time)	Fulfillment (%)	50 ± 52.22	66.66 ± 49.23	0.254
	Total time (s)	80.91 ± 14.93	69.41 ± 20.37	0.066
	Score	6.83 ± 3.32	7.00 ± 2.86	0.254
	penality	0.00 ± 0.00	1.12 ± 0.64	**0.004***
Navigation Task 2 (Second time)	Fulfillment (%)	91.66 ± 28.86	100.00 ± 0.00	0.156
	Total time (s)	50.41 ± 24.15	61.62 ± 14.37	0.149
	Score	9.25 ± 1.71	9.50 ± 0.53	0.337
	penality	0.3 ± 0.48	0.50 ± 0.53	0.251
Coordinatio n Task 3 (First time)	Fulfillment (%)	100.00 ± 0.00	91.66 ± 28.86	0.374
	Total time (s)	29 ± 14.36	18.72 ± 15.12	**0.014***
	Score	8.83 ± 2.24	9.90 ± 1.37	0.077
	penality	0.00 ± 0.00	0.00 ± 0.00	NC
Coordinatio n Task 3 (Second Time)	Fulfillment (%)	100.00 ± 0.00	100.00 ± 0.00	0.086
	Total time (s)	16.25 ± 6.99	10.25 ± 4.36	**0.026***
	Score	8.66 ± 2.42	10.62 ± 1.06	**0.006***
	penality	0.00 ± 0.00	0.00 ± 0.00	NC
Coordinatio n Task 4 (First time)	Fulfillment (%)	0.00 ± 0.00	0.00 ± 0.00	0.488
	Total time (s)	67.66 ± 12.29	51.75 ± 11.24	**0.003***
	Score	6 ± 1.32	7.16 ± 1.64	0.051
	penality	4 ± 1.32	2.83 ± 1.64	0.051
Coordinatio n Task 4 (Second time)	Fulfillment (%)	0.00 ± 0.00	90.90 ± 30.15	0.254
	Total time (s)	59.66 ± 13.04	40.50 ± 10.63	**0.003***
	Score	6.3 ± 1.88	8.12 ± 1.55	**0.030***
	penality	3.7 ± 1.88	1.87 ± 1.55	**0.030***

Table 3 Results of Construct validity

There were significant differences between the experienced group (Expert) and non-experienced group (Novice) in several tasks.
At least one of the metrics of each task presents significant differences.
It is only task 4 (coordination) the one that differentiates between experts and novices in all the evaluated parameters.
There were significant differences between the experienced group and non-experienced group in the task 3, in terms of “total time” and “score”; this task shows a better executions accomplished by experts than the ones accomplished by novices.
The task 2, about navigation, show a better percentage of fulfilment in favour of expert group (100% fulfillment).
Total time, shows significant diffrences in task 4,3,2.
There weren’t significant differences between the experienced group and non-experienced group in the task 1.
As previously described in the methodology, metrics that are evaluated in all tasks are total time, fulfillment, score and penality

3.2 Discussion

Laparoscopic surgery simulators are important in the training process of surgeons in laparoscopic surgery.
A validation of simulators is always necessary in order to determine their capacity for surgeons training although as far as we know, there is not any mandatory validation strategy (6).
The Face validity and the Construct validity are two important steps of this process.
The Construct validity determines the capacity of the simulator to punctuate the execution according to the level of experience of the subject who is accomplishing the task.
So, a construct validated simulator will be able to distinguish between surgeons with different levels of experience in laparoscopic surgery.
The Face Validity is just based on the opinion and experience of surgeons and cannot be used in every case to define the validity of a new simulator.
As the face validity is very subjective, it is usually used at the first stages of validation. (Gallagher AG et al., 2003)
The aim of this work is to validate “eLaparo4D” simulator
accomplishing a face and construct validity in order to determine whether it is adequate for basic skills training.
Expert group agree with usefulness of the simulator in reference to 'acquisition of skills, "basic" hand-eye coordination and confidence in the ability of this device to allow an accurate performance measurement.
The realism of the targets and the scenario is a great characteristic, like the position of the instruments.
The haptic feedback is considered by expert as acceptable, most important elements in this kind of virtual simulators.
The results of the study show that there are significant differences between the execution of tasks by novices and by experts for the evaluated metrics.
Among all, navigation and coordination tasks show the clearer results.
The task1 about navigation not present any difference between the different levels of experience: this result can be due to the fact that novices have experience virtual games and in video camera use.
In task 3 and 4, the difference between novices and experts is evident; total time, score and penalty are in favour of experts.
Nevertheless, task 4 results analysis shows a percentage of fulfilment equal to 0% in both the groups.

The “total time” are evaluated in all tasks because is an important variable; novices need more time than experts to finish the tasks in all cases and experts fulfil the majority of the tasks and more efficiently than novices.
To evaluate the reliability, we decided to performe the correlation index to the metrics: total time and score.
The results of this test show an high value of correlation for the total time (0.664 – 66%) and a lower value for the score (0.296 – 30%).
From these values, the Split half Methodology was applied, to calculate the coefficient of Reliability; we applied the Spearman-Brown correction and the final result was: 0.79.
The table 4 show the coefficient.

Metric	Coefficient of Reliability
Total time	0.664
Score	0.296

Table 4 Correlation index result

This conclusion leads us to the point that eLaparod4D
could be used in training programs as an assessment tool.
Nevertheless, the limited size of the sample for this study implies that this conclusion should be checked again with a wider number of subjects.
In this sense we suppose to use the results of this work to choose objectives for a second study (Molina CR et al. , 2008)

ACKNOWLEDGMENTS

We would like to thank G. Vercelli, L. Lagomarsino, V. Zappi of Dept. of Informatics, Bioengineering, Robotics and Systems Engineering, E. Bellanti, L.Lagomarsino and S. Marcutti for their precious collaboration.

REFERENCES

1. htpp://www.nodjes.org
2. htpp://unity3d.com
3. htpp://sensable.com
4. htpp://blender.org
5. Max V. Wohlauer, Brian George, Peter F. Lawrence, Carla M. Pugh, Erik G. Van Eaton, Debra DaRosa. 2013. Review of Influential Articles in Surgical Education: 2002–2012. Journal of Graduate Medical Education 5:2, 219-226.
6. Gallagher AG, Ritter Em, Satava RM (2003) Fundamental principles of validation, and realiability: rigorous science for the assessment of surgical education and training. Surg Endosc 17:1525– 1529
7. Molina CR, de Win G, Ritter O, Keckstein J, Miserez M, Campo R (2008) Feasibility and construct validity of a novel laparoscopic skills testing and training model. Gynecol Surg 5(4): 281–290