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LOW COST LAPAROSCOPIC TRAINING PLATFORM: PRIMARY VALIDATION PROCESS

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***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 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 aim of the present project is to show the validation process results of this system using two instruments: the face validity and the construct validity.

The face validity was used for an ergonomic analysis of the simulator the construct to test the system's ability to differentiate expert users (experienced surgeons in laparoscopy) from non-experts (student without experience in laparoscopic surgery).

A sample of 20 students was selected, divided into 2 homogeneous groups with respect to the level of confidence with the use of video games, consolles, smartphones (this has been possible thanks to the use of a questionnaire, administered before the practical phase of training).

The groups participated in a training program based on 5 basic laparoscopic skills (laparoscopic focusing and navigation, hand – eye – coordination and grasp coordination). So, a second and third study sample was chosen, consisting of 20 post graduate students (intermediate group) and 20 experienced surgeons in laparoscopy; for these groups was provided a training program identical to the previous group as well as their subdivision into 2 group.

We analyzed the results of the three samples obtained by comparing variables such as: score, % of fulfillment, penalities, time

At the same time, the students improvements has been motorized, developing a customized learning curve for each user.

To evaluate the structural characteristics of the simulator a specific questionnaire has been used.

The results encouraged us. The simulator is ergonomically satisfactory and its structural features are adapted to the training. The system was able to differentiate the level of experience and also has therefore met the requirements of "construct validity".

Index Terms— **construct validity, face validity, learning curve, low cost simulation, training.**

I. INTRODUCTION

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.

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 platform validation results using two instruments: the face validity and the construct validity.

II. MATERIALS AND METHODS

This study validates eLaparo4D simulator: face and construct validity.

A. The simulator system

The system is based on a node js [1] application server that manages the visualisation system, the communication with hardware interfaces and the database where users' data are stored.

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The server technology is indeed a sort of data gateway between the several different elements, regardless they are hardware or software. The 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).

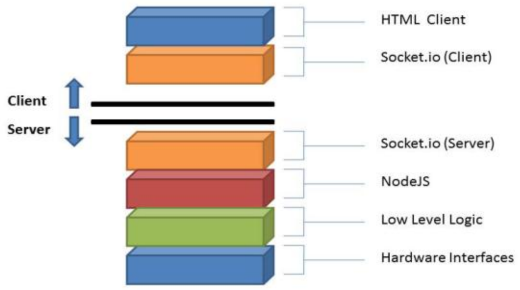

Fig. 1: part of the system simulation

The user interface is a simple HTML5 web page running a Unity3D engine [2] 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.

As previously introduced, visual modelling is a very important aspect of the entire project. A video laparoscopic 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 [4], 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 following figure, a screenshot of the current virtual environment is shown.

Fig. 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 Video laparoscopy 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.

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The 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 following figure is possible to see the 3 different collider layer for a gallbladder model.

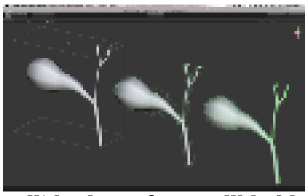

Fig. 3: I.e of a collider layer for a gallbladder model

B. HAPTIC FEEDBACK

Haptic feedback is implemented thanks to the use of three Phantom Omni devices from Sensable [3]. 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).

III. THE PRIMARY VALIDATION PROCESS

A valid simulator measures what it is intended to measure. There are a variety of aspects to validate; subjective approaches are the simplest. In this sense, we have chosen 2 different kind of validation: [7]

1. The Face Validity
2. 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. [5]

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 non competent (junior or

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inexperienced residents). These evaluations are much simpler to perform when a specific task like Hand-eye coordination and laparoscopic navigation and focusing.

A. Construct validity program

We have involved a total of 60 subjects to the validation program. This entire group is divided into 3 categories: cluster A is composed by 20 students of Medical and Pharmaceutics Sciences of the University of Genoa without any experience in laparoscopic surgery, cluster B by 20 general surgery residents with moderate laparoscopic experience and cluster C by 20 surgeons with high experience in laparoscopic surgery.

B. Selection criteria

Selection criteria and inclusion of "Intermediate" and "Expert" pattern: we have chosen the number of laparoscopic surgical procedure as first operator as parameter.

Group A: 20 novices (NO experience in laparoscopic surgery)

Group B: 20 intermediate (at least 20 total laparoscopic operations in the last year)

Group C: 20 experts (at least 50 laparoscopic operations as first surgeon in the last year and at least 100 laparoscopic operations in the last 3 years)

Validation process currency:

The validation process has been organized in three rotations of 5 workdays (from Monday to Friday). We have chosen this method to avoid the possible bias due to a excessive and unnatural number of participants.

C. Methodology

For the platform validation, 5 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 5 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° optic, have to focus different solid targets in a static scenario. This task evaluates the macro – focusing.

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

Fig. 4: a screenshot of task 2

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:

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Exercise 3: the student have to touch a defined point in an "circular target" with the left and right instrument simultaneously .

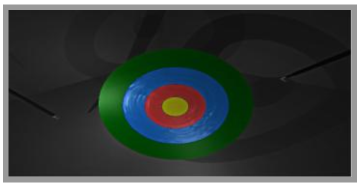

Fig. 5: a screenshot of task 3

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.

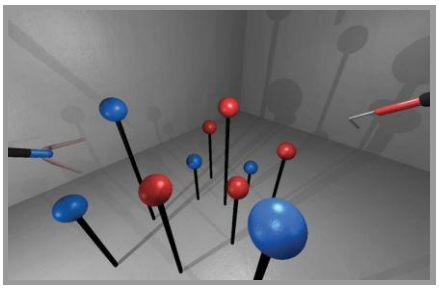

Fig. 6: a screenshot of task 4

Exercise 5: the student have to grasp 3 objects and to put these in a selected form.

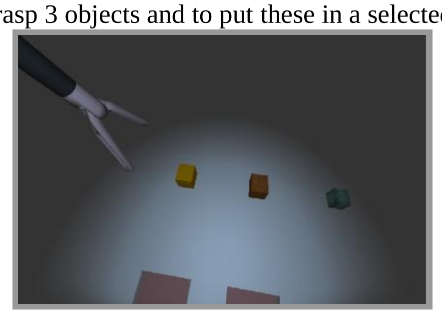

Fig. 7: a screenshot of task 5

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
- *Fulfillment.* Percentage of partial tasks done within the established time.
- *Penalty:* number of penalty about each task.
- *Score: task's* score
- *Coordination*
- *Accuracy*

Which metrics are recorded for each task is shown in following table.

Table I "Metrics and Tasks" in the Construct Validity

Task	**Description**	**Metrics**
Navigation	ability to navigate a laparoscopic camera with a 30º optic	Fulfillment (%) Total time (s) Score penalty
Navigation and focusing	the student have to focus different solid targets in a static scenario	Fulfillment (%) Total time (s)

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		Score penalty
Coordination (HEC) **1st exercise**	the student have to touch a defined point in an "circular target"	Fulfillment (%) Total time (s) Score Penalty Coordination Accuracy
Coordination (HEC) **2nd exercise and 3rd exercise**	the student have to touch a lot of spheres that appear sequentially and in random positions. The student have to grasp 3 objects	Fulfillment (%) Total time (s) Score penalty

In particular we have guaranteed assistance to all participants divided in morning/afternoon turnations: 5 days (one week) for each group to permit the best compliance as possible to every subject involved.

Each group has been divided into two smaller homogeneous groups based on the questionnaire about the personal level of confidence in the use of videogames, virtual platforms, etc:

- Subgroup A1, B1, C1: little/absolutely not confident
- Subgroup A2, B2, C2: confident/very confident

The questionnaire has been administered to each subject before the beginning the test. To guarantee a correct statistic analysis, we have adopted a closed testing system where the subjects had a limited number of attempts (an open testing system might show bias like weakness, time delays or methodological limits).

When finished the test, the expert group has been completed the "Face validity" questionnaire to explore the ergonomic adequacy of the system.

Each subject had max two attempts for every examination (2 attempts for exercise 1 level easy, 2 attempts for exercise 1 level intermediate, 2 attempts for exercise 1 level difficult). Each participant have finalized 6 examinations for a total of 30 at the end of the process.

D. Setting
The setting has been the same during all the parts of the process. To increase the subject's perception of the scenario in which it will operate, every subject had to dress surgical gloves, coat, mask and headdress. Similarly, the platform has been prepared with the virtual utilities present on the surgical field to make the hand pieces movements more adherent to reality.

E. Data analysis
We have collected for each group several variables about the level of confidence with virtual platforms, and data about execution time, score, penalties where applicable, motion accuracy where applicable, motion coordination where applicable.

F. Face validity questionnaire
All Expert and intermediate subjects 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:
- Strongly disagree
- Disagree
- gNeither agree nor disagree
- Agree
- Strongly agree

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G. 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, intermediate and expert group are compared with the Mann-Whitney U test; about this, differences were considered significant at $P \leq 0.05$.

In this first validation program, we decided to use also the Cronbach's Alpha Test to measure the "Reliability" of the internal consistency of the simulator.

III. RESULTS AND DISCUSSION

A. Results

Face Validity

The questionnaire analysis has shown the following data:

Expert's opinion:

- 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) Excellent degree of usefulness of simulation in reference to 'acquisition of skills, "basic" hand-eye coordination (4,4 ± 0,69)

Intermediate opinion:

- An excellent degree of realism in the management of the 30° optic
- A great quality of scenario
- A very good capability of the simulator to teach gestures and action
- The devices position show a good degree of realism

Table II Face Validity (expert sample) Questionnaire results Construct validity Construct validity

Characteristics	Experts (n=20)
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 techniques	3,8 ± 1,03
Confidence in the ability of this device to allow an accurate performance measurement	4 ± 0,81

About construct validity, there were significant differences between the experienced group (Expert), intermediate group and non-experienced group (Novice) in several tasks. At least one of the metrics of each task presents significant differences. The tasks 3, 4 and 5 (about coordination) discriminates 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", "score", "coordination" and "accuracy"; this task shows a better executions accomplished by experts than the ones accomplished by novices.

The task 2, about navigation, shows a better percentage of fulfilment in favour of expert group (90/100% fulfilment). Total time, shows significant differences in task 2,3,4,5. 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, fulfilment, score and penalty.

B. Discussion

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. [6] 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 and intermediate 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 and intermediates for the evaluated metrics. Among all, navigation and coordination tasks show the clearer results.

The task 1 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 3,4 and 5 the difference between novices and experts is evident; total time, score and penalty are in favour of experts. In task 3, the expert group showed a better coordination and accuracy than novices.

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 perform 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 and a lower value for the score. 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: 0.91 this conclusion leads us to the point that eLaparod4D could be used in training programs as an assessment tool. In this sense, the next phase of development will include the completion of laparoscopic cholecystectomy. It will provide for the final validation of the system, a fundamental point which will allow the development of a marketable model.

The development of the system will create an excellent training system similar to those currently on the market but economically beneficial to universities, who usually do not have large financial resources. The VLS simulator the Authors are working on could become an useful tool for training and accreditation of young surgeons as well a good way to practice new procedures for expert surgeons. All these items, if confirmed, could have a positive effect on accident in surgery.

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