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TRAINING IN LAPAROSCOPIC SURGERY: FACE VALIDITY OF A LOW COST VIRTUAL SIMULATOR

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ABSTRACT

Aim of this study is to investigate the importance of acquiring basic and advanced laparoscopic skills using a virtual reality low cost simulator in laparoscopic surgery in a defined theathre, a Medical Simulation Centre.

The study shows and describes the Medical Simulation Centre in terms of utilization and activities. The article describes also the technical features of the system and its validation process about the basic skills using a primary method: the face validity.

It consents to evaluate the structural simulator characteristics through a specific questionnaire, used after the system testing (we have chosen a basic skill training). A sample of 40 participants was selected: 20 post graduate students, 20 expert surgeons.

The groups were divided into two homogeneous subgroups according to the level of confidence with the use of video games, consolles, smartphones (a questionnaire has been used before the practical phase of training).

We analyzed the results of the face validity obtained by comparing the two groups reported impressions. The simulator appears ergonomically satisfactory and its structural features are adapted to the laparoscopic training.

KEYWORDS: Advanced simulation centre, laparoscopic surgery, low cost, face validity.

1. Introduction

The mission of a simulation center in medical reality is to improve patient safety and clinical outcomes by integrating medical simulation based on teaching methodologies into the educational curriculum for all students, residents, attending physicians, nurses and other ancillary health care staff.

Current and future health care professionals “practice on plastic” honing their skills, refining advanced techniques and learning valuable social interactive tools for delivering important news to patients. This translational research becomes vital for creating the gold standard in patient safety and medical teaching.

In this set, the surgical department teachers of University of Genoa have cooperated with bioengineering research group of the same University to develop a laparoscopic training system.

Nowadays laparoscopic surgery is considered the gold standard to treat a lot of surgical diseases. But not all surgeons have acquired the skills necessary for laparoscopic procedures, for example such as proficiency in ambidextrous maneuvers with new tools, enhanced hand-eye coordination, depth perception and compensation for the camera angle. The need to repeat the same exercises to improve these laparoscopic skills has made basic laparoscopy amenable to simulator-based training. The continually increasing demand of more complex laparoscopic simulators has led to a rise in prices of these tools and has inspired us 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. The simulator allows working in team, two surgeons can work together like in reality and the system allows the use of real operative instruments, all equipped with tactile feedback. But before using this simulator to assess skills and competencies it needs to be seriously and thoroughly validated: among the five validities Recognized (content, face, construct, concurrent and predictive) we has decided to employ the face validity and the construct validity: the first is usually used informally to define the realism of the simulator or whether the simulator represents what it is supposed to represent and the second because mandatory in distinguishing the experts from inexperienced operators based on a performance score. Aim of this work is to describe the structure and the acitivities of the Advanced Simulation Centre and the platform validation results about face validitiy.

2. Materials and methods

2.1 The Advanced Simulation Centre

The Advanced Simulation Center from October 2011, was born apart from the need to offer students and graduate students of the School of Medical Sciences and Pharmaceutical a more adequate professional training to the health needs.

The strongest motivations for the use of simulation in training the future health professionals have been well documented in several experiences and could be summarized as following:

The need to train to perform safety maneuvers increasingly complex and invasive;
The need to reduce the learning time curves of innovative procedures;

The increase in the medical-legal litigation and the carrying out of clinical maneuvers on the part of students must take place after an appropriate training that allows learning from mistakes;

The introduction on the market of more sophisticated devices for the simulation that allow reproducing more and more realistic clinical scenarios.

The Advanced Simulation Centre, designed on the model of the Simulation Centre in Montreal at McGill University, is organized into sections:

- **Macro simulation:** using mannequins to the whole person or body parts that, depending on the technological complexity of the dummies and the complexity of clinical scenarios to be played, it is divided into high- medium-low fidelity.

- **Micro simulation:** consists of computer workstations for the solution of interactive clinical cases in order to train students and make clinical decisions correct in the right time.

- **Relational simulation:** using clinical environments realistically reproduced in which, using the technique of the game of roles and the use of "standard patients" students are trained to report the relationship with patients and working in a team.

- **Virtual Reality:** consists of devices with different technological complexity, from box trainers in computerized tools that can restore the sense of touch, by which you acquire manual skills such as basic surgical techniques or performing complex laparoscopic procedures.

The Advanced Simulation Centre is divided into two wings involving an area of about 400 sq.

The curricular courses offered at the Advanced Simulation Centre are as follows:

Bachelor of Science in School of Medicine
- First Aid (first year): 270 students divided into 14 groups for 8 hours at group
- Biophysical and Clinical methodology (III year): 280 students divided into 32 groups for 20 hours in group
- Gynecology and Obstetrics (V year): 240 students divided into 8 groups for 8 hours at group
- Radiology (IV year): 240 students divided into 12 groups for 20 hours in group
- Pediatrics (V year): 240 students divided into 8 groups for 8 hours at group
- Emergencies (VI year): 240 students divided into 32 groups for 44 hours in group
- Vocational training medical-surgical (VI year): 240 students divided into 32 groups for 20 hours in the group.

Bachelor of Science in Nursing
- Vocational training (II, III): relational workshops for 80 students of the S. Martino Universitary Hospital pole divided into 4 groups for a total of eight hours per group.
- Check certification service according to the method OSCE (Objective Structured Clinical Evaluation) for 470 students of all Liguria poles (8 hours for 20 days)
- Bachelor in Physiotherapy
- Aesthetics of passive mobilization (II and III year): 40 students divided into 4 groups for 4 hours every group

Bachelor of Science in Dental Hygiene
- relational laboratory (III year): 40 students divided into 4 groups for 4 hours every group

Bachelor of Science in dietetics
- relational laboratory (III year): 20 students divided into 2 groups for 4 hours every group

Specialization schools
- Anesthesiology and Intensive Care
- Emergency Medicine
- Internal Medicine
- Cardiology
- Nephrology
- Gynecology
- General Surgery

We can estimate a commitment to teaching between 50 and 20 hours each year for each specialization school.

The total number of students trained annually at the centre has been estimated at around 2800 for a total of about 2500 hours of teaching imparted.

Students, on request, may attend the centre individually or in small groups to self-study in the free zones of the programmed teaching.

At the end of each course, every student receives a quality assessment questionnaire perceived.

The simulation centre also hosts and offeres courses aimed at external users, health professionals for their continuing education or categories of citizens who for various reasons are related to health issues. It is, therefore, offered to BLSD Courses (Basic Life Support and Defibrillation), ATLS (Advanced Trauma Life Support), First Aid, CRM (Crisis Resource Management), etc.

According to the ARS (Regional Health Agency), the Coordination of Rare Diseases and ATM Rare Diseases of IRCCS Gaslini Pediatric Hospital, at the Centre are held free courses for caregivers, family, or household employees of patients, especially children, suffering from chronic disabling diseases, in order to reduce the hospital stay and ensure a more safe and comfortable home care. These courses have a half annual basis and over 150 caregivers formats are involved.

For each type of training activity, the teaching methodology derived from the training of flight personnel, adopted a long time ago by the aeronautical companies. In particular, each procedure is broken down into a check-list of actions that learners construct with the guidance of the tutors in order to acquire the necessary automatism in critical or emergency conditions.

The evaluation of 'learning takes place using the method OSCE (Objective Structured Clinical Examination), consisting of a "stations" exam where the student must perform the procedures using the check-list he has built.

It's already on a successful attendance of the centre by the students of Biomedical Engineering courses and Bioengineering School. The centre offers these students the opportunity to make contact with simulators of the latest generation and to study the materials they are made of is the software that govern them, the video-recording system and audio connection between systems of the center and between the center environments and operating rooms IRCCS San Martino Universitary Hospital, in the simulation devices for measuring air quality and dispersion of medical gases and fumes of which are equipped the rooms of Macro simulation to high-fidelity.

2.2 The simulator system

The development of a video laparoscopic surgery simulator is nowadays one of the most important subjects in the field of MIS. There are many important aspects that need to be considered when designing such a kind of simulator. As described in surgical simulators are very complex systems, mainly because MIS techniques are characterized by a very high level of visuo-motor coordination and multiuser cooperation within reduced operating spaces. Moreover, the implied technologies are sophisticated and expensive. Videolaparoscopy simulators are a powerful way to improve the skill gamut for the medical doctors to master such systems at a very low cost. Developing a simulator with this kind of purpose is not easy and has many concerns to take into account. For instance, other than having a well structured visualization environment, aspects such as information communication, feedback capabilities, human factors, operative constraints, ergonomics and training aspects need great attention. Although at the current state not all of them has been fully developed yet, the whole design process of the project, including the choice of hardware and software technologies, has been specifically approached to reach the introduced goals.

The system is based on a node is application server that manages the visualization 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. Figure 2 shows how communication data are exchanged from the very low part of the system (Hardware Interfaces, bottom) to the user interface (HTML Client, top). 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 web.

A. Visual and Physical Modeling

As previously introduced, visual modeling 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 Modeling software3, 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 modeled tissues. In Figure 3, a screenshot of the current virtual environment is shown.

A great effort has been made to realistically simulate physics avoiding system overloads (excessive computational loads, affecting usability). 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 per- formed (the task), and the type of manipuli used (the means). This implies that, according to these 3 components, not all the elements included in a training scene need the same level of realism, especially in terms of physical behavior. In general, the targets of the operation are supposed to have a more accurate physical behavior with respect to an organ in background; but also among the targets the level of accuracy can vary. Even in the same scene the physical simulation of the targets can change over time, according to the manoeuvre the operator is currently performing with the manipuli (e.g. a simple grasping vs. a precise carving). Furthermore, the learning of a complex task - carried out with complex means - should be achieved subdividing the task itself into several simpler steps, preparatory to a complete simulation; so, often, the global complexity of the physical simulation of the same set of organs can vary from scene to scene.

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 three layer collider components, driving a vertex deformation script. The first layer is a simple box collider; 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 Figure 4 it is possible to see the 3 different collider layer for a gallbladder model. According to the relevance the 3D object has in the scene (depending on target, task and means of the currently simulated operation), one of the 3 layers is activated, modifying the physics behavior defined in the vertex deformation script. When the box collider layer is active, the script handles collisions, allowing motion but not modifying the aspect of the colliding objects. This configuration is proper for background objects, far from the target. The second, composite, layer supports a more precise collision detection and introduces a script-based rough surface deformation when simple collisions occur (e.g. two organs collide while one is grasped and moved by the operator). This configuration provides a level of realism suited for the organs that surround the actual target of the operation, or for the targets undergoing simple manipulations (simple tasks like flipping, pushing, lifting, etc.). Finally, the mesh collider layer allows the deformation script to perform a precise local vertex deformation, whenever a collision is detected. Such a detailed behavior supports inward surface deformation caused by pressure, as well as tissue stretching, folding and cutting, typical of manipuli-based surgical manoeuvres. Indeed, this configuration fulfills the strong needs for realism of the targets of the surgical operation, especially when the task is demanding and complex manipuli are the main means.

The use of each layer is characterized by a different computational load: light for the first layer, intermediate for the second one and heavy for the third one. The load, obviously, depends also on the level of detail of the modeled meshes. In addition, the chosen layer can be switched dynamically. This means that the same organ can have a more or less accurate physical response to manipulation, according to the evolution of the system (e.g. the operator's activity, the currently interacting manipulus), limiting as much as possible the CPU load while preserving realism. Moreover the real-time setting of the layer, coupled with the monitoring of the operator's performance, offers the intriguing possibility to dynamically adjust the complexity of the task, automatically choosing a level of realism that fits or challenges the operator's skill.

Using a Unity stereoscopic plugin, we are able to visualize the scenes in stereoscopic 3D. The possibility to train operating with a stereoscopic visual feedback engaged our colleagues of the Videolaparoscopy Unit of Clinical Surgery Dept., since stereo cameras for real videolaparoscopy have been accurately assessed in biomedical engineering research, and are quickly spreading in the medical industry.

2.2.1 Haptic Feedback

Haptic feedback is implemented thanks to the use of three Phantom Omni devices from Sensable4. 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 board5 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).

The current feedback solution, coupled with the web- based structure of the application, makes available a haptic- based remote guidance, during which a supervisor, even if not physically present in the same room, can haptically guide the hands and the manipuli of the trainee to show him/her the proper way to execute a critical task.

At the moment we are using a very basic force feedback calculation algorithm, based on compliant contact. Although a much more detailed force feedback solution is needed, at the current state eLaparo4D allows a first comparison with real videolaparoscopy systems and permits the collection of feedback from medical doctors.

2.2.2 The training interface

Training is a key aspect in the eLaparo4D system as already outlined. The user has his/her own profile, is tracked over time and has is/her own history as shown in Figure 5. Every exercise has its own allowed/not allowed actions letting the user earn or loose points. The scale and points assigned have been decided with the consultancy of several medical doctors, giving us feedback about what are the needs of a well skilled surgeon. The possibilities given by a HTML5 user interface allow us to be very versatile in the user profile management.

2.3 The 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, in this primary phase, we have chosen the following kind of validation:

- The Face 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).

2.3.1 Sample and inclusion criteria

We have involved a total of 40 subjects to the validation program. This entire group is divided into 2 categories: cluster A is composed by 20 intermediate students residents with a poor laparoscopic experience, cluster B by 20 general surgery residents with moderate laparoscopic experience.

For this first prothotipal phase we have decided to exclude experts in laparoscopic surgery.

About "Selection criteria" we have chosen the number of laparoscopic surgical procedure as first operator as parameter.

- **Group A:** 20 intermediate (at least 4 total laparoscopic operations in the last year) – Validation Group

- **Group B:** 20 general surgeons residents (at least 10 total laparoscopic operations in the last year) – Referent Group

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.

2.3.2 Testing mode and setting

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 two groups have 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.

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.

2.4 Basic skills

For the platform validation, 5 tasks have been selected. These exercises are 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.

5 tasks are selected:

1. laparoscopic - focusing - navigation (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.

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

- **Exercise 3:** the student have to touch a defined point in an "circular target" 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.
- **Exercise 5:** the student have to grasp 3 objects and to put these in a selected form.

2.4.1 Metrics
For each of these tasks, a certain number of metrics have been automatically recorded:

- Total time (time that the user needs to accomplish the task)
- Fulfillment (% of partial tasks done within the established time)
- Penality (number of penality about each task)
- Score (task's score)

3. Face validity Results
3.1 Statistical Analysis
The results are expressed as mean ± standard deviation, median, minimum/maximum values, and percentages. The Shapiro-Wilk test was applied to evaluate the normal distribution of continuous variables. Differences for answer scores between validation and reference group were evaluated using the Wilcoxon-Mann-Whitney test. The Spearman's rho was used for correlation analysis. A two-tailed P value ≤0.05 was assumed for statistical significance. Statistical analysis was performed using the R software/environment (version 3.2.5; R Foundation for Statistical Computing, Vienna, Austria).

3.2 Results
Forty surgeons were enrolled in the face validation process and assigned to validation (n = 20) (VG) or referent (n = 20) group (RG).

All respondents were based in the Liguria Region hospitals.

VG was composed by 8 females and 12 males, median age 28 years (form 25 to 31). RG was composed by 1 female ans 19 males, median age 61 years (from 49 to 64).

The total percentage of the enrolled surgeons were right-handed.

In the face validity questionnaire, the higher overall mean scores occurred for the following questions (Q): Q3, Q4, Q7, Q9, and Q11; the lower mean values were observed in Q2, Q6, and Q8 **(Table 1)**.

Question	Mean ± SD	Min	Max
Q1 – Realism	4.00 ± 0.78	3	5
Q2 - Degree of realism of the positioning of the instruments	3.95 ± 0.78	3	5
Q3 – Quality of images	4.42 ± 0.63	3	5
Q4 – Degrre of relaism of targets	4.22 ± 0.77	3	5
Q5 – Dgree of relaism movement	3.77 ± 0.80	2	5
Q6 – Haptic feedback (sensation)	3.90 ± 1.00	2	5
Q7 – Degree of realism in the management of the optic	4.15 ± 0.80	3	5
Q8 - Degree of the utilty of the haptic feedback	3.65 ± 1.00	2	5
Q9 - Degree of usefulness of the simulator	4.12 ± 0.96	1	5
Q10 - Degree of usefulness about acquisition (non-dominant hand)	4.05 ± 0.81	3	5
Q11 -Degree of usefulness about acquisition (laparoscopic techniques)	4.17 ± 0.81	2	5
Q12 - Confidence in the ability to allow an accurate measurement	4.07 ± 0.83	3	5

Table 1. Face validity questionnaire and overall mean score for each question, rating on a scale of 1 (highly inadequate) to 5 (very good).

No significant difference between validation and referent group was found for each item of the face validity questionnaire **(Table 2)**.

Question	Validation Group (*n* = 20)	Referent Group (*n* = 20)	*P* value
Q1	4.00 ± 0.85	4.00 ± 0.72	1.000
Q2	3.95 ± 0.76	3.95 ± 0.82	0.988
Q3	4.50 ± 0.51	4.35 ± 0.74	0.649
Q4	4.30 ± 0.73	4.15 ± 0.81	0.570
Q5	3.65 ± 0.81	3.90 ± 0.79	0.362
Q6	4.10 ± 0.85	3.70 ± 1.13	0.282
Q7	4.10 ± 0.85	4.20 ± 0.77	0.729
Q8	3.85 ± 0.99	3.45 ± 0.99	0.210
Q9	4.20 ± 0.77	4.05 ± 1.14	0.953
Q10	4.10 ± 0.85	4.00 ± 0.79	0.687
Q11	4.30 ± 0.66	4.05 ± 0.94	0.497
Q12	4.00 ± 0.92	4.15 ± 0.74	0.605

Table 2. Between-group comparisons for face validity questionnaire, with score for each question rating on a scale of 1 (highly inadequate) to 5 (very good).

Before the beginning of the face validation, to each participants was administered a questionnaire about the personal level of confidence in the use of videogames, computers, smartphone, and virtual platforms [Riportare in dettaglio nella sezione "Materials and Methods" domande e score del questionario pre-face validation]. No significant difference in the overall mean score related to this questionnaire was found between validation (30.05 ± 12.61; median: 29) and referent group (31.10 ± 11.42; median: 31) (P = 0.694). Stratifying by the median score values of the questionnaire related to level of confidence in the use of videogames/virtual platforms, a significantly difference (P = 0.016) was observed only for Q8 of the face validation in the validation group (median ≤29: 4 ± 0.82; median >29: 2.9 ± 0.87). Spearman correlation between score of the face validation questionnaire and score of the questionnaire related to level of confidence in the use of videogames/virtual platforms returned a whole significant association for face validation Q2 (coefficient: -0.349; P = 0.027) and Q6 (coefficient: 0.320; P = 0.043) **(Figure 1)**.

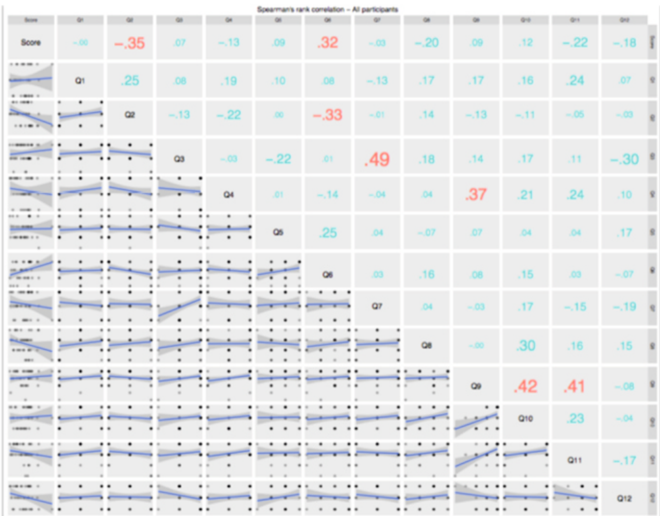

Figure 1. Spearman correlation for all participants between score of each question (Q) of the face validation questionnaire and score of the questionnaire related to level of confidence in the use of videogames/virtual platforms (Score).

In the validation group, a significant correlation between score of the face validation questionnaire and score of the questionnaire concerning the use of videogames/virtual platforms occurred for the face validation Q2 (coefficient: -0.566; P = 0.009), Q6 (coefficient: 0.489; P = 0.028), and Q8 (coefficient: -0.529; P = 0.016) **(Figure 2).**

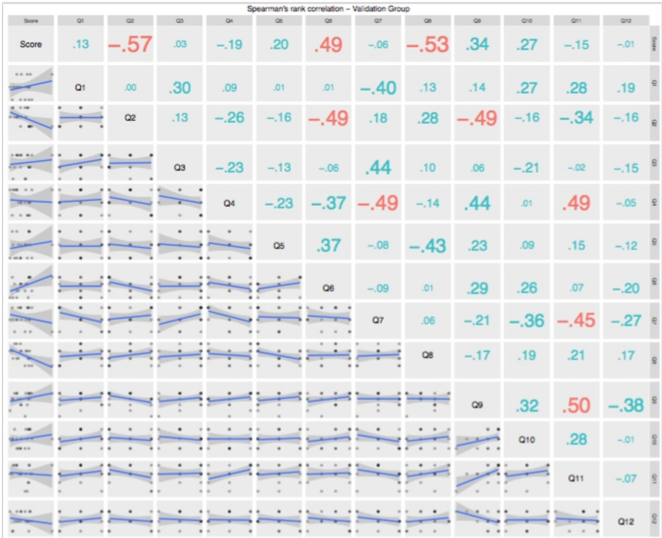

Figure 2. Spearman correlation for the Validation Group between score of each question (Q) of the face validation questionnaire and score of the questionnaire related to level of confidence in the use of videogames/virtual platforms (Score).

Conversely, in the referent group no significant correlation was found between score of the face validation questionnaire and score of the questionnaire concerning the use of videogames/virtual platforms **(Figure 3)**.

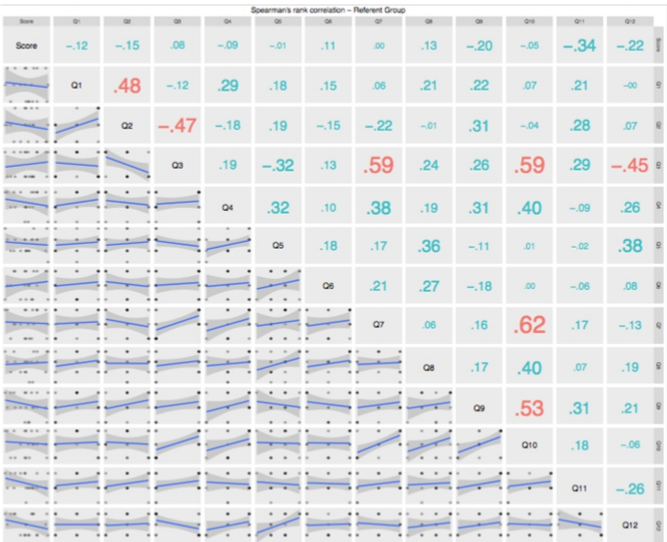

Figure 3. Spearman correlation for the Referent Group between score of each question (Q) of the face validation questionnaire and score of the questionnaire related to level of confidence in the use of videogames/virtual platforms (Score).

4. Discussion

The advent of new surgical methods and devices, such as endoscopic, laparoscopic and robotic surgery, caused the need for systematic skills training in an efficient and safe environment. In particular, researchers have shown that laparoscopic training not only improves the trainee's operative time, but also reduces the complication rate. Moreover, a recent randomized study demonstrated that a preoperative warm- up session improves the psychomotor performance and reduces the possible errors during laparoscopic surgery even in experienced lapa- roscopic surgeon.

There are several commercial laparoscopic traning systems. These devices are generally expensive, and not every centre can afford to incorporate them into their education curriculum. Besides these expensive training boxes/ simulators, some authors have developed themselves either low-cost laparoscopic simulators. This is also our centre experience. We have developed in the contex of our Advanced Simulation Centre a laparoscopic simulator prothotype, at the present time in the validation process period.

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.

We have started from the face validity is an important step of this process; it's 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.

Expert group and intermediate group agreeed 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 experts as acceptable: we consider this chataristic one of the most important element in this kind of virtual simulators. 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 our prothotype could be proposed to complete the validation process before its use in training program.

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