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ELVIS - Educational Laparoscopy with Virtual Instructive Simulations and robotics

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Abstract

Laparoscopic surgery is the standard approach for most surgical operations because of its benefits for the patients, although it requires a significant learning curve. For this reason, the FDA established the need for certified laparoscopic training programs, supported by validated surgical simulators. A multidisciplinary team of SMEs has submitted an ambitious project with the aim to develop a high-tech and low-cost multimodal simulator for laparoscopic surgery in order to ensure residents a proper training path. SMEs are working in close collaboration with the Department of Integrated Surgical and Diagnostic Sciences (DISC) from University of Genova, in order to have verified as relevant in clinical setting and training, the technical and functional requirement of the device, as well as for the validation stage, when it will be verified the ability of the device to distinguish between students, resident and experienced surgeon and to measure improvement in the learning curve.

Keywords: Surgical Simulator, Virtual Reality, Training, Validation, Risk management

1. Introduction

Minimally invasive surgery (MIS) is now a standard procedure for a multitude of clinical cases, since, compared to open surgery, it has objective advantages, especially related to the faster recovery of the patient and the reduction of the risk associated with the surgery. Examples can be reduced trauma of the abdominal wall and internal organs thanks to the use of small incisions and specific instrumentation, and less postoperative pain with a consequent faster recovery of physiological functions. The use of mechanical arms also has the advantage of allowing a three-dimensional view with a steadier image, and perform more delicate and precise maneuvers, also thanks to the distal articulation of the instruments.

The improvement obtained on the patient brings positive effects on the National Health System, in terms of reduction of hospitalizations and reduction of problems associated with complications, which can lead to further hospitalizations or chronicity.

Since these are still invasive techniques, in order to be able to fully exploit the reduction of the risk for the patient actually offered by technology, it is essential to set up an adequately innovative training course, which allows to combine the consolidated specialization path of the surgeon with activities with greater technological and application content.

In this context, the simulation finds its perfect application, as it allows the student or the resident to train maneuvers or procedures as per the clinical surgical protocol not directly on the patient, but in a safe and protected environment, where mistakes are allowed.

Over the past 20 years, the use of simulation techniques has increasingly become an integral part of surgical training. To confirm this, the American College of Surgeons has codified, starting from 2005, a network of accredited Education Institutes (ACS-AEI American College of Surgeons Accredited Education Institutes) with the specific peculiarity of teaching and training through simulation, promoting hence patient safety, identifying best practices and technologies, setting standards for training.

Simulation can be a standardized and safe method for training and assessing surgeons.

Thanks to advances in technology, today a wide variety of techniques can be simulated, taking advantage of the different models available (high / low fidelity and high / low technology) to cover a significant portion of the surgical procedures performed.

Although it is common knowledge that a simulated procedure is not a complete replacement of an intraoperative experience, without doubts it represents an important step in the current training of the surgical profession, which has as the primary goal the acquisition of skills and skill sets which, if optimized, lead to improved clinical outcomes and patient safety.

The ongoing project aims to develop a new prototype of a laparoscopic, high-fidelity and high-tech surgery simulator, exploiting what has already been experienced thanks to projects co-financed by the POR FESR in 2011 (Action 1.2.2) and in 2017 (Action 1.1 .3) in collaboration between Ligurian companies and the University of Genoa.

Two simulator prototypes are currently in use at the University Center for Simulation and Advanced Training of the University of Genoa (SimAv), but they have criticalities, also identified thanks to the feedback received from the medical world, which must be addressed in order to get to a configuration suitable for the market:

- the hardware structure is fragile and unable to withstand intensive use
- the position of the trocars allows to simulate only one type of intervention
- the user interface is not user friendly
- the data management architecture does not comply with the security requirements currently required by the regulations.

The project activities aimed at designing a prototype that addresses those criticalities, enrich by innovative tasks and can be the starting point for a product that can be placed on the market. The new tasks will therefore be:

- study of a human-device interface (MMI) for the development of a robotic system for laparoscopy
- the creation of a multi-platform system for the simulation of various operations in laparoscopy
- integration of the real time measurement of biometric parameters aimed at better monitoring performance, for a complete 360 ° training of learners.
- design, modeling and integration of 3D models for a modern and user-friendly interface
- redesign of the application code in order to build a modular, extensible, scalable, and integrable architecture with industrial communication framework, improving the simulation features of virtual reality
- integration with the learning portal with the score statistics on the exercises
- creation of a data set which, thanks to the use of Artificial Intelligence, will allow the identification of a personalized training path.

Aside from technological innovation, the project will address important topics related to methodological innovation, aimed at defining and outlining the methods of use of the device and performance evaluation, to validate not only the new technology, but also the effectiveness of the training course implemented.

The achievement of the ambitious project goals will be possible only thanks to a very close relationship and collaboration between the clinical world, research centers, companies and end users. Innovation will be created through mutual contamination, in which research and business are interdependent and mutually reinforce each other. Even the end-users, traditionally seen only as possible validators of the innovations produced, will have a much more active role and will be directly involved from the initial stages of the project, in defining the requirements.

Figure 1. Project overview

2. Consortium and project finance

The project Elvis - Educational Laparoscopy with Virtual Instructive Simulations and robotics was submitted under the POR FESR 2014-2020 call - Axis 1 - Action 1.2.4 and evaluated as first of the list of 13 projects approved by Filse (Finanziaria Ligure per lo Sviluppo Economico), the only one with full score (100/100), out of a total of 96 participating proposals.

The consortium is composed by 5 SMEs based in Liguria:

- EMAC srl (coordinator) - https://www.emac.it/
- Gruppo FOS spa - https://www.gruppofos.it/
- Nextage srl – https://nextage-on.com/
- Dema srl - https://www.demasassi.it/
- Mectrotech srl - https://www.mectrotech.com/

That had collaboration agreement with several research institutes:

- DISC - Department of Integrated Surgical and Diagnostic Sciences of University of Genova
- IIT – Italian Institute of Technology
- SimAv – Advanced Simulation Center at University of Genova
- DIME - Mechanical Engineering Department of University of Genova

In order to get to the final goal, activities are divided in 5 Work Packages:

- WP1 - Realization of the Innovative Prototype of Multimodal Simulator of Laparascopic Surgery and validation for traditional interventions
- WP2 - Prototype of robotic system for Laparoscopic Surgery to be interfaced with the Multimodal Simulator of Laparoscopic Surgery
- WP3 - Integration of the complete Multimodal Simulator Prototype and functional test
- WP4 - Clinical validation of the developed multimodal prototype based on quantitative and objective metrics
- WP5 - Coordination and dissemination of results

planned along the dedicated 18 months, as shown in Figure 2.

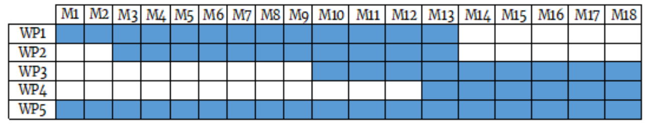

Figure 2. Project Gantt

Project submission has been done in July 2020, the ranking published in March 2021 and final approval was received on June 2021. As the consortium was eager to start, work begun immediately, with the target to conclude all the activities within 18 months, so by November 2022.

The total amount of the not-refundable grant is Euro 935,607.50, divided in industrial research (Euro 746,918.00) and experimental development activities (Euro 188,689.50), against a total amount of Euro 1,554,050.00.

3. Project goals

The project aims to innovate, improve and develop, for the future introduction on the market, a high-tech and low-cost multimodal laparoscopic surgery simulator, moving from an already existing prototype (eLaparo4D). The device will be updated by incorporating the feedback collected from the medical world and enriched by the addition of a human-device interface (MMI) for the development of a robotic system for laparoscopy, by the integration of biometric parameters for the monitoring of correlated stress and by an AI-based structure for identifying a personalized training path. The objective metric quantification of learners' performance allows the creation and feeding of a data set destined to grow, which, thanks to the use of Artificial Intelligence, will allow the identification of a personalized training path, optimizing the training outcome. and professional of the trainees.

The software architecture will be re-designed according to an innovative modularity and scalability paradigm in order to allow integration with several separate modules such as e-learning platform. The software redesign will also allow the introduction of a modern user interface and user-friendly and compliant with the principles of privacy and security by design.

An important aspect of the project task is the methodological innovation: the ambition is to outline the performance evaluation, that will validate not only the new technology, but also the effectiveness of the training course implemented.

The mission of the project is therefore to finalize a device that can then reach the market. Thanks to the work already done on available prototypes, in terms of technology development and validation process, the consortium will be able to focus on the re-design of technical and technological elements that will origin a competitive product, introducing elements of innovation and intervening both on design elements related to hardware and software, and on the development of the methodology.

4. Project status update

Consortium has almost reached the first year of work and at the current moment, the prototype is in the assembly phase and pre-integration test between hardware and software are ongoing.

4.1. Sensors, electronics and structure

To ensure a multi-surgery training, the following scheme has been identified and implemented:

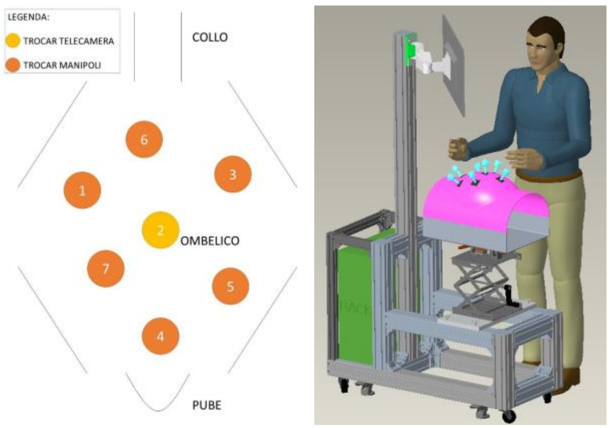

Figure 3. Mechanical design

Great attention has been used to reproduce the relative position between patient and surgeon, allowing all possible adjustments possible in the operating room (bed height and tilting, screen positioning).

To ensure usability, the system has been designed in a "all-in-one" solution, so that no special settings or installation are needed and the device can be easily moved.

The abdomen structure has a round shape, to reproduce the insufflation made for surgery needs. The realization was made with 3D printing and the application of a surface treatment is foreseen to makes the surface more similar to the skin to the touch.

The trocar is simulated by a ball joint and a small case applied to the surgical tool will provide the needed information to transfer its real position in the corresponding one in the virtual reality environment. The case includes batteries, so that the tool is completely wireless during the simulation, USB cable connection will be needed only to recharge batteries.

Figure 4. Sensorized surgical tool

4.2. Virtual reality for training

Four exercises with different difficulty level have been designed and implemented, with specific learning goal: the exercises allow the user to learn the basic skills the surgeon needs to master the handpieces and the camera before being able to practice laparoscopy, following a specific training course with different levels of difficulty to overcome:

1. learning the correct wide, narrow and fluid movements of depth and rotation of the camera in searching for a static target
2. learning the correct fluid movements of depth and rotation of the camera in pursuit of a moving target.
3. training of spatial depth perception on the 2D screen and synchronization e precision in the use of the two handpieces in reaching movements.
4. hand-eye coordination training in fine movements

Each exercise is characterized by three different levels (easy, intermediate and difficult), with increasing difficulty through the insertion of obstacles or obfuscation of the view on the target objects . At the end of each exercise, an evaluation score is assigned to the performance of the exercise which is saved by the system.

The first exercise has the learning goal of becoming familiar with the optics tool (camera) by applying large, fluid and deep movements to it. The user, starting from a panoramic point of view, must explore the field and identify the objects illuminated in turn by a red light approaching it until the light changes color to green.

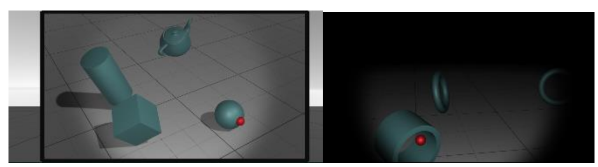

Figure 5. Exercise 1

The second exercise still involves the use of optics but with the intent of enhancing the ability to manage in tight spaces using sudden movements as well as begin to understand the effect of rotations on a 30° lens as occurs for laparoscopic cameras. The aim is to follow a target that randomly moves and "teleport" instantly to other points of a scenario (having more or less accentuated grooves depending on the difficulty).

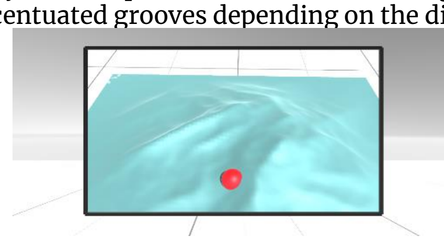

Figure 6. Exercise 2

These two exercises involve only the use of the camera.

The third exercise involves no longer the use of the camera, but of surgical tools and its learning goal is to train hand-eye coordination. The goal is to correctly touch a target object, at different depth, with one or more tools without colliding with the surrounding environment and without passing through the object.

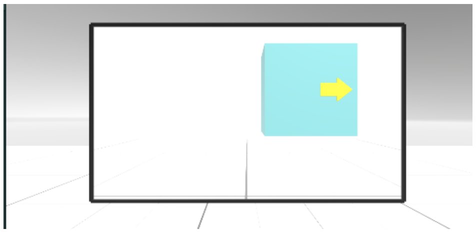

Figure 7. Exercise 3

The objective of the fourth exercise is to improve the combined use of two surgical tools in a scenario in which the user's task is to reach a sequence of marked blue and red targets with the tip of the instrument of the corresponding color. The targets are placed according to different levels of depth and height and the sequence criterion varies according to the level of difficulty in which you are.

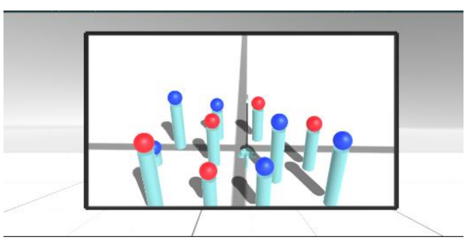

Figure 8. Exercise 4

5. Conclusion

The last Work Package of the project will be dedicated to prototype testing and validation performed through the construct and face validities.

The first important step will be to exclude the possible impact of videogame experience on ELVIS users.

The construct validity will be used to objectively assess the surgical value of basic skills by comparing the performances between two groups with different levels of laparoscopy experience. The presence of a learning curve will also be investigated by comparing the results of the first and second attempts.

Face validation will be performed using a specific questionnaire, administered only to experienced surgeons, investigating the realism and accuracy of the simulator.

The tests will be performed at SimAv – Advanced Simulation Center of Università degli Studi di Genova, on residents, collecting the data that will be structured and analyzed, to verify their ability to discriminate the level of training of the surgeon.

Figure 8. Prototype in testing at SimAv - UniGe

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