ECONOMIC ANALYSIS OF A LOW-COST LAPAROSCOPIC SIMULATOR: A DESCRIPTIVE STUDY

M. Frascio[a], M. Sguanci[b], F. Mandolfino[c], A. Testi[d], M. Parodi, G. Vercelli[e]

[a]DISC - Department of general surgery
[b]DISC - Department of general surgery
[c]DISC - Department of general surgery
[d]DIEM - Department of economics and quantitative methods
[e]DIBRIS – Department of Informatics, Bioengineering, Robotics and Systems Engineering

[a]mfrascio@unige.it, [b]marcosguanci@yahoo.it, [c]fcmandolfino@gmail.com [d] testi@economia.unige.it
[e]gianni.vercelli@unige.it

ABSTRACT

Simulation plays a basic role in medical education. At School of Medicine in Genoa a prototype of virtual reality simulator for videolaparoscopy is now in development phase. This simulation platform includes haptic interface for force feedback and autostereoscopic displays for glasses-free 3D rendering.
Aim of this study is to present the simulation as a training method in medicine for laparoscopic surgery. The analysis also studies the economic impact of a market-ready, low cost, multi-user virtual reality simulation platform engineered starting from prototype currently under development.
Videolaparoscopy application is analyzed. The investigation is based on 2011-2012 data obtained from queries to "Datawarehouse Sanitario" of Regione Liguria. Secondly, benefits provided by the introduction and use of prototype of a virtual reality simulation platform prospectively and quantitatively examined.
The processing relates the possible reduction in total length of hospital stay due to the introduction of prototype simulator and the consequent reduction of laparotomic cholecystectomies.

Keywords: training, skill, laparoscopic surgery, simulator, haptic feedback

1. BACKGROUND

Simulation plays a basic role in medical education. In Italy there are many "physical" simulators and few virtual reality simulators for videolaparoscopy training.
University of Genoa includes an Advance Simulation Center in which a virtual reality simulator prototype for videolaparoscopy is now in developing.
This prototype, eLaparo4D, has been designed as a simulation platform allowing an immersive training space for videolaparoscopic surgery. In particular elaparo4D is a low-cost training space which integrates haptic devices with realistic surgery tools and 3D rendering with physically deformable 3D CG models of the human internal organs.
The simulator is based on a client/server layered architecture in order to act as a sort of data gateway: the hardware is interfaced with the physics 3D engine to obtain real-time performances, with an HTML5-based 3D output visual interface in order to integrate the tracking of operating sessions within a custom training platform.

1.1 The literature review

Despite in Italy the spread is limited, evidences on the clinical and medical virtual reality simulators have been widely documented.
Some research has focused on basic laparoscopic techniques. A study carried out by "University of Michigan analyzed how training with virtual reality simulator (LapMentor) can improve the performance of organizing some general laparoscopic techniques.
Two groups of surgeons have performed a specific training for six basic laparoscopic procedures (exercises for the operation of the camera, the eye-hand coordination, for cutting and grasping, for suturing, for the "electrocautery and for moving objects). One group used the simulator, while the "other, control, has followed the training course provided for by "University. After each subject had reached the level of proficiency required, the two groups have carried out a series of exercises on anesthetized pig. Such exercises were then evaluated by two experts. For each type of exercise, the running time of the tests was significantly lower for the group that had carried out the training on the simulator. Similarly, the precision in the fulfillment of the procedures performed was superior for subjects using the simulator.
A similar study was done by Korean researchers. The authors used a simulator with haptic feedback to test the improvements in the training process both medical students without previous knowledge of both

Proceedings of the European Modeling and Simulation Symposium, 2013
978-88-97999-22-5; Bruzzone, Jimenez, Longo, Merkuryev Eds.

244

laparoscopic trainees with previous experience in minimally invasive surgery. The subjects performed five sessions of the simulator tests, spaced in time, in which four exercises performed laparoscopic technical base: grasping, cutting, clipping, suturing. For each test was evaluated the execution time and the level of accuracy through the measurement of some parameters. The study showed that the "use of the simulator allows rapid and significant improvements in the accuracy in the" execution of the tasks offered. Even the time spent in completing exercises decreases significantly in the progress of the sessions. In addition, the curves to improve performance and decrease the execution time are similar for both groups in question, although composed of individuals with different levels of knowledge laparoscopy.

Another study carried out by researchers in Sweden analyzed the "effect of" use of the simulator in "learning basic laparoscopic techniques considering the first 10 laparoscopic cholecystectomies performed by interns. Thirteen subjects were divided into two groups. The first group carried out the simulator training for six specific tasks at three levels of difficulty, until you reach the level of proficiency required to operate. The second group, the control, on the other hand reached the level of competence necessary to follow the training classic. For the study we used a simulator without haptic interface for force feedback (LapSim). Were then recorded and analyzed by groups of experts the first 10 laparoscopic cholecystectomies performed by each subject.

The group that has carried out the training to the simulator is the best result in a statistically significant manner, as regards the operating performance. The total number of errors committed during the operations analyzed turns out to be three times lower than the control group (figure 4).
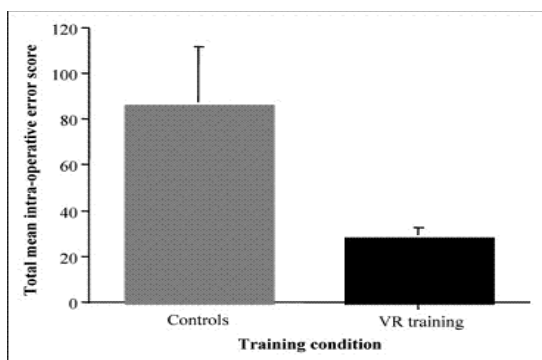

Figure 4: Number of errors in laparoscopic cholecystectomy

The surgical intervention has been divided into three distinct phases, and the ratio of the number of errors is maintained in each of these three parts. Furthermore, the total time of the "operation of the control group is greater than 58%, although this result was not considered significant from a statistical standpoint.

2. OBJECTIVE

The aim of analysis is to study the economic impact of a market-ready, low cost, multi-user virtual reality simulation platform engineered starting from prototype currently under development.

3. MATERIALS AND METHODS

3.1 The simulator system

The system is based on a nodejs 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).
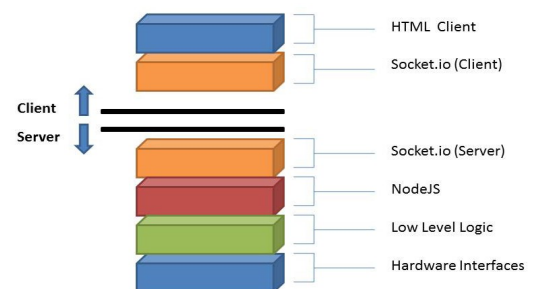

Figure 1: part of the system simulation

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

3.1.1 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, and then imported in Unity3D, including textures and UV

Proceedings of the European Modeling and Simulation Symposium, 2013
978-88-97999-22-5; Bruzzone, Jimenez, Longo, Merkuryev Eds.

245

maps. Eventually, in Unity3D render 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.
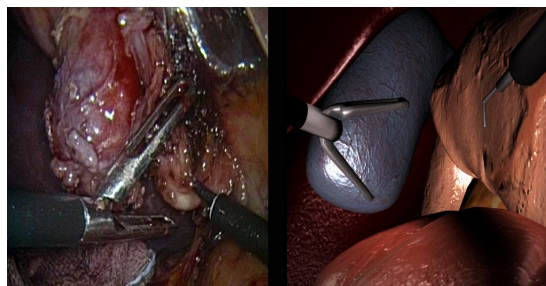

Figure 2: a screenshot from the current aspect of the virtual environment compared to a screenshot of the camera view of a real surgical operation.

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 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 (figure 3) is possible to see the 3 different collider layer for a gallbladder model.
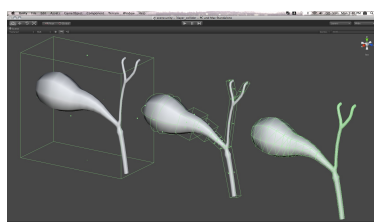

Figure 3: I.e of a collider layer for a gallbladder model

3.1.2 Feedback system

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

3.2 The statistical economic analysis

In general surgery there are Numerous kind of interventions which can be performed with laparoscopic access. For some types of these, such as cholecystectomy and plastic gastro-oesophageal reflux, the advantages of "laparoscopic approach are now defined and well-established, so that the laparoscopic technique represents the gold standard for the" execution. Other interventions via laparoscopic access is by way of affirmation but still require satisfactory clinical evidence, as in the case of "appendectomy. Other interventions are still quite complicated or require a learning curve quite wide, such as surgery of the colon and rectum, liver resections and pancreatectomy, such as to be carried out only in highly specialized centers.

An analysis of the DRG used in Italy, which classify each episode of hospitalization in homogeneous groups for absorption of resources involved, showing how a single operation, cholecystectomy, showing already divided at the level of DRG surgical approach employed.

Even a "cataloging analysis of surgical procedures by ICD-9 codes reveals that the" indication of "surgical approach used is present only for a very few interventions, and only in the case of" appendectomy clearly divides the "intervention depending on the technique used. The purpose of this study was examine the use of laparoscopic approach, and the benefits

Proceedings of the European Modeling and Simulation Symposium, 2013
978-88-97999-22-5; Bruzzone, Jimenez, Longo, Merkuryev Eds.

246

present and future, in relation to cholecystectomy.

This intervention was also one of the first interventions for which guidelines have explicitly defined as the "gold standard" laparoscopic procedure for all clinical cases that do not present obvious complications or severe comorbidities.

Firstly, the current Ligurian region (north-west of Italy) environment concerning videolaparoscopy applications was analyzed in order to understand the features of future market segment of such kind of simulator. The investigation is based on 2011 data and it refers to Ligurian hospitals cholecystectomy surgical operation. Laparoscopic approach application, presence of complications and comorbidities, average length of hospital stay and splitting of hospitalization cases for classes of severity data are shown.

Data are obtained from queries to a specific regional database called "Datawarehouse Sanitario".

The system allows an additional classification of interventions in clinical severity classes through the" use of APR – DRG.

The APR - DRG (All Patient Refined - DRG) are a classification system of "episode of hospitalization depending on the severity of the clinical condition of the patient, and allow you to review the role of the complications and comorbidities that is not fully central DRG classification . Every APR - DRG is divided into four classes that differentiate patients in relation to the complexity of care, the severity of the disease and the risk of death: the lower or absent, moderate, major, extreme. The attribution of the classes is realized through a specific software that processes data from the Hospital Discharge Data using a complex algorithm that takes into account mainly of secondary diagnoses present.

Are then extrapolated from the data warehouse, through the "use of filters in cascade, all data concerning the" cholecystectomy further divided into classes of severity. This prospective analysis is performed according to two different points of view:

- the division of the interventions by DRG
- the division of clinical interventions by classes of severity

For the purposes of processing it is assumed that, thanks to the introduction of the simulator, the percentage of interventions decrease (that are deemed inappropriate) depending of "surgical approach used in relation to the clinical conditions of the case.

4. RESULTS AND DISCUSSION

The economic analysis can demonstrate a reduction in total length of hospital stay due to the introduction of prototype simulator and the consequent reduction of

laparotomic cholecystectomies estimated as not appropriate.

In Italy, gallstones affects the rate varying from 10% to 20% of the population. Cholecystectomy is now a routine surgical operation, which presents a operative mortality low, about 0.1 to 0.05%.

Even morbidity, namely on lethal complications, is very modest. It's estimated that at the national level are carried out approximately 100,000 cholecystectomies every year, so Liguria, with the interventions of 2825 2011 therefore represents a portion percentage around 2-3%.

A regional level interventions are distributed in a more or less uniform among the various Health and hospital in Liguria. For what concerns instead the fees associated to the DRG relative to cholecystectomy, both to those adopted in 2009 by the Liguria Region, both for newer ones introduced in 2013 at national level, the main differences given to the presence of complications or comorbidities.

However, a level playing field clinics, the rate is higher for the laparoscopic approach. Laparoscopic surgery (compared to laparotomy) maybe at a higher cost of "intervention in itself, because of the" use of a "high-tech equipment and instrumentation.

The intervention as the case of hospitalization has a lower cost, mainly due to the significant reduction in hospital days post-op.

The cholecystectomies in Liguria are in most cases (73%) associated with the DRG 494, namely the intervention that does not present complications or comorbidities performed by laparoscopic approach.

In the remaining percentage the greater portion of the work is associated with the DRG 49 (18%).

Finally, smaller percentages are relative to the DRG 197.

The laparoscopic technique is now widely recognized for many years to internationally as the "gold standard approach for the cholecystectomy.

Thanks to the advantages that the approach laparoscopic approach attorney, fundamentally linked to the reduction of hospitalization, currently the laparoscopic access is indicated not only in healthy adult subjects, but also in children and the elderly.

About training, the result very good about the current use of laparoscopic access shows how the surgeons much sympathetic use this approach. In an learning optical, the starting point is already possess a relevant knowledge of such techniques that will allow cost savings of the training.

This advantage is not, however, currently, quantifiable.

The decision to intervene by laparoscopy allows a decrease in hospitalization average of approximately 7.5 days in the case of presence of complications and about 3.5 days in case of absence of complications.

In both cases, both in the presence that in the absence of complications and comorbidities, the corresponding average hospital stay in lower for the complete laparoscopic approach (45-46%) than the laparotomic one.

Proceedings of the European Modeling and Simulation Symposium, 2013
978-88-97999-22-5; Bruzzone, Jimenez, Longo, Merkuryev Eds.

247

The analysis for classes of severity with APR - DRG examines in more the specific situation from the point of view of the clinical condition of the case of hospitalization. The cholecystectomies are classified using the severity as parameter in minor (74%) and in moderate (21%).

Only the remaining 5% presents clinical conditions rather critical with greater severity if extreme. In general, the percentage of operations performed laparoscopically increases with decreasing the severity of the clinical case of hospitalization.

If compared to a reduction of inappropriate interventions and higher tariff are attending increase charges and appropriate interventions with lesser rate, would produce a savings from the Region for the remuneration of interventions cholecystectomy.

In this case, the savings could range from 14,754 € due to the change of only 6 interventions inappropriate in the corresponding appropriate, until you get to € 322,129 for the ideal situation for which all 131 inappropriate interventions are carried out by laparoscopy. The parallel processing done with classes of severity APR – DRG showed similarly positive results. In this case are considered a inappropriate interventions classified with severity moderate or minor were performed by laparotomic procedure.

The prospective study has suggested the decrease of this type of interventions.

Unlike the previous processing, in this case, equal to percentage decrease the reduction of hospital days is greater. For a reduction of 57 interventions (-2% of the total) approached by laparotomy instead laparoscopic in the absence of complications (about 27% of the interventions considered inappropriate in this process), the decrease of total hospital stay expressed in number of days was 301. The theoretical ideal situation, for which the number of interventions considered inappropriate in this analysis were reduced to zero, would result in the reduction of 1,136 days of hospitalization at regional level.

The prospective analysis on the benefits of the introduction of the simulator in Liguria suggests a possible intervention on the inappropriateness of some types of cholecystectomies.

The premise of the clinical analysis, instead, it's based on evidence, demonstrated by numerous scientific articles where the use of the simulators for learning laparoscopic techniques improves performance and efficiency of surgeons.

In Liguria the introduction of virtual reality simulator for videolaparoscopy, equipped with a highly technology reproducing a totally realistic scenario, and its use as a support for the learning in curricular path or as exercise device for surgeons, would lead to a greater use of laparoscopic approach instead of laparotomic. The surgeons, as demonstrated by several studies, would show in safer to undertake the decision to perform the surgery using the minimally invasive procedure.

In this sense would be decreased interventions carried out by laparotomy that are achieved despite the absence of complications and comorbidities or presence of a condition with low clinical severity, or most would follow the indications given by the guide lines.

From the point of view of cost savings, the benefits would be for both the Region (in the case would use the new rates for DRG-2013) for what regarding the remuneration of performance, both for the individual hospital that would reduce its cost of production for a single admission since the days of hospitalization would be much lower.

The laparoscopic simulator could include a system of evaluation of surgeons. If the high degree of realism were verified and approved, you would have a tool with which it would be possible to check in a objective skills of those who work.

It could, for example, evaluate the improvements made during the learning curve, or verify through periodic testing the degree of knowledge of the techniques of those who already work routinely. The possibilities, of course, from this point of view are innumerable. The simulator then it could also be implemented at the level technology in order to simulate operations "tailored".

Using radiological data, you could virtually recreate the endo abdomial anatomy of the patient who will be operated.

In this way the whole operation that will be carried out could be simulated, addressing and resolving any difficulties and problems in a completely safe ambient.

ACKNOWLEDGMENTS

REFERENCES

Ahlberg G, Enochsson L, Gallagher A G, Hedman L, Hogman C, et al. 2007. Proficiency-based virtual reality training significantly reduces the error rate for residents during their first 10 laparoscopic cholecystectomies. *The American Journal of Surgery,* June; (193)6: 797-804

Andreatta P B, Woodrum D T, Birkmeyer J D, Yellamanchilli R K, Doherty G M, Gauger P G, Minter R M. 2006. Laparoscopic Skills Are Improved With LapMentor™ Training. *Annals of Surgery*, June; (6)243: 854–863

Attinà G, Rulli F, Galatà G, Ridolfi C, Tucci G, Grande M. 2007. Appendicectomia laparoscopica vs tecnica tradizionale: rapporto costi-benefici. *Congresso Società Italiana di Chirurgia,* 109 Verona

Derossis AM, Fried GM, Abrahamowicz M, Sigman HH, Barkun JS, Meakins JL. 1998.

Proceedings of the European Modeling and Simulation Symposium, 2013
978-88-97999-22-5; Bruzzone, Jimenez, Longo, Merkuryev Eds.

248

Development of a model for training and evaluation of laparoscopic skills. *American Journal of Surgery,* 175(6):482–487

Dhariwal K, Prabhu R Y, Dalvi A N, Supe A N. 2007. Effectiveness of box trainers in laparoscopic training. *Journal of Minimal Access Surgery*, Apr-Jun; (3)2: 57-63

Kim T H, Ha J M, Cho J W, You Y C, Sung G T. 2010. Assessment of the Laparoscopic Training Validity of a Virtual Reality Simulator (LAP Mentor™). *Korean Journal of Urology*, Nov; (11)51: 807

Köhler L.1999. Endoscopic surgery: what has passed the test? *World Journal of Surgery*, Aug;23(8):816-24.

Lamata P, Gomez E J, Sanchez-Margallo F M, Lamata F, Antolin M, Rodriguez S, Oltra A, Uson J. 2005. Study of Laparoscopic forces perception for defining simulation fidelity *Studies in Health Technology and Informatics*, (119): 288-292

Nuzzo G, Giuliante F, Murazio M. 2008. Complicanze biliari della colecistectomia: la gestione della fase acuta delle lesioni iatrogene della via biliare principale. *Ospedali d'Italia Chirurgia*, 14:126-136

Paige J T, Kozmenko V, Yang T, Paragi Gururaja R, Hilton C W, Cohn I, Chauvin S W. 2009. High-fidelity, simulation-based, interdisciplinary operating room team training at the point of care *Surgery*, Feb; (2)145: 138-146

Zendejas B, Wang A T , Brydges R, Hamstra S J, Cook D A, 2013. Cost: The missing outcome in simulation-based medical ed ucation research: A systematic review. *Surgery*, Feb; (2)153: 160-76.

Proceedings of the European Modeling and Simulation Symposium, 2013
978-88-97999-22-5; Bruzzone, Jimenez, Longo, Merkuryev Eds.

249