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## Is In-Vivo laparoscopic simulation learning a step forward in the Undergraduate Surgical Education?



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### HIGHLIGHTS

- Low-fidelity laparoscopic simulation model is an equal alternative at the early undergraduate training.
- No statistically significant difference was noted in the scores among different gender, year of study, school and handedness of students.
- There was no statistically significant difference in the scores among different gender, year of study, school and handedness groups.

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### ABSTRACT

**Background:** Essentials Skills in the Management of Surgical Cases – ESMSC is an International Combined Applied Surgical Science and Wet Lab course addressed at the Undergraduate level. Laparoscopic Skills is a fundamental element of Surgical Education and various Simulation-Based Learning (SBL) models have been endorsed. This study aims to explore if there is any significant difference in delegates' performance depending on whether they completed In Vivo module prior to the equivalent in the laparoscopic simulator.

**Materials and methods:** 37 Medical Students from various EU countries were divided in 2 groups, and both completed the "Fundamentals in Laparoscopic Surgery" module in the Dry-lab Laparoscopic Simulator as well as the same module "In Vivo" on a swine model. Group A (18 students, 48.6%) completed the "Fundamentals in Laparoscopic Surgery - FLS" module prior to the "In Vivo", whereas group B completed the "In Vivo" module first. Direct Observation of Procedural Skills (DOPS) were used to assess delegates' performance.

**Results:** The mean DOPS scores for the "FLS" and "In Vivo" models were  $2.27 \pm 0.902$  and  $2.03 \pm 0.833$ , respectively, and the delegates' performance was not statistically significantly different between them ( $p = 0.128$ ). There was no statistically significant difference in the scores among different gender, year of study, school and handedness groups. The alteration in the sequence between Dry-lab "FLS" and "In Vivo" modules did not affect the performance in neither the "FLS" nor the "In Vivo" models.

**Conclusions:** The inexpensive, but low-fidelity "FLS" model could serve an equal alternative Simulation-Based Learning model for the early undergraduate training. Our study demonstrated that high fidelity

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In Vivo simulation for laparoscopic skills does not affect significantly the improvement in the delegates' performance at the undergraduate level. Further studies should be conducted to identify at which stage of training should high fidelity simulation be introduced.

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## 1. Introduction

Undergraduate Surgical Education shifts towards the early involvement of students in simulation skills-based learning in order to achieve a more efficient and safe generation of future surgeons [1,2]. Simulation-based learning has been proven to improve future surgeons' skills, and also protects patients' safety, as all procedures are performed in a safe environment [3]. Moreover, the progress in technology and its implementation in surgery have widened the range of new surgical techniques, methods and tools that the competent new surgeon has to be well familiar with. The rising question is how we can train many medical students in all these new surgical techniques, overcoming the challenge of steep learning curves and, simultaneously assuring patients' safety [4–6].

Technology has opened new horizons in SBL, via the introduction of a huge variety of facilities that promote safe, cheap and effective learning [7–9]. SBL in surgical training is traditionally divided into “dry” and “wet” lab types. Wet-lab type refers to the use of animal-model materials, and can be further divided into “In Vivo” models, which employ anaesthetized, living animals, and “Ex Vivo” models, which use animal tissues [8,10]. On the contrary, dry lab modules only use synthetic materials and technological equipment [11]. The setting of the environment is defined also by its fidelity level, with a range from low- to high-fidelity modules [12].

Essential Skills in the Management of Surgical Cases—ESMSC, is an international course which combines high fidelity in vivo simulation with traditional ex vivo and dry lab modules, aimed primarily at the undergraduate level [13]. ESMSC curriculum has been extensively discussed in previous study [10], and students from all participating countries seem to consider it as a potential part of the Medical School curriculum. As part of the revised ESMSC Ci4R (4 cores integrated for Research) curriculum, laparoscopic skills stations were introduced to cover the relevant skills.

The aim of this study was to explore if there is any significant difference in delegates' performance depending on whether they completed In Vivo module prior to the equivalent in the laparoscopic simulator.

## 2. Material and methods

### 2.1. The ESMSC concept

The ESMSC concept has been discussed extensively in a previous study [10]. In a nutshell, the latest curriculum involves a mix of interactive applied surgical science lectures, with basic science workshops and skills-based learning. The latter involves a combination of low fidelity ex vivo wet lab modules of various difficulty with other dry lab stations which form altogether a 2-level difficulty SBL curriculum. The third part of these skills consist of high-fidelity in vivo open and laparoscopic skills which are paired with ex vivo or dry lab equivalent i.e. diagnostic and operative laparoscopy or open dissection skills.

37 undergraduate students [Male = 22 (59.5%)] from the UK (King's College London, Imperial College London, Leeds Medical School etc.) and other countries of the EU, as well as from American

University of Beirut (AUB) attended a single series of the course. In the UK, medical school course last for 5 years and Year 3–5 students, are on clinical rotation. In contrary, in Greece and other EU countries clinical rotation Years start from the 4th–6th Year. Therefore, based on each curriculum, we assured equality in terms of level of clinical knowledge was assured between the groups, by recruiting students, whose background covers first-third clinical rotation Year knowledge. Delegates submit their application through a portal ([esmsc.gr](http://esmsc.gr)) and the selection is based on CV criteria. The application process in led by 2 consultant-level Academics who score the statements and the actual CV performance. All applicants should be proficient in English and hold an interest for pursuing a career in Surgery. In this study, we compared the training outcome of a classic low-fidelity laparoscopic simulator (dry lab) with a similar module performed in vivo on a swine model.

Both modules contain of similar difficulty modules, and students were assigned either on the Fundamentals in Laparoscopic Surgery - FLS dry-lab simulator first (Group A, N = 18) or the actual In-Vivo set laparoscopic skills station (Group B, N = 19). The basis of the assignment to either group A or B was to assure equality between the groups. Demographics and more specifically in the gender ( $p = 0.325$ ), year of studies ( $p = 0.699$ ), handedness ( $p = 0.580$ ) and school ( $p = 0.858$ ) was compared between groups in order to ascertain equality was achieved.

With regards to the size of the sample, this was pre fixed to 37. It is true that, ESMSC is a really expensive, complex and demanding course to run, and the actual lab (ELPEN Research Lab) can accommodate up to 40 students maximum. This would be the upper limit in order for the course to run safely and efficiently.

Both groups complete the same modules. FLS station consists of a plain laparoscopy to assess orientation in space, depth perception movements and grasping of small elements, haptic feedback whilst “untying” a chocolate cover, and fitting an elastic band across 2 metal columns. In-Vivo laparoscopy station contains an initial laparoscopy to identify common anatomic features, tissue manipulation (bowel), mobilization of bowel plain as well as identification of an existing mucosal bowel injury. The pig was anaesthetized according to standard operational procedures of the local lab and an experienced veterinarian was next to the animal to maintain viability of the experiment.

Performance of the participants was objectively assessed using Direct Observation of Procedural Skills (DOPS) forms, which are validated by the ISCP [14–24]. Two instructors served as assessors in each one of the “FLS” and “In Vivo” modules to maintain integrity and minimize inter-observers-bias. The assessors, did not know whether each group had performed the FLS or the In-Vivo Station first and this was documented by a third administrating person in the end of each rotation. DOPS form are attached in [Appendix I](#), and primarily comprised of 5 domains, each one of which had to be marked with “N” (Not observed or not appropriate), “D” (Development required) or “S” (Satisfactory). These 5 domains focused on instrument use, tissue handling/respect the tissue, time/speed, confidence and dexterity. The DOPS form contained also one more element, the “Global Summary” scale, which reflected the overall performance of the trainee, and was measured in a 5-point Likert-scale (“0” standing for insufficient evidence observed to support a

summary judgment” to “4” for competent to perform the procedure unsupervised and could deal with any complications that arose).

## 2.2. Statistical analysis

Statistical analysis was conducted using the SPSS version 20.0 (IBM Corp., Armonk, NY, USA). Cronbach's alpha was measured to test the reliability of the data.

Performance of delegates was compared between “FLS” and “In Vivo” modules using with the Related Samples - Wilcoxon Signed Rank test as well as Pearson chi-square correlations. Subgroup comparisons among different Gender, Universities and Handedness was performed using Mann-Whitney *U* test. Kruskal-Wallis test was used to detect differences in “Global Summary” score among the different years of study.

## 2.3. Ethics

All the research is in accordance with the Ethical Principles for Medical Research Involving Human Subjects (Declaration of Helsinki) and the European and National Legislation, Directive 63/2010, PD 56/April 2013.

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## 3. Results

$N = 20$  (54.1%) of the students were Year 4,  $N = 10$  (27%) Year 5 and  $N = 7$  Year 6 (18.9%).  $N = 17$  (45.9%) of the students came from a medical school in Greece, where the rest had a European University except for Greece as an origin. The majority of the trainees,  $N = 34$  (91.9%) were right-handed.

Cronbach's alpha was 0.819 for the total of the 37 trainees and 0.806 and 0.839 for the A- and B- subgroups, respectively, and was interpreted as accepted ( $>0.8$ ). The “FLS” D1-D5 scores are summarized in Table 1. There was no statistically significant difference in the D1-D5 scores between “FLS” and “In Vivo” modules, except for the D3 (Tissue handling/respect the tissue) and the D5 (Confidence and dexterity), which demonstrated superior results for the “FLS” procedure. The “Global Summary” score for the “FLS” module was  $2.27 \pm 0.902$ , whilst for the “In Vivo” module was  $2.03 \pm 0.833$ . However, no statistically significant difference was demonstrated, when comparing them ( $p = 0.128$ ). (Table 1).

The subgroup analysis failed to show any statistically significant difference in the “FLS” and “In Vivo” Global Summary score, when comparing male vs. female, different University-based performance, as well as dominant handedness. Nevertheless, Year 6 students were found to influence only the “In Vivo” Global Summary score, scoring higher than Year 4 students ( $p = 0.016$ , mean difference = 1.057, CI: 0.379, 1.735), while there was no difference when comparing Year 4 vs. 5 students ( $p = 0.746$ ) or Year 5 vs. Year 6 students ( $p = 0.055$ ). (Table 2).

There was no significant difference between A- and B- groups, in most of the DOPS scores, and specifically in the D1, D2, D3, D5 and Global Summary scores. While the D4 was not found to be affected by the group in the FLS procedure ( $p = 0.655$ ), the D4 – In Vivo score in the B-group was a significantly higher ( $p = 0.046$ ) than the one in the A-group. (Table 3).

## 4. Discussion

FLS in dry-lab simulation is a well-established training tool in laparoscopic surgery with widely acknowledged educational benefits [9,25,26]. Both “FLS” and various equivalent “In Vivo” models have been widely used, as training models in the literature [27–31].

Systematic training with FLS models and, even with more economical improvised FLS surrogates, was found to shorten the time needed to gain proficiency in some techniques [27,28]. The literature suggests that low-fidelity FLS-like models can prepare the trainee for other more expensive, high-fidelity, “wet-lab” modules, reducing the time and funds required for to train the future generation of surgeons [12].

Our results suggest that, there is no statistically significant difference when comparing FLS students' performance to high-fidelity in-vivo simulation equivalent. The only two scores significantly higher in the “FLS” setting, were in the section of confidence and dexterity, as well as in the tissue handling. The lower confidence and dexterity score demonstrated in the “In Vivo” may be associated with the increased anxiety, as delegates were not used to live tissue handling [32]. The subgroups of different genders, years of studies, schools and handedness did not show different “Global Summary” scores. The only significant difference observed was between the 6th and the 4th year students in the “In Vivo” module, but not in the “FLS”. This could potentially reflect the fact that final year students, may had already been exposed to similar training in the past, and hence an improved performance could be justified [33,34].

Nevertheless, the most important aspect of our study is the comparison between Group A- and B-performance. Trainees of the A-group, which did the “FLS” module prior to the “In Vivo”, were not found to have a significantly different performance in both “FLS” and “In Vivo” scores, compared to the B-group, which did the “In Vivo” prior to the “FLS”. This finding is of great interest when considering the potentially higher cost of In-Vivo setting, especially for the Undergraduate level. Indeed, the “In Vivo” setting offers high-fidelity simulation, as the trainees apply the surgical procedures directly to a live tissue. However, it is an extremely expensive setting that cannot easily be offered repeatedly to a wide number of students. On the other hand, the “FLS” setting may be of low-fidelity, but it is relatively inexpensive, and as proven equally effective [12,28,35]. Dry-lab simulation is easily reproducible, can be applied to a wider audience with no restrictions, and ethics-wise it does not require any preparation. As shown in the literature, it can improve students' performance and it is provided in the vast majority of curricula. On the other hand, high-fidelity simulation has been successfully used in higher postgraduate training, where detailed and meticulous teaching is required to achieve the standards of a highly-demanding learning curve. Modern surgical training required SBL to prepare students for being future surgeons.

Our study concludes that there is no difference on the actual performance, in other words In-Vivo simulation does not expedite more the laparoscopic skills learning. Although this may be true, however, we cannot deny the fact that mentorship and inspiration are primary values of surgical training, and therefore students should be motivated with a “taste” of high quality teaching. When evaluating the educational environment of “ESMSC” [36], we demonstrated that students tend to burn out during their studies and motivation is decreased throughout the passage of time. Hence, although In-Vivo simulation may not affect directly students' performance, however it may act as a “placebo” motivating factor towards better concentration and inspiration for future learning. Also, when combined with dry lab simulation, there may be the “synergy” effect, which means a much better result than In-Vivo or “dry lab” simulation on their own. Thus, the combination of a mixed “FLS” and “In Vivo” training model could be so effective, but more economical than the high-fidelity “In Vivo” model alone.

In our previous study [13], we concluded to similar results for the use of In Vivo simulation in open-dissection skills. Both “Dry-Lab” and “In Vivo” models require a long and copious learning curve until the trainees acquire proficiency in the skill.

**Table 1**

DOPS scores for the “FLS” and “In Vivo” modules.

DOPS domains	Interpretation of the results	Modules		p-value
		FLS	In Vivo	
D1	N/D/S	14/16/7	5/24/8	0.450
D2		1/21/15	4/22/11	0.082
D3		0/9/28	9/20/8	<0.05
D4		3/15/19	4/2/11	0.165
D5		2/17/18	28/4/5	<0.05
Global Summary	mean ± SD	2.27 ± 0.902	2.03 ± 0.833	0.128

Note: DOPS - Direct Observation of Procedural Skills, SD – Standard deviation, D1 - Instrument use, D2 - Suturing Skill, D3 - Tissue handling/respect the tissue, D4 - Time/speed, D5 - Confidence and dexterity, N - Not observed or not appropriate, D - Development required, S - Satisfactory (no prompting or intervention required), FLS – Fundamentals of Laparoscopic Surgery.

**Table 2**

Demographic characteristics and Global Summary score among different groups.

Different subgroups	N (%)	Different modules			
		FLS		In Vivo	
		Mean	SD	Mean	SD
Gender					
Male	22 (59.5%)	2.18	.853	2.14	.889
Female	15 (40.5%)	2.4	.986	1.87	.743
p-value		0.491		0.453	
Year of studies					
4th	20 (54.1%)	2.1	0.788	1.8	.696
5th	10 (27%)	2.7	.949	1.9	.738
6th	7 (18.9%)	2.14	1.07	2.86	.9
p-value		0.203		0.031	
School					
GR	17 (45.9%)	2.29	.985	2.24	.831
Non-GR	20 (54.1%)	2.25	.851	1.85	.813
p-value		0.892		0.232	
Handedness					
Right-handed	34 (91.9%)	2.29	.906	2.03	.834
Left-handed	3 (8.1%)	2	1	2	1
p-value		0.693		1.000	
Total	37 (100%)	2.27	.902	2.03	.833

Note. SD – Standard deviation, N(%) – Number of subjects and their % proportion, FLS – Fundamentals of Laparoscopic Surgery, GR – Schools from Greece, Non-GR – Schools from the European Union except Greece.

**Table 3**

Analysis of the DOPS scores for the two groups (A- and B-) of the seminar.

DOPS domains	Module	Groups		p-value
		A-group	B-group	
D1 (N/D/S, mean ± SD)	FLS	6/9/3	8/7/4	0.722
	In Vivo	4/11/3	5/9/5	0.675
D2 (N/D/S, mean ± SD)	FLS	0/12/6	1/9/9	0.367
	In Vivo	1/13/4	4/11/4	0.379
D3 (N/D/S, mean ± SD)	FLS	0/4/14	0/5/14	0.772
	In Vivo	1/11/6	3/11/5	0.587
D4 (N/D/S, mean ± SD)	FLS	2/8/8	1/7/11	0.655
	In Vivo	3/13/2	1/9/9	0.046
D5 (N/D/S, mean ± SD)	FLS	1/7/10	1/10/8	0.696
	In Vivo	14/2/2	14/2/3	0.917
Global Summary (mean ± SD)	FLS	2.17 ± 0.924	2.37 ± 0.895	0.480
	In Vivo	2.22 ± 0.732	1.84 ± 0.898	0.150

Note: DOPS - Direct Observation of Procedural Skills, SD – Standard deviation, D1 - Instrument use, D2 - Suturing Skill, D3 - Tissue handling/respect the tissue, D4 - Time/speed, D5 - Confidence and dexterity, N - Not observed or not appropriate, D - Development required, S - Satisfactory (no prompting or intervention required), FLS – Fundamentals of Laparoscopic Surgery, A-group – Trainees who did “FLS” prior to “In Vivo”, B-group – Trainees who did “In Vivo” prior to “FLS”.

However, we recognize some limitations for this study. The statistical results have to be strengthened with a bigger sample of trainees and the effect of both the “FLS” and “In Vivo” models to be

measured for a long-term period. Moreover, the sample of trainees used, is a pilot sample of undergraduate students the performance of whom might differ significantly from a sample of post-graduate trainees. These results, derived from a short-term evaluation, and long-term evaluation should be essential to optimize the combination of dry lab and in-vivo simulation.

## 5. Conclusions

In-Vivo High Fidelity Simulation seems to be an equally effective model with Dry-lab Simulation, which is widely used and accepted, cheaper form of training in the undergraduate level. Future research should focus on the optimal combination of in-vivo and dry lab simulation in order to maximize their “synergy” effect and promote inspiration at the earlier stage. A united approach to incorporate a structured multi-modal SBL will result in more effective and motivational learning towards a surgical career in the future.

## Ethical approval

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## Authors contribution

Main Contribution: MS and PP are equal main contributors who drafted the manuscript and analyzed the data. GT, GKZ, PT, TA, and AP conceived the study, and acted as senior authors, editing and providing feedback on the manuscript. EMG, NS, IT are medical students who contributed to the ESMSC set-up and helped in the data analysis and presentation. All authors approved the submitted version of the manuscript. GS and NP contributed to the conduction of the experiments as they hold expertise in animal model research.

## Conflict of interest

None.

## Guarantor

Michail Sideris, Panteleimon Pantelidis, Apostolos Papalois.

## Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.amsu.2017.01.025>.

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