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DEVELOPPEMENT D'UNE FORMATION EN PARCOURS DE SOIN SIMULE EN CHIRURGIE COLORECTALE LAPAROSCOPIQUE

Pour obtenir le grade de DOCTORAT D'AIX-MARSEILLE UNIVERSITÉ
Spécialité : Pathologie Humaine - Santé Publique et Recherche Clinique

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RESUME

Rationnel : L'intérêt d'un entrainement hors du bloc opératoire a été démontré pour les compétences techniques basiques. La simulation en chirurgie colorectale laparoscopique (CCL) a jusqu'à présent été peu évaluée : l'accès à ces procédures est limité pour les internes et un tel entrainement pourrait réduire leur courbe d'apprentissage. Par ailleurs, les compétences périopératoires des chirurgiens ont un impact démontré sur les suites opératoires, et jusqu'à présent aucune étude n'a évalué la simulation sous l'angle d'un parcours de soin.

Objectifs : Etudier et développer une formation en parcours de soin simulé (FPSS) en CCL en faisant intervenir des patients virtuels (Second Life™) en périopératoire et un programme d'entrainement virtuel (PEV) sur simulateur en peropératoire. Déterminer si une telle formation améliore la prise en charge des malades, en particulier en terme de respect des objectifs réhabilitation précoce (ORP), ainsi que la participation des internes au bloc opératoire en CCL.

Méthodes : Lors d'un travail préliminaire, nous avons développé une FPPS pour une pathologie basique : l'appendicite aiguë. Nous avons testé la faisabilité de mise en place d'une telle FPSS auprès de l'ensemble des internes d'un service de chirurgie digestive, et évalué prospectivement son impact sur la prise en charge de 38 patients consécutifs admis pour appendicectomie avant (n = 21) et après (n = 17) la FPSS **(Etude 1)**. Nous avons ensuite développé une FPPS en CCL, en créant des patients virtuels dont la prise en charge respectait les recommandations de chirurgie colorectale et de RP, et en validant un PEV en CCL. Nous avons enfin évalué l'impact de cette FPPS, mis en place auprès de l'ensemble des internes d'un service, sur le respect des ORP et la participation des internes en CCL auprès de 20 patients « réels » consécutifs, inclus prospectivement avant (n=10) et après (n=10) la formation **(Etude 2)**.

Résultats : Etude 1 : La FPSS a pu être réalisée pour l'ensemble des internes. Les données pré- et peropératoires des patients étaient comparables entre les groupes pré- et post-FPSS. Les délais de réalimentation liquide et solide étaient significativement réduits dans le groupe post-FPSS (7 heures (2-20) *vs.* 4 (4-6); *P* = 0.004, et 17 heures (4-48) *vs.* 6 (4-24); *P* = 0.005) sans modifier la morbidité postopératoire (4 (19%) *vs.* 0 (0); *P* = 0.11) ni la durée d'hospitalisation (48 heures (30-264) *vs.* 44 (21-145); *P* = 0.22). **Etude 2 :** La participation des internes comme opérateur en CCL a significativement augmenté après formation (0% (0-100) *vs.* 82.5% (10-100); *P* = 0.006). Les données pré- et peropératoires des patients étaient comparables entre les groupes pré- et post-FPSS. Le respect des ORP était meilleur à J2 dans le groupe post-FPSS (3 (30%) *vs.* 8 (80%); *P* = 0.035). La morbidité postopératoire était également inchangée, avec une diminution de la morbidité majeure à la limite de la significativité (5 (50%) *vs.* 1 (10%); *P* = 0.07). La durée d'hospitalisation n'était pas modifiée (228 (96-624) *vs.* 156 (120-720); *P* = 0.74).

Conclusion : Une FPSS en CCL a été développée. La mise en place d'une telle formation a démontré sa faisabilité en service de chirurgie. Elle a permis d'améliorer le respect des ORP. Elle a aussi augmenté la participation des internes comme opérateur sans altérer les suites opératoires des patients. Des études futures pourraient appliquer cette FPSS à d'autres procédures chirurgicales complexes, à de nouvelles approches chirurgicales (robotique, mono-trocart), voire à des disciplines interventionnelles non chirurgicales.

ABSTRACT

Summary Background data: Training out of the operating room (OR) has proven its positive impact on basic skills. Few studies have assessed simulation in laparoscopic colorectal surgery (LCS) so far : such training could reduce learning curves and provide safe implementation during real operations in the OR for junior surgeons who have limited access to these procedures as a primary operator. Moreover, perioperative non-technical skills have demonstrated some impact on patients' outcomes, and no studies have assessed simulation in a care pathway approach (CPA) manner.

Objectives: To design a CPA to training in LCS, involving virtual patients (VP) on Second Life™ for pre- et postoperative training, and a virtual competency-based curriculum on a simulator for intraoperative training. To implement such CPA, and to look whether such training may improve patients' management in terms of compliance for enhanced recovery programs (ERP), and residents' participation in LCS in the OR.

Methods: In a preliminary study, a CPA to training in a common disease requiring basic skills was designed and implemented: acute appendicitis. All junior residents of our department were trained in CPA. Thirty-eight patients undergoing appendectomy were prospectively included before (n=21) and after (n=17) the training **(Study 1)**. Then, we deigned a CPA to training in LCS: VP were designed in accordance with LCS and ERP recommendations, and a curriculum in LCS was validated on a virtual reality simulator. We finally implemented this CPA: all senior residents of our department were trained, and 20 consecutive patients undergoing colorectal surgery were prospectively included before (n = 10) and after (n = 10) CPA. Residents' participation in LCS was measured as the percentage of time during which they were primary operator **(Study 2)**.

Results: Study 1: All junior residents were trained. Pre- and intraoperative data were comparable between pre-training and post-training patients. Times to liquid and solid diet were significantly reduced after training (7 hours (2-20) *vs.* 4 (4-6); *P*=0.004, and 17 hours (4-48) *vs.* 6 (4-24); *P*=0.005) without changing postoperative morbidity (4 (19%) *vs.* 0 (0); *P*=0.11) and length of stay (48 hours (30-264) *vs.* 44 (21-145); *P*=0.22). **Study 2 :** Residents' participation in LCS significantly improved after the training (0% (0-100) *vs.* 82.5% (10-100); *P* = 0.006). Pre- and intraoperative data were comparable between pre-training and post-training patients. Compliance for ERP improved at day 2 in post-training patients (3 (30%) *vs.* 8 (80%); *P* = 0.035). Postoperative morbidity was comparable, with a trend to less major morbidity (5 (50%) *vs.* 1 (10%); *P* = 0.07). Length of stay was not modified (9,5 days (4-26) vs. 6,5 (5-30); *P* = 0.74).

Conclusion: A CPA to training in LCS has been designed and implemented. It improved compliance for ERP and residents' participation as primary operator without adversely altering patients' outcomes. Forthcoming studies should assess FPSS in other fields of advanced surgery, new techniques (robotics, single-port surgery), or non-surgical procedures.

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VT = video trainer; VR = virtual reality simulator; AR = Augmented reality simulator.

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VT = video trainer; VR = virtual reality simulator; AR = augmented reality simulator; TS = transfer of skills; Pre/post test: training and pre- and post-assessment. * VT training is basic skills in these 4 studies.

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Whiskers stand for the 5^{th} and 95^{th} percentile, points stand for outliers within the 1^{st} and the 99^{th} percentile, and stars for outliers beyond these percentiles. 1, 11 and 12 stand for trainee 1 (who was an experienced surgeon), and trainees 11 and 12 (who were novices).

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The data are reported as the median and range.

LISTE DES ABBREVIATIONS:

ACS AEI: american college of surgeons accredited education institutes

APHM: assistance publique hopitaux de Marseille

AR: augmented reality

ATLAS: advanced training in laparoscopic abdominal surgery

CCL: chirurgie colorectale laparoscopique

CERC: centre d'enseignement et de recherche chirurgicale

CIL: correspondant informatique et liberté

CPA: care pathway approach

CS: colorectal surgery

ERP: enhanced recovery program

FPSS: formation en parcours de soin simulé

HAL: hand-assisted laparoscopic

HAS: haute autorité de santé

HTC: habileté technique chirurgicale

LAPP: laparoscopic appendectomy

LBA: laboratoire de biomécanique appliquée

LCS: laparoscopic colorectal surgery

LSC: laparoscopic sigmoid colectomy

OR: operating room

ORP: objectifs de rehabilitation précoce

OSATS: objective scale for assessment of technical skills

PEV: programme d'entrainement virtuel

SL: straight laparoscopic

RCT: randomized controlled trial

RP: rehabilitation précoce

VP: virtual patients

VT: video trainers

VR: virtual reality

W-NOTECHS : Ward Non Technical Skills

SOMMAIRE

1 PRÉAMBULE

L'enseignement hors du bloc opératoire s'est largement développé ces 15 dernières années, essentiellement dans les pays anglo-saxons (Royaume-Uni, Amérique du Nord).[1,2] Les axes de recherche ont jusqu'à présent surtout porté sur l'enseignement des compétences purement techniques au bloc opératoire, ainsi que sur la gestuelle chirurgicale basique en laparoscopie,[3,4] avec des résultats positifs quant à l'impact d'un tel enseignement sur les compétences techniques.[5–8]

Les travaux de cette thèse sont issus de deux hypothèses. La première est qu'une approche purement technique de l'enseignement en chirurgie est réductrice, et que cet enseignement doit peut être s'envisager en « parcours de soin », à savoir porter non seulement sur les compétences techniques peropératoires, mais également sur les compétences chirurgicales non-techniques en amont et en aval d'une éventuelle intervention chirurgicale. En effet, un chirurgien doit certes savoir bien opérer, mais il doit également connaître les bonnes indications opératoires, savoir quand il ne doit pas opérer, et prendre les bonnes décisions en période postopératoire, ainsi que détecter les complications médico-chirurgicales éventuelles. La seconde est qu'un tel enseignement trouve particulièrement sa place en chirurgie laparoscopique complexe (gastrique, colorectale, hépatique, splénique, pancréatique…) pour laquelle les notions de stratégie et de prise de décision sont particulièrement fondamentales. De plus, sur le plan des compétences techniques, c'est pour ces interventions peu accessibles aux internes en tant qu'opérateur, et associées à une plus longue courbe d'apprentissage, qu'une formation sur simulateur paraît particulièrement intéressante.

L'objectif final de cette thèse était le développement et la mise en place d'une formation en parcours de soin simulé (FPSS) en chirurgie colorectale laparoscopique, en collaboration avec les équipes : française du Centre d'Enseignement et de Recherche Chirurgicale (CERC), Université d'Aix-Marseille, du Pr Berdah, britannique du Département de Chirurgie et Cancer, Hôpital St

Mary's, Imperial College London, du Pr Darzi sous la direction du Dr Aggarwal, et canadienne du Département de Chirurgie, Université de Toronto, du Dr Grantcharov. Pour cela nous avons tout d'abord réalisé une revue de la littérature sur la simulation en chirurgie laparoscopique complexe, puis nous avons développé une FPSS portant sur des compétences basiques (prise en charge d'un syndrome appendiculaire) en vue d'un travail préliminaire. Nous avons enfin développé une FPPS en chirurgie colorectale laparoscopique, en faisant intervenir les principes de réhabilitation précoce en périopératoire. Enfin, nous avons étudié l'impact d'une telle formation sur la prise en charge des malades dans le service de chirurgie colorectale de l'Hôpital St Mary's à Londres. Pour une meilleure lisibilité, nous avons intégré les articles soumis ou publiés sous une police différente de celle du reste de la thèse.

2 INTRODUCTION

Afin de développer une FPSS en chirurgie complexe, nous avons réalisé un état de l'art de ce sujet, illustré autour de 3 thèmes : la place de la simulation en chirurgie laparoscopique complexe, qui a fait l'objet d'une revue systématique de la littérature publiée dans Surgery (Chapitre 2.1) et présentée en Mars 2013 au congrès de l'ACS-AEI à Chicago ; la place et l'intérêt des simulateurs de réalité virtuelle, que nous avons utilisés dans nos travaux, sous la forme d'une revue publiée dans Scandinavian Journal of Surgery (Chapitre 2.2); enfin, un état de l'art sur la formation en compétences périopératoires, en s'attachant particulièrement au patient virtuel, support que nous avons choisi pour les FPSS (Chapitre 2.3).

2.1 ADVANCED TRAINING IN LAPAROSCOPIC ABDOMINAL SURGERY (ATLAS)

[Précédemment publié sous la référence : Beyer-Berjot L, Palter V, Grantcharov T, Aggarwal R. Advanced training in laparoscopic abdominal surgery (ATLAS): a systematic review. Surgery 2014; 156:676-88.]

2.1.1 ABSTRACT

Background: Simulation has widely spread this last decade, especially in laparoscopic surgery, and training out of the operating room (OR) has proven its positive impact on basic skills during real laparoscopic procedures. However, few articles dealing with advanced training in laparoscopic abdominal surgery (ATLAS) have been published so far. Such training may reduce learning curves in the OR for junior surgeons with limited access to complex laparoscopic procedures as a primary operator.

Methods: Two reviewers, using MEDLINE, EMBASE, and The Cochrane Library, conducted a systematic research with combinations of the following keywords: (teaching OR education OR computer simulation) AND laparoscopy AND (gastric OR stomach OR colorectal OR colon OR rectum OR small bowel OR liver OR spleen OR pancreas OR advanced surgery OR advanced procedure OR complex procedure). Additional studies were searched in the reference lists of all included articles.

Results: Fifty-four original studies were retrieved. Their level of evidence was low: most of the studies were case series, one fifth purely descriptive, and there were 8 randomized trials. Porcine models and video trainers, as well as gastric and colorectal procedures were mainly assessed. The retrieved studies showed some encouraging trends in terms of trainees' satisfaction, improvement after training (but mainly on the training tool itself). Some tools have been proven to be construct-valid.

Conclusions: Higher quality studies are required to appraise ATLAS educational value.

2.1.2 INTRODUCTION

Surgical training out of the operating room (OR) using simulation has widely spread this last decade, especially in laparoscopic surgery.[1,2] Training models may be inanimate such as video trainers (VT), virtual reality (VR) and augmented reality (AR) simulators, as well as live animals or cadavers. Many studies have assessed simulation for basic laparoscopic skills (such as basic drills, laparoscopic cholecystectomy and appendectomy),[3,4] and training out of the OR has proven its positive impact on basic skills during real laparoscopic procedures in patients.[5–8]

A further step in laparoscopic simulation is to train surgeons in complex procedures requiring more advanced technical skills, such as gastric and colorectal procedures, splenectomy, hepatectomy, pancreatectomy, adrenalectomy or small bowel anastomoses.[9] The aim of such training is to reduce learning curves and provide safe implementation during real operations in the OR for junior surgeons who have limited access to advanced laparoscopic procedures as a primary operator.

However, few articles dealing with training in advanced laparoscopic skills have been published so far, and only one study assessed the impact of advanced training in laparoscopic abdominal surgery (ATLAS) in the OR.[10] Furthermore, in their systematic review of laparoscopic colorectal surgery (LCS), Miskovic *et al.* found only 6 studies assessing simulation, and no randomized controlled trials (RCT). They concluded that there was a "notable lack of available data on the educational value of simulated training in LCS".[11]

The aims of this systematic review were to identify and evaluate the place of ATLAS in surgical education and define ways to improve this type of training.

2.1.3 METHODS

This review was planned, conducted, and reported in adherence to PRISMA standards of quality for reporting systematic reviews and meta-analyses.[12]

2.1.3.1 Study Identification

We sought to include all original studies dealing with simulation in ATLAS. This simulation could be used either as a training or assessment tool. We considered as advanced technical skills all procedures except those already considered as basic in literature[9,13] (Table I) such as basic drills (camera navigation, peg transfer, cutting, clip applying…), suturing on a pad, and basic procedures (diagnostic laparoscopy, laparoscopic cholecystectomy, appendectomy and hernia repair). These advanced laparoscopic procedures were: gastric procedures (Nissen fundoplication, gastrectomy, bariatric procedures), colorectal procedures, small bowel procedures (anastomosis, enterotomy closure), pancreatectomy, splenectomy, hepatectomy, and adrenalectomy.

Table I: Definition of basic and advanced laparoscopic procedures.

Basic laparoscopic procedures	**Advanced laparoscopic procedures**
Diagnostic laparoscopy Cholecystectomy Appendectomy Hernia repair	Gastric procedures (fundoplication, bariatric procedures, gastrectomy) Colorectal procedures Small bowel procedures (anastomosis, enterotomy closure) Pancreatectomy Splenectomy Hepatectomy Adrenalectomy

A strategy was designed (Appendix 1) to search MEDLINE, EMBASE, and The Cochrane Library using search terms (MeSH terms and equivalent free-text terms) for the intervention (*i.e.,* Teaching OR Education OR Computer Simulation) combined with the term "Laparoscopy" and free-text terms for the procedures (gastric OR stomach OR colorectal OR colon OR rectum OR small bowel OR liver OR spleen OR pancreas OR advanced surgery OR advanced procedure OR complex procedure). No beginning date cutoff was used, and the last date of search was July 18, 2012. Additional studies were searched in the reference lists of all included articles.

2.1.3.2 Exclusion criteria

Editorial letters, reviews, guidelines, technical notes, and non-English-language publications were excluded. Studies assessing the impact of basic-skills training by an advanced procedure performed in a real-life situation (OR) were also excluded.

2.1.3.3 Study Selection

Two reviewers (L.B. and V.P.) independently screened all titles, and selected studies based on titles and/or abstracts. Studies that met the defined inclusion criteria were selected for article review. If it was not clear from the abstract whether a study fulfilled the inclusion criteria, the full article was reviewed independently and in duplicate. Any discrepancies between the two reviewers were resolved by consensus.

2.1.3.4 Data extraction

The following data were extracted: type of training model used for simulation, *i.e.* VT, VR or AR simulators, animals (porcine or others), cadavers; type of advanced procedure evaluated, *i.e.* gastric, colorectal, or small bowel procedures, pancreatectomy, splenectomy, hepatectomy, or adrenalectomy; type of study, *i.e.* RCT, non-randomized controlled trial, single-group pre-/ post-test, case series assessing any outcome or being only descriptive; purpose(s) of the study, *i.e.* training or assessment, model description (*i.e.* description of either a procedure on a tool or a whole course), satisfaction of trainees, construct validity of a model, transfer of skills and learning curve.

According to standard definitions,[14] the qualities of different training models were assessed for each procedure. These qualities were fidelity, content, construct, predictive and concurrent validity, reliability, and training ability. Training ability referred to any kind of impact of ATLAS, whether it assessed progression on the simulation device itself (pre- and post-test), transfer of technical skills, or impact on practice. It was judged that no data were suitable for statistical pooling due to the heterogeneity of the results.

2.1.3.5 Assessment of methodological quality

The instructions given in the *Cochrane Handbook for Systematic Reviews of Intervention*[15] and the Cochrane Hepato-Biliary Group module[16] were followed. Owing to the risk overestimation of intervention effects in RCTs with inadequate methodology quality, the influence of methodological quality on the results was assessed by evaluating the reported randomization and follow-up procedures in each trial: generation of allocation sequence, allocation concealment, blinding and follow-up were examined. Because participants and trainers cannot be blinded, double blinding was not feasible, but outcome assessor blinding was feasible and trials were considered to have adequate blinding if outcome assessors were blinded. If information was not available in the publication, authors were contacted in order to assess the trial correctly. Trials were considered to be of low risk of bias if the above 4 methodological qualities were adequate.

2.1.4 RESULTS

2.1.4.1 Description of studies

We identified 1605 potentially relevant articles identified from the database research. We retrieved 235 articles for abstracts screening, and 102 articles for more detailed evaluation. From these, we identified 51 appropriate articles for systematic review and found 3 articles through the references of the retrieved articles. Finally, 54 articles were included in this review (Figure 1) involving 1030 surgical trainees and 33 nurses.

There were 8 RCTs,[10,17–23] 12 non-randomized controlled trials (including 7 comparing different levels of experience for construct validity),[9,24–34] and one single-group pre-/ post-test.[35] Cases series were found in 35 studies. No RCT had adequate methodological quality in all 4 components and therefore could be considered to have a low risk of bias. Allocation sequence was given in all 8 studies, assessors were blinded in 5 studies, type of allocation concealment was given in 2 studies but follow-up was given in only one study: Stefanidis *et al.*[19] follow-up was a retention test, performed 6 months after the initial training.

2.1.4.2 Types of advanced procedures

The different types of laparoscopic advanced procedures evaluated are listed in Figure 2. Simulation for gastric, colorectal, small bowel, splenic and hepatic procedures, as well as for adrenalectomy was found whereas no study assessing simulation for pancreatic surgery has been published so far. One study over five assessed multiple procedures.

Gastric procedures

Twenty-nine studies assessed simulation in gastric surgery. Whilst most procedures were Nissen fundoplication,[19–22,26,32–34,36–47] there were also bariatric procedures (either gastric banding[29,48,49] or by-pass[9,50]), gastrointestinal anastomoses,[43,51,52] gastrectomy and seromyotomy.[53,54] Four of these studies were RCTs.[17–20]

Twelve studies implemented gastric procedures in a laparoscopic simulator. The majority of these used VT: 7 of them used animal organs whilst 2 used synthetic models (foam stomach) and one used both. Two studies implemented VR simulators, both for laparoscopic gastric banding procedure. Sixteen studies used live animal models: most of them resorted to swine models but 4 studies involved other animals. Finally, 2 studies were conducted on cadavers.

Colorectal procedures

Twenty-two studies assessed simulation in LCS, including 2 RCTs.[10,18] The types of LCS assessed were a sigmoid colectomy,[17,18,24–27,30,47,55,56] a right hemi-colectomy,[10,57] an anterior resection,[58] all 3 procedures[43,59–61] and colonic devascularization.[46] In 4 studies, the type of procedure was not specified.[36,38,52,62]

Ten studies implemented LCS in a simulator. The majority of them used the same AR simulator, the ProMIS™ (CAE Healthcare, Montreal, QC, Canada) for a laparoscopic sigmoid colectomy. Two studies utilized VR simulators in order to describe a right hemi-colectomy and an anterior resection. Finally, one study used VT with animal organs and involved both colorectal and gastric procedures. This study was also purely descriptive. Seven studies were conducted on animals, including 4 on porcine. Finally, 8 studies were conducted on cadavers, including one RCT assessing the transfer of skills in the OR as described below.[10]

Small Bowel procedures

Nine studies assessed simulation for laparoscopic small bowel surgery, including one study utilizing multiple models[23] and 4 studies assessing multiple procedures.[42,43,52,63] Six studies involved entero-enteral anastomosis,[28,42,43,51,52,64] 3 involved enterotomy closure,[23,28,63] and one consisted in running the small bowel.[35] One of these studies was a RCT.[23] Six studies involved laparoscopic simulators, all being VT: 4 used animal organs, one used synthetic models and one used both. Three studies were conducted on animals. In 2 of these 3 studies, the animal model was used as an assessment tool. Stelzer *et al.* showed a positive impact of a 6-week VT training on both VT and running the small bowel in porcine,[35] whilst Heinrich *et al.* conducted a RCT comparing the impact in both rabbits and VT of a training in either live rabbits or rabbit gut in VT (biopsy and enterotomy closure).[23] Both groups improved but the *in vivo* assessment improved significantly only in the live rabbit group. Finally, one study involved cadavers.

Splenectomy

Simulated splenectomy was found in 8 studies, including 6 studies involving multiple procedures.[26,38,43,46,47,63] None of these studies were randomized. Adrales *et al.* described multiple procedures on a synthetic model in VT.[63] Six studies involved live animals: rats were

Figure 1: Study Flow for Advanced Training in Laparoscopic Abdominal Surgery (ATLAS).

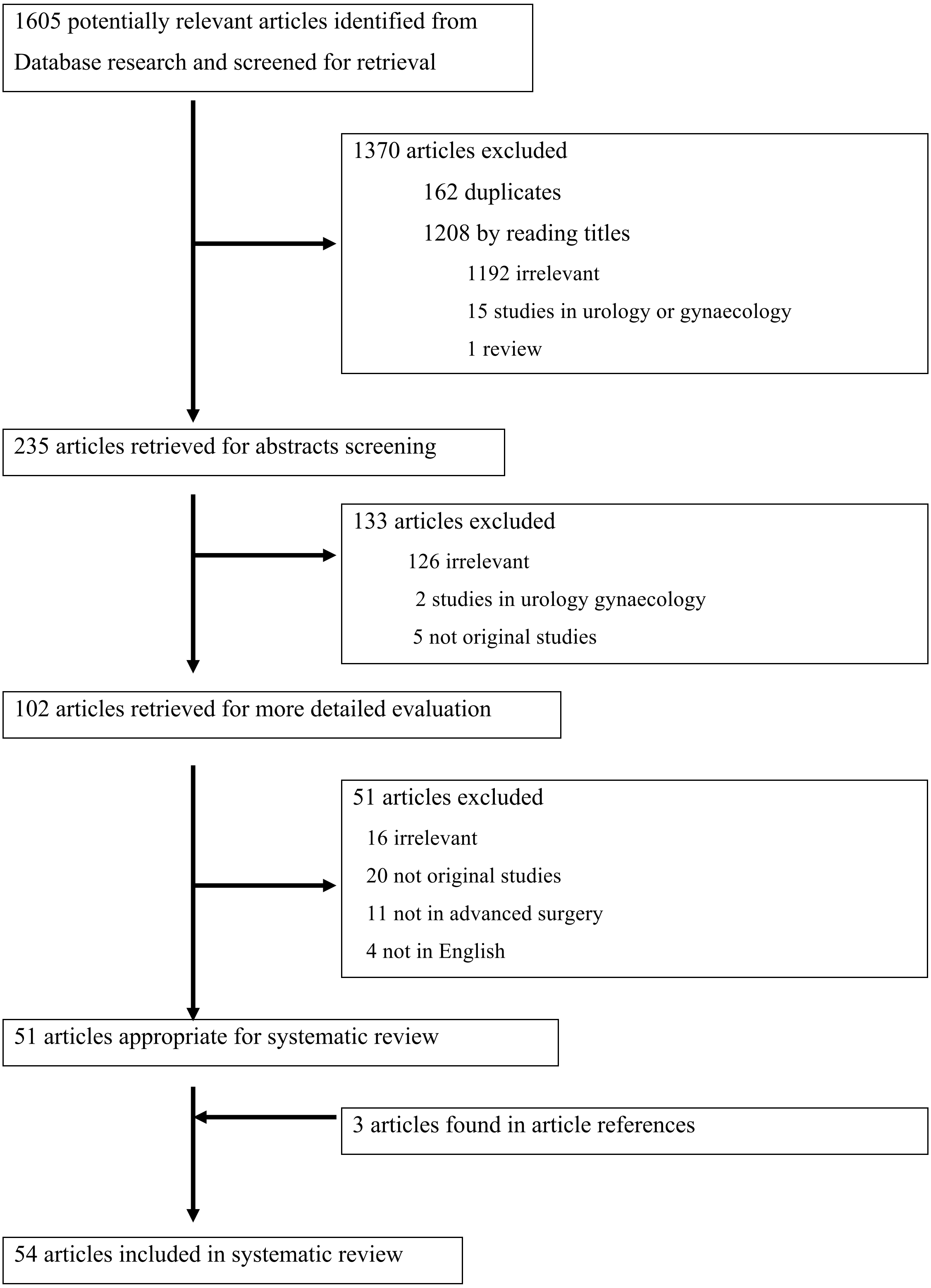
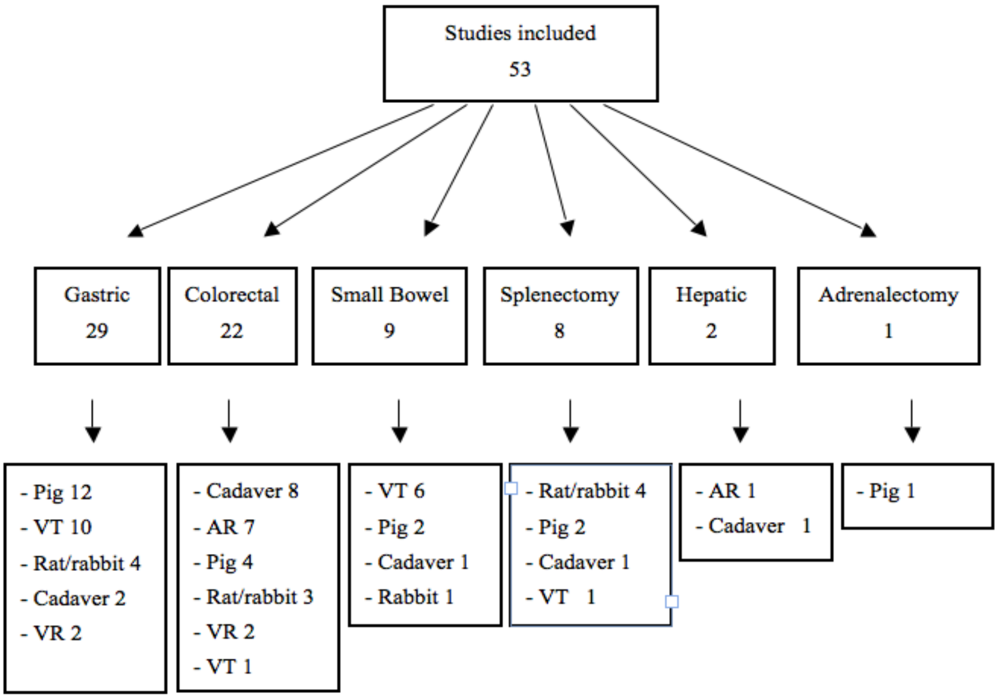


Figure 2: Types of implemented procedures in advanced laparoscopic surgery simulation.

VT = video trainer; VR = virtual reality simulator; AR = Augmented reality simulator.



used in 3 studies,[26,47,65] porcine in 2[38,66] and rabbits in one.[46] Finally, one study assessed laparoscopic splenectomy training in cadavers.[43]

Hepatic procedures

Simulated hepatic procedures were found in 2 studies. Strickland *et al.* assessed the construct validity of a liver tumorectomy in an AR simulator,[31] whilst Udomsawaengsup *et al.* described a training course on cadavers involving, along with other resections, a liver procedure. However, the type of procedure was not specified.[43]

Adrenalectomy

One study described a simulated laparoscopic adrenalectomy on a porcine model.[67]

Multiple procedures

As described above, 12 studies assessed multiple advanced laparoscopic procedures: 6 of them used VT,[36,38,42,51,52,64] 2 used cadavers,[43,50] 5 used porcine models[38,42,52,64,68] and 3 used other animals.[26,46,47] Most of these studies were purely descriptive, either for a model or for a training course.[36,43,46,47,50,51]

2.1.4.3 Types of training models

The different types of training models used for ATLAS and the different types of studies are listed in Figure 3. The qualities of different training models are reported Table II. Most devices were assessed for fidelity and content validity in every procedure, but only 2 devices were assessed for all the required qualities: the ProMIS™ for laparoscopic sigmoid colectomy, and an unspecified VT with organic tissue for gastric by-pass.

Laparoscopic simulators

VT

Fifteen studies used VT to assess ATLAS: 10 studies used animal organs, 3 used synthetic models and 2 used both. Two of these studies were RCTs. The ATLAS assessed was mostly gastric surgery (10 studies) and small bowel procedures (6 studies).

Twelve studies utilized VT only as a training tool. Most consisted of model description. Three studies assessed trainees' satisfaction as well as face and content validity. The study of Palter *et al.* [42] compared the satisfaction of residents after training for suturing on different models: the model perceived as having the best educational value was the porcine model, then the synthetic Nissen model. Two studies assessed the learning curves of anastomoses. Rodriguez *et al.* assessed learning curves for hand-sewn jejuno-jejunal (JJA) and gastro-jejunal anastomoses on VT with a plateau for operative time after 70 hours of practice.[52] Hamad *et al.* assessed learning curve for JJA on VT with a plateau after 40 anastomoses in one surgeon.[64]

Finally, the other items assessed after training on VT were the cost of a course and the impact of feedback.

Three studies used VT both as a training and assessment tool, with both pre- and post-test on the same simulator. Aggarwal *et al.*[28] showed that novices in laparoscopic surgery could meet some experts' benchmarks for enterotomy closure, and demonstrated both construct validity and improvement after training on an organic gastric by-pass model.[9]

AR

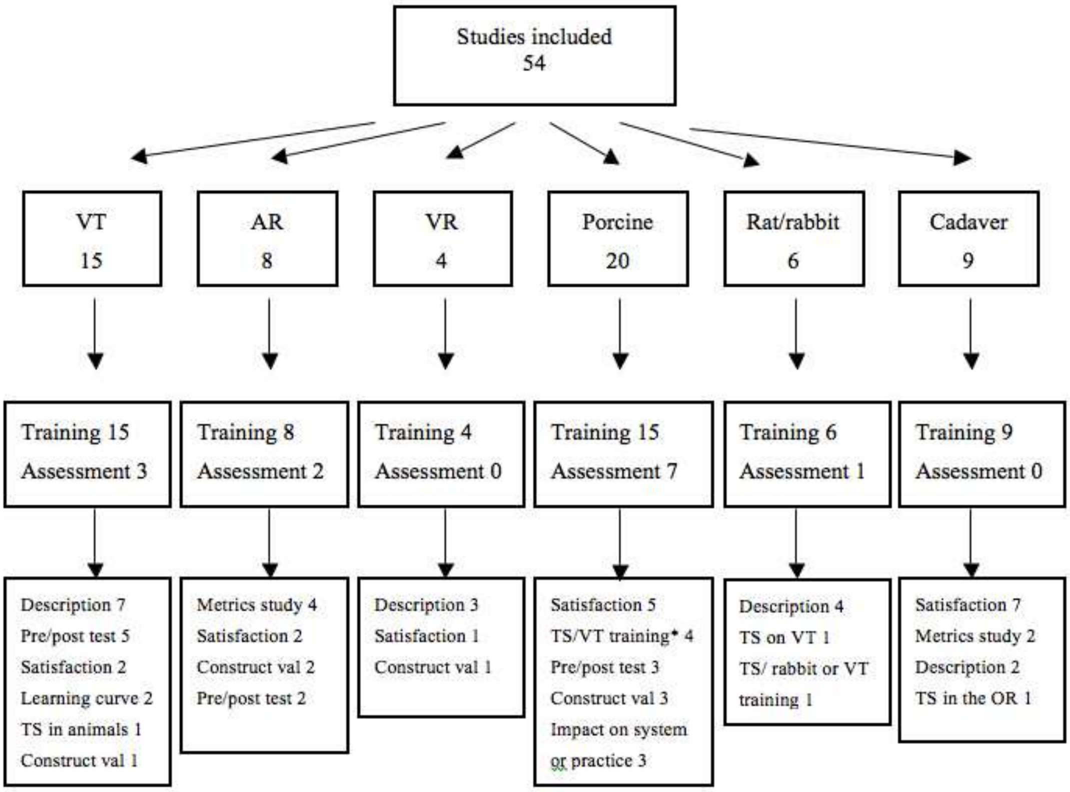
Eight studies resorted to AR to assess ATLAS, including 7 studies assessing LCS and one assessing a liver tumorectomy. Two studies were RCTs. [17,18]

Six studies involved AR simulators only as a training tool. Two studies assessed construct validity for the ProMIS™, either for laparoscopic sigmoid colectomy[30] or for hepatic tumorectomy.[31] Leblanc *et al.* assessed metrics and rating scales for laparoscopic sigmoid colectomy in 4 studies: 2 randomized crossover studies[17,18] compared hand-assisted (HAL) and straight laparoscopic (SL) sigmoid colectomies, and 2 other studies compared rating scales and trainees' satisfaction on ProMIS™ and cadavers.[24,25] Whilst satisfaction was significantly better with cadavers ($p < 0.001$), trainers rated generic ($p = 0.008$) and specific skills ($p = 0.028$) more accurately on the simulator.

Two studies used AR simulators both as a training and assessment tool. Essani *et al.* demonstrated significant improvement for time and leak rate ($p < 0.05$) after 8 weeks of training for SL sigmoid colectomy.[55] Boyle *et al.*[27] showed significant improvement for path length and smoothness after 5 HAL sigmoidectomies, with no difference between a group getting feedback and a control group.

Figure 3: Types of implemented models in advanced laparoscopic surgery simulation (only main groups of studies are reported in this diagram).

VT = video trainer; VR = virtual reality simulator; AR = augmented reality simulator; TS = transfer of skills; Pre/post test: training and pre- and post-assessment. * VT training is basic skills in these 4 studies.



VR

Four studies used VR to assess ATLAS, half of them implementing colorectal procedures and the other half gastric procedures. Three of these studies were purely descriptive whilst the latter assessed construct validity, as well as satisfaction, face and content validity for a laparoscopic gastric band VR simulator.[29] None were RCTs.

Live animals

Porcine

Twenty studies used porcine model to assess ATLAS. The type of procedure assessed was mostly gastric (14 cases), then colorectal (6 cases). Three studies were RCTs: they used porcine only as an assessment tool.

Fifteen studies used porcine model as a training tool. Satisfaction of trainees was assessed with good results, between 4.5 and 4.7/5,[61,66] and 82% to 100% of the trainees found training on porcine very helpful.[42,54] Three studies assessed the construct validity of rating scales and metrics during a Nissen fundoplication, and 3 studies looked at the impact of training on practice: Lin *et al.*[68] showed an increasing participation of trainees to laparoscopic colectomies without any alteration in patients' outcomes; Kinoshita *et al.*[54] found promising results for laparoscopic gastrectomy (2 thirds of the surgeons improved in terms of operative time and number of lymph nodes resected); however Heniford *et al.*[66] demonstrated a far better impact of intraoperative preceptorship compared to simulation for laparoscopic splenectomy.

Two studies used live porcine both as a training and assessment tool.[44,45] Both showed significant improvement after training, even after 6 months.

Five studies utilized live porcine only as an assessment tool. One study assessed a rating scale for SL sigmoid colectomy and found that trainees overestimated their own performance.[56] Four studies, including 3 RCTs, used porcine to assess transfer of skills during an advanced procedure after training in basic skills on VT. In the 3 RCTs, performance was significantly better in the intervention group compared to controls (in each case, $p < 0.001$). In the fourth study, there was no control group, but the authors found significant improvement between the pre- and the post-test ($p < 0.001$).

Other animals

Six studies used other live animals to assess ATLAS, including 4 studies in rats[26,47,49,65] and 2 studies in rabbits.[23,46] Half of these studies involved multiple procedures. Again, gastric and colorectal procedures were mainly involved. One of these studies was a RCT. [23]

Five studies used rats or rabbits only as training tools. Four of them were purely descriptive. In the fifth, Gutt *et al.*[26] assessed the impact of training on multiple advanced procedures in rats on basic technical skills in VT. Trainees were assessed before and after the course, and compared to a control group: their progression was significantly better than in the control group. One study used rabbits both as a training and assessment tool.

Cadavers

Finally, 8 studies used cadavers to assess ATLAS, including 2 studies involving multiple procedures.[43,50] The major type of surgery involved was colorectal. There was one RCT.

All studies involved cadavers only as a training tool. Palter *et al.* assessed for the first time the transfer of skills of ATLAS in the OR with good results, as mentioned above: training in LCS on cadavers was the last step of a whole training curriculum involving also basic skills training on a simulator and cognitive courses. Trainees were then assessed during a real right hemi-colectomy, using validated rating scales. Curricular-trained residents demonstrated higher performance in the OR ($p = 0.03$).[10]

The other studies assessed satisfaction of trainees: 5 assessed the model itself whilst 3 assessed a whole course; Wyles *et al.*[61] compared the satisfaction of surgeons for colorectal procedures on cadavers and porcine: overall satisfaction was even, but cadavers were thought to be better for anatomy and as a training tool; as described above, Leblanc *et al.* compared AR simulators and cadavers for satisfaction and rating scales.[24,25]

2.1.5 DISCUSSION

This is the first systematic review of simulation for advanced abdominal laparoscopic surgery. Fifty-four studies were retrieved. These studies were very heterogeneous in terms of tools, type of procedures, and type of studies. The main tools used in ATLAS were porcine and VT despite very different costs (swines are far more expensive models than VT)[1] and most VT studies used animal organs, which are cheaper than synthetic models.[38] Gastric and colorectal procedures were mainly assessed, most of the time during a laparoscopic Nissen fundoplication and a sigmoid colectomy (either SL or HAL). The level of evidence of the retrieved studies was low. Most of the studies were case series, and one fifth was purely descriptive. There were only 8 RCTs, and none could be considered to be of low risk of bias. However, one RCT assessed the transfer of skills in the OR with good results[11] and despite their relative weaknesses, the retrieved studies showed some encouraging trends, in terms of trainees' satisfaction,[42, 52, 59, 64, 66] and improvement in advanced technical skills after training (but mainly on the training tool itself).[9,28,44,45,55] Furthermore, some tools have been proven to be construct-valid.[9,29–31] However, very few studies assessed the transfer of advanced technical skills from training tools to live procedures, especially in the OR.

2.1.5.1 Is ATLAS a genuine need?

In their systematic review on mentoring and simulation in LCS, Miskovic *et al.* stated that only limited structured guidelines and few reports on dedicated programs existed for ATLAS:[11] only Fleshman *et al.* developed experts guidelines for education in LCS.[69] However, learning curves have been estimated as being 20 cases for Nissen fundoplication,[70] and between 30 and 60 cases in the technically challenging field of LCS.[71–73] Unfortunately, residents' experience is far from reaching these goals. In Palter *et al.* study, the majority of 14 PGY 3-5 had no experience in laparoscopic foregut and bariatric surgery as the primary

Table II: Qualities of simulation devices in ATLAS. VT: Video Trainers, VR: Virtual Reality simulators, AR: Augmented Reality simulators, NS: Not Specified, FLS: Fundamentals of Laparoscopic Surgery.

Procedures	Simulation Devices	Fidelity	Validity			Reliability	Training Ability
			Content	Construct	Predictive Concurrent		
Gastric							
Nissen fundoplication	**VT**						
	- Organ						
	• Tuebinger MIC-trainer[36]	X					
	• NS[37,37, 39-41]	X	X				
	- Synthetic						
	• FLS[42]	X	X				
	• Pelvic trainer (USSC, Norwalk, CT, USA)[20]				X	X	
	• NS[41]	X	X				
	Porcine[19,21,22,32-34,44,45]	X		X		X	X
	Other live animals						
	- Rabbits[46]	X					
	- Rats[26,73]	X					X
	Human cadavers[43]	X	X				
Gastric banding	**VR** PHANToM Omni haptic interface devices (Sensable Technologies, Inc., Boston, MA)[29,48]	X	X	X			
	Other live animals						
	- Rats[49]	X					
Gastric by-pass	**VT**						
	- Organ NS[9]	X	X	X	X	X	X
	Human cadavers[50]	X	X				
Gastro-intestinal anastomosis	**VT**						
	- Organ						
	• Pier/Götz trainer (MEDING GmbH, D-5138 Oberbruch)[51]	X					
	• Endotrainer[52]	X					X
	Human cadavers[43]	X	X				
Gastrectomy	**Porcine**[54]	X	X				X
Seromyotomy	**Porcine**[53]	X					

Procedures	Simulation Devices	Fidelity	Validity			Reliability	Training Ability
			Content	Construct	Predictive Concurrent		
Colorectal							
Sigmoidectomy	**AR** ProMIS™ (CAE, Toronto, Ontario)[17,18,24,25,27,30,55]	X	X	X	X	X	X
	Porcine[56]					X	
	Other live animals **- Rats**[26,47]	X					X
	Human cadavers[24,25,43,50, 59-61]	X	X		X	X	
Right hemi-colectomy	**VR** PHANToM Omni haptic interface devices (Sensable Technologies, Inc., Boston,MA)[57]	X					
	Human cadavers[10,43,50,59-61]	X	X				X
Anterior resection	**VR** PHANToM Omni haptic interface devices (Sensable Technologies, Inc., Boston,MA)[58]	X					
	Human cadavers[43,59-61]	X	X				
Colonic devascularization	**Other live animals** **- Rabbits**[46]	X					
NS	**VT** **- Organ** • Tuebinger MIC-trainer[36] • NS[38]	 X X					
	Porcine[52]						X
	Human cadavers[62]	X					

Procedures	Simulation Devices	Fidelity	Validity			Reliability	Training Ability
			Content	Construct	Predictive Concurrent		
Small Bowel							
Jejuno-jejunal anastomosis	**VT**						
	- Organ						
	• Pier/Götz trainer (MEDING GmbH, D-5138 Oberbruch)[51]	X					
	• Endotrainer[52]	X					
	• Limbs & Things Ltd, Bristol,England[64]						X
	• NS[28]			X			X
	- Synthetic NS[28]			X			X
	Porcine[42]	X	X				
	Human cadavers[43]	X	X				
Enterotomy closure	**VT**						
	- Organ						
	• Limbs & Things Ltd, Bristol,England[64]						X
	• NS[23,28]			X	X	X	X
	- Synthetic						
	• NS[28]			X			X
	• University of Kentucky laparoscopic models[63]	X					
	Other live animals						
	- Rabbits[23]				X	X	X
Running	**Porcine**[35]				X	X	
Splenectomy	**VT**						
	- Synthetic University of Kentucky laparoscopic models[63]	X					
	Porcine[38,66]	X	X				X
	Other live animals						
	- Rats[26,47,65]	X					X
	- Rabbits[46]	X					
	Human cadavers Thiel cadavers[43]	X	X				

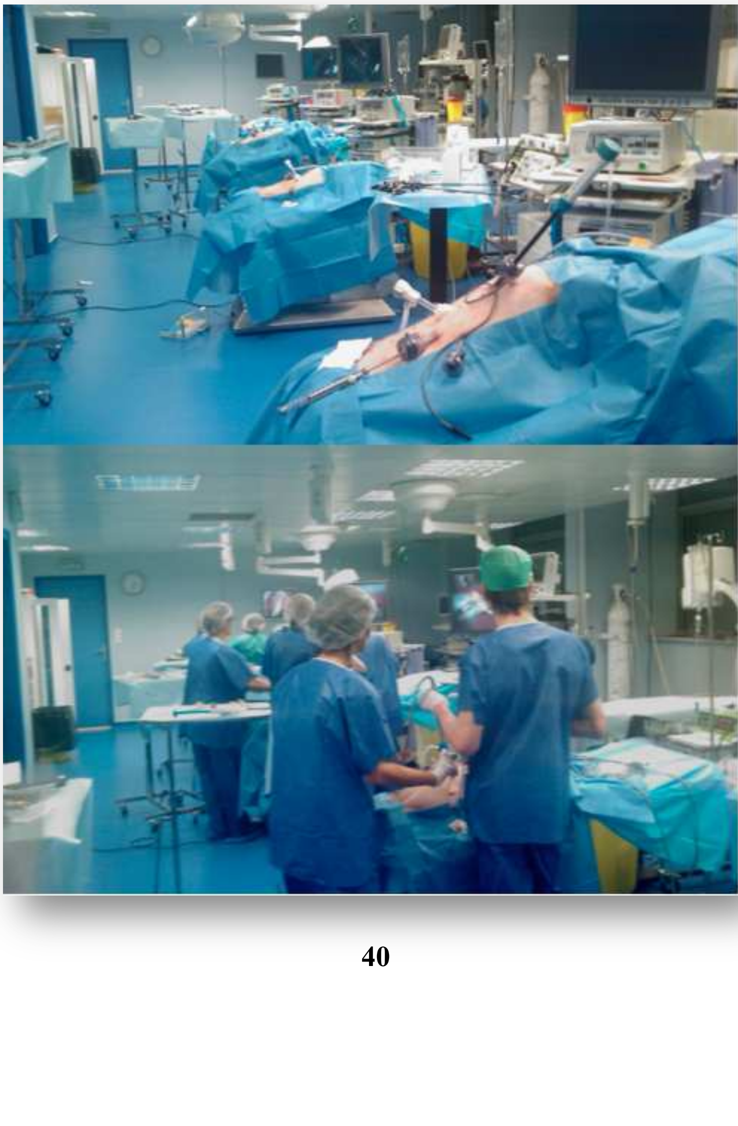
operator, and 36% had performed no LCS.[42] Rattner *et al.* interviewed 85 residents, being at least PGY 4, with similar findings: 60% had performed ≤ 3 laparoscopic Nissen fundoplications, 81% had performed ≤ 3 LCS, and 86% had done ≤ 3 laparoscopic splenectomies.[74] This gap between expected level and actual practice has prompted Essani *et al.*[55] to write that "the adequacy of Dr. Halsted's one-century-old apprenticeship model is questionable in LCS", and to promote the use of ATLAS. Training out of the OR may indeed reduce learning curves and favor a safe implementation of advanced procedures (Figure 4 & 5). Moreover, Lin *et al.*[68] found that ATLAS favored residents' participation in the OR without altering patients' outcomes. The need for ATLAS is therefore real, and studies implementing ATLAS with higher level of evidence should be designed. Other fields of simulation, medical or otherwise, may inspire this forthcoming research.

Figure 4: Advanced training on a VR simulator, laparoscopic sigmoidectomy (St. Mary's Hospital, Imperial College, London).

2.1.5.2 Lessons from basic skills simulation

There is a wealth of data on simulation for basic laparoscopic skills, but many studies in basic simulation have similar flaws to studies assessing ATLAS: small sample sizes, multiple simulation models (simulators, cadavers, live animals), varying rating scales, and lacks of objective tools to assess skills acquisition.[2,4] ATLAS RCTs' weakness in methodological quality is also comparable to basic skills studies': among 23 RCTs, Gurusamy *et al.*[3] found only 3 trials at low risk of bias. We could however debate the use of follow-up as a criterion of methodological quality in educational studies: in this field, follow-up is given mainly as a

Figure 5: Advanced training on live porcine (Center for Surgical Teaching and Research, CERC, Université de la Méditerranée, Marseille, France).



retention test, and retention test is more an outcome than a proof of quality. Some studies assessed the transfer of basic skills on VT or porcine,[3] and a few studies demonstrated that training out of the OR had some positive impact on basic skills during real laparoscopic procedures in the operating room.[5–8] In their systematic review, Sturm *et al.*[75] found 4 RCTs and one non-randomized comparative trial assessing the transfer of basic skills during a real laparoscopic cholecystectomy in the OR: groups who underwent simulation performed better in the OR, but the difference with controls was not significant in all parameters, and the authors concluded that more studies were required to strengthen the evidence of such transfer. In ATLAS, there is a lack a data concerning the transfer of advanced technical skills, especially in the OR. Only one study assessed the impact of simulation for ATLAS on technical skills during real procedures on patients (a laparoscopic right hemi-colectomy): there was a significantly better performance compared to conventionally trained residents.[10] Furthermore, a major advance in basic technical skills literature was the implementation of training curricula, using proficiency goals on construct-valid measures.[76,77] Only the pre-cited study of Palter *et al.*[10] has implemented such training curriculum in ATLAS so far. In short, lessons learned from basic skills training are the following: ATLAS still needs studies of higher quality to assess its educational value, especially RCTs; implementation of training curricula and transfer of technical skills in the OR are the most lacking fields of research in ATLAS.

2.1.5.3 Simulated non-abdominal advanced procedures

Simulation for advanced procedures has also been implemented in other medical specialties, such as vascular surgery (with carotid artery stenting), craniofacial surgery (congenital or traumatic facial deformities), neurosurgery (brain tumors), colonoscopy (flexures and loops) or interventional radiology (radiofrequency thermal ablation).[78–82] Two leads of research that have been developed in this field could be applied to ATLAS. First, advanced procedures could be split in procedural modules (also called part-procedural tasks) to strengthen the impact of training, as a short duration of training may produce better results.[3] Such procedural modules have been implemented in vascular surgery and endoscopy. Willaert *et al.*[79] demonstrated that training on a carotid stenting module was as effective as training on a full procedure, whilst Sugden *et al.*[78] developed a VR curriculum in colonoscopy, progressing from basic modules (intubating the sigmoid and descending colon) to advanced modules (intubating the splenic flexure), and then to the full procedure (a full colonoscopy). In ATLAS, a few studies set a workflow analysis with specific steps,[32,44] but no study has dichotomized a full procedure into modules so far. Second, training on patient-specific models could be an answer to the "ceiling effect associated with the fixed nature of the anatomy model" described by Essani *et al.*[55] whilst using an AR simulator. Patient-specific models have been implemented on various medical fields such as vascular, craniofacial or neurosurgery,[82] whereas only the descriptive study Suzuki *et al.*[57] has resorted to patient-specific simulation in ATLAS.

2.1.5.4 Advanced simulation in non-medical fields

The main fields concerned are commercial and military aviation, space missions and sports.[82] The first and most well-known is the aviation industry where advanced simulation on high-fidelity models has proven to be time- and cost-effective compared to real-life test flights.[83] In ATLAS, only one study evaluated the cost of a course,[38] but no study assessed ATLAS cost-effectiveness compared to standard training. There is a need for such a study which would assess the cost of the training itself, as well as the cost of care (such as operative time and patients' outcomes). Furthermore, the notion of strategy is very present in non-medical advanced simulation, especially in the military field: fighter pilots train on navigation, targeting, flight paths, but also on evaluation of strategic plans.[84] The complexity of advanced procedures in ATLAS also requires strategy, raising the question of feasibility for deliberate practice. In the present review, only 2 studies assessed the impact of feedback in ATLAS with conflicting results: Bergamashi *et al.*[20] found better results only for accuracy error in the feedback group ($p = 0.01$), whereas Boyle *et al.*[27] found better path length ($p = 0.01$) and smoothness ($p = 0.045$) in the control group. However, no study assessed deliberate practice for ATLAS. Moreover, strategy implies knowledge and decision-making whereas ATLAS is almost only about technical skills.

2.1.5.5 Future initiatives for ATLAS

Looking at the other fields of simulation helps to appraise forthcoming research in ATLAS. The main leads are the design of training curricula and the assessment of ATLAS educational value. There is a need for a competency-based curricular approach in ATLAS, using simulation to train on both technical and non-technical skills. Technical skills curricula should use construct-valid metrics and include part-procedural tasks and full procedures, based on the basic skills and endoscopic experience.[76-78] Non-technical skills should imply cognitive training (such as knowledge and decision making) and teamwork. Such a global approach would provide the full pathway care training that a complex procedure requires. Moreover, curricula's impact should be assessed both on technical skills in the OR and on the quality of care. Other fields of research could assess the impact of deliberate practice in ATLAS or design patient-specific models in VR, to overcome the fixed nature of the simulated procedures.[55]

2.1.6 CONCLUSION

Simulation in advanced laparoscopic surgery is needed, but only 54 studies addressed the question of ATLAS with a generally poor level of evidence. Higher quality studies, and especially RCTs are still awaited to appraise ATLAS educational value. Forthcoming studies should assess the following: transfer of advanced technical skills in the OR, and construct validity for models and metrics, in order to build training curricula. Other leads to improve ATLAS may be the design of patient-specific models, the assessment of deliberate practice, and the development of a pathway care approach involving both technical and non-technical skills.

2.2 TOWARDS TECHNOLOGY-SUPPORTED SURGICAL TRAINING: THE POTENTIAL OF VIRTUAL SIMULATORS

[Précédemment publié sous la référence : Beyer-Berjot L, Aggarwal R. Towards technology-supported surgical training: the potential of virtual simulators in laparoscopic surgery. Scand J Surg 2013; 102:221-6.]

2.2.1 INTRODUCTION

The mastery of manual skills that is indispensible for the performance of surgical tasks, which we call "surgical technical skill" (STS), is a competence specific to surgery (as there are technical skills specific to anesthesia, interventional radiology, or cardiology). According to Epstein, it represents one of the essential dimensions of professional competence.[85] William Halsted introduced in 1889 the notion of surgical apprenticeship, based on the gradual transfer of tasks and responsibility.[1] This system remains the cornerstone of surgical training more than a century later. However, its limits are now growing, due to both evolution of surgical practice and management of teaching hospitals. We can cite the following: the ethical question of surgery performed by a novice; the reduction of time residents spend in the operating room (OR) due to the compensatory rest; the economic pressure to optimize the use of OR; the increasing medico-legal pressure. Furthermore, the acceleration of technical innovation increases the numbers of skills to be acquired, even by teaching surgeons, and this evolution is paramount in the field of laparoscopic and robotic surgery. One way of facilitating the acquisition of STS is to move the training out of the OR and all of its restrictions, using simulation.[86] The inspiration for this approach came from the aeronautics sector within which simulation has been used for over 50 years.[87]

Surgical simulation has widely spread this last decade, especially in laparoscopic and endoscopic surgery.[1,2] Furthermore, regulatory bodies such as the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the European Association of Endoscopic Surgeons (EAES) have promoted training both in and outside the OR for laparoscopic surgery.[69,88,89] Training tools may be inanimate models such as virtual reality (VR) simulators and video trainers (VT), as well as live animals or cadavers. Though expensive (at least 60 000 €), VR simulators allow more advanced training than VT without presenting the ethical issue of live animals and cadavers. Moreover, traditional training is not without its cost. Bridges and Diamond estimated this cost to be approximately 40,775 € per graduating resident,[90] based on the time "lost" by primary operator residents in the OR. In addition, the application of faculty costs leads to approximately 62,810 € to 172,682 € per resident.[91,92] VR simulators are therefore an increasingly attractive option: once bought, they require little running cost, are easily available for use and allow iterative skills training.[93]

2.2.2 VR SIMULATORS: PRINCIPLES AND MODELS

VR simulators consist of laparoscopic instruments that are connected to a desktop computer: trainees have to select the tip of the instrument they need, then are able to follow the instrument's path on the computer screen as they move it, in real time. Furthermore, VR simulators have the ability to provide automatic and instantaneous measures of performance, also called metrics, such as time, number of movements, path length or accuracy.[94] These metrics can be used as an assessment tool: they can serve to monitor progress while learning a technical skill, aid in the provision of structured feedback, and ultimately ensure that proficiency criteria have been reached.[95] Furthermore, it is possible to record the trainees' performance in a database from which it can be recovered for analysis.

There is a wealth of simulators, ranging from low-fidelity trainers such as the MIST-VR® (Mentice, Gothenburg, Sweden) that only comprises basic skills and has no haptic feedback to high-fidelity simulators such as the LAP Mentor™ (Simbionix, Cleveland, OH, USA) that allows to practice on full procedures and has force feedback (Figure 6).[96] The MIST-VR® comprises abstract basic tasks, enabling the acquisition of psychomotor skills rather than cognitive knowledge. The LapSim® (Surgical Science, Gothenburg, Sweden) has more realistic tasks than the MIST-VR®, involving structures that are deformable and may bleed (Figure 7), and comprises 3 levels of difficulty. It also has more advanced tasks such as laparoscopic suturing and running the small bowel, as well as full procedures such as laparoscopic cholecystectomy, appendectomy and hysterectomy. It does not have haptic feedback. Finally, the LAP Mentor™ is the latest generation VR simulator, incorporating haptic feedback. It comprises basic tasks, suturing tasks, procedural modules and full procedures that range from basic (cholecystectomy, hernia repair) to advanced laparoscopic surgery (gastric by-pass, hysterectomy, sigmoid colectomy). The VR images are based on MRI images and in vivo laparoscopy for procedural modules and full procedures.[2]

Figure 6: Virtual laparoscopic cholecystectomy on the LAP Mentor™.

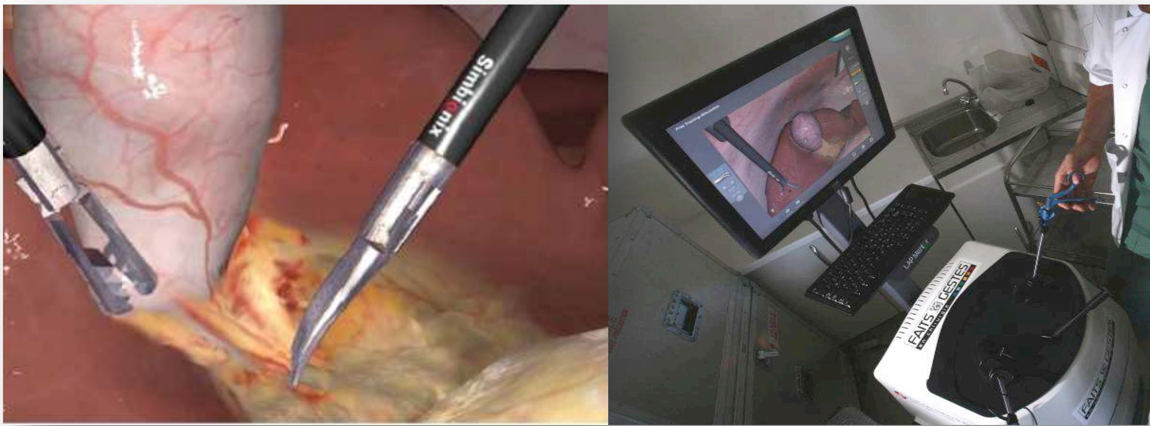
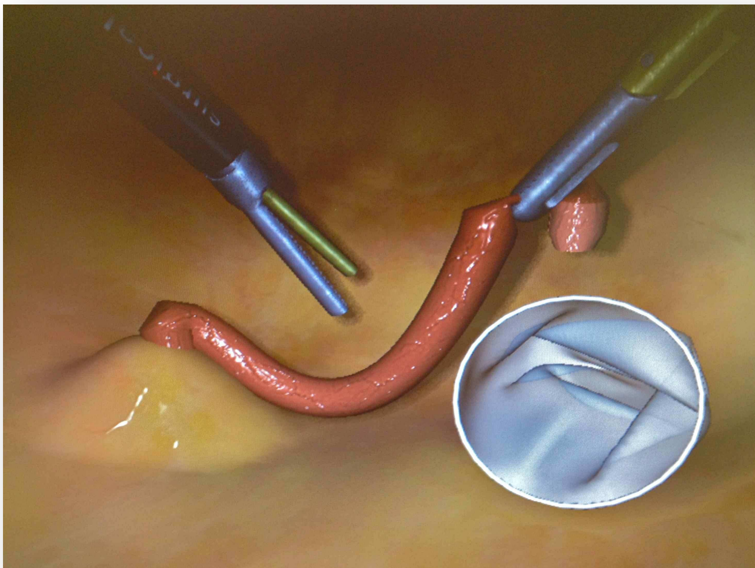


Figure 7: Basic laparoscopic task on the LapSim® (Cutting exercise)



2.2.3 VALIDATED TOOLS FOR SURGICAL TRAINING AND ASSESSMENT

VR simulators have shown acceptable fidelity, or face validity (*i.e.* the extent to which the tasks or procedures resemble real life situations), content validity (*i.e.* if the domain that is being measured is actually measured by the tool: for example, while trying to assess technical skills we may actually be testing knowledge), predictive and concurrent validity (*i.e.* respectively, the ability of the tool to predict future performance, and the extent to which the results of the assessment tool correlate with the gold standard for that domain).[14,95] Furthermore, a variety of VR simulators have demonstrated construct validity, *i.e.* their metrics can discriminate between expert and novice performance. The MIST-VR® has demonstrated construct validity,[97] as well as the LapSim® for lifting and grasping task, clipping task and cholecystectomy.[77,98] More sophisticated simulators such as the LAP Mentor™ or the Olympus ENDO-TS1 (Olympus Keymed, Southend, UK) colonoscopy simulator model have also demonstrated construct validity.[76,78,99,100] However, regarding the literature, not all metrics are construct-valid measures. The parameters that have the most evidence to support their use are time taken, number of movements, path length (*i.e.* the distance covered by the instrument's tip) and, to a certain extent, error scores for particular tasks. These assessment parameters are consistent across various types of simulators. However, they are not necessarily meaningful for trainees, and may not provide them with insight into the level of their performance.[95]

2.2.4 LEARNING CURVES AND CURRICULAR APPROACH

Based on these construct-valid metrics, learning curves have been shown on a variety of VR simulators. In most studies, novices reached expert proficiency after approximately 10 trials, but learning curves presented with individual variations: trainees with similar baseline level may indeed take different amounts of time to reach expert level.[95,101,102] Furthermore, Ahlberg *et al.* showed that training without proficiency goals was not optimal.[103] Indeed, they compared the STS of medical students that trained on the MIST-VR® to a control group during a laparoscopic appendectomy on a porcine model. The intervention group trained only for a certain amount of time but with no proficiency goal. There was no difference between the 2 groups.

A major advance in basic technical skills training is therefore the implementation of structured competency-based curricula, using proficiency goals on construct-valid measures (Figure 3).[76,77] Proficiency measures are based on the performance of experienced surgeons. The aim is to acquire a basic level of proficiency prior to entering the OR, and to reduce the learning curve on real patients: predefined benchmark criteria can ensure that skills acquisition has been successful. Training sessions are short and iterative (a maximum of 3 sessions are allowed per day, performed at least one hour apart) in order to ensure a distributed rather than massed approach to skills training. Indeed, the distributed training has demonstrated higher impact on STS in VR.[104] Such curricular approach has also been implemented in endoscopy[78] and may as well be used in the future for advanced laparoscopic surgery. Finally, retention of STS has been shown up to 7 months after training to proficiency on VR simulators.[105]

2.2.5 TRANSFER OF TECHNICAL SKILLS

There is a wealth of data on VR simulation, but many studies have major flaws: small sample sizes, multiple VR models, varying rating scales and lacks of objective tools to assess the transfer of STS.[2,4] There is therefore a great amount of data in the literature that has prompted Champion and Gallagher to state that "poor scientific reflection in medical simulation has become too common".[106] However, some studies have assessed the transfer of STS after training on VR simulators. Several randomized controlled trials have shown that training to expert levels of proficiency on VR simulators results in improved performance in a porcine model compared to conventional apprenticeship[107–110] and a recent systematic review found 4 RCTs and one non-randomized comparative trial assessing the transfer of basic skills during a real laparoscopic cholecystectomy in the OR.[75] Grantcharov et al.[5] appraised the impact of MIST-VR® simulator training in a multicentre study, comparing their intervention group to controls. Evaluation criteria were the time required to perform a laparoscopic cholecystectomy, an error score and a score for economy of movements (analogue scale). There was a significant difference between the 2 groups for all 3 criteria. Seymour et al.[6] also studied the impact of MIST-VR® training *vs.* controls on STS in the OR: a significantly positive effect was again demonstrated. However, there was no baseline evaluation in the OR

Figure 8: Example of evidence-based virtual reality curriculum, designed on the LapSim by Aggarwal *et al.*[77]

Easy Level – settings
7 tasks performed twice on the same day in 2 sessions, each session >1 hour apart

↓

Medium Level – settings
7 tasks performed twice on the same day in 2 sessions, each session >1 hour apart

↓

Difficult Level – settings
2 tasks (Lifting and Grasping and Clip Applying)
Performed for a maximum of 2 sessions per day, each session >1 hour apart
Completion of training when all of the following levels of skills are achieved on 2 consecutive sessions

↓ ↓

Difficult Level (Lifting & Grasping)
R Path length <1.2m
L Path length <1.2m
Time taken <40 s

Difficult Level (Clip Applying)
Error score <0.33
R Path length <1.2m
L Path length <1.2m
Time taken <80 s

↓ ↓

Dissection module (Calot triangle)
2 sessions per day, each session >1 hour apart
Completion of training when all of the following levels of skills are achieved on 2 consecutive sessions:
Time taken (450 s); Dissected volume (>20%);
R Path Length (3.0 meters); L Path Length (3.0 meters)

and the time between training and assessment was not stated. Likewise, Scott et al.[7] reported an improvement in STS after VR training. In gynaecology, Larsen *et al.* demonstrated that training on the LapSim® resulted in improved STS during a laparoscopic salpingectomy with respect to time and to a validated score.[111] Moreover, both Xitact LS500® (Xitact, Morges, Switzerland) and LAP Mentor™ demonstrated a significantly positive impact on STS in the OR in nonrandomized comparative studies.[8,112] Finally, beyond training to acquire STS, VR simulators have also demonstrated a positive impact as a warm-up tool for surgeons before doing a laparoscopic cholecystectomy.[93]

2.2.6 ARE VR SIMULATORS BETTER THAN VT?

Training out of the OR has proven its positive impact on basic skills during real laparoscopic procedures in patients on both VT and VR. However, few studies have yet compared VT with VR. Considering the staggering difference in cost, it seems pertinent to determine whether the higher cost of VR simulators is associated with an increased efficiency or whether in contrast a VT, around 20 times less expensive, is just as valuable a learning tool.

Studies comparing VT and VR showed mixed results, and only 2 studies have compared the impact of VT against VR on STS in the OR.[8,113] One systematic review[3] concluded a superiority of VR simulators in terms of scores of performance established outside of the OR but also mentioned that “the advantages of VR over VT training are not evident”. Munz *et al.*[114] compared the performance of 3 groups out of the OR before and after training. The first group received training sessions on the LapSim® and the second on a VT; a third control group received only conventional apprenticeship. They concluded that there existed a significant progression of the 2 groups trained on the simulators compared to the control group and that there was no significant difference between the 2 simulators, with however a tendency in favor of the VT. However, the transfer of skills to the OR was not assessed in this study. In 2005, Youngblood *et al.*[115] compared the impact of the Tower Trainer® (Simulab Corporation Seattle, WA, USA), VT, and the LapSim® on STS in live pigs. They found a superiority of the LapSim®. However, this study had several limitations. First, no baseline testing was performed, which would have ensured that the 2 groups were comparable. Second, the assessment tool was not a validated score. Two studies have compared the impact of VR *vs.* VT on STS in the OR. Hamilton *et al.*[113] compared the MIST-VR® with a VT, the SCMIS GEM® (Karl Storz Endoscopy, Culver City, CA, USA). The performance of 19 residents in the OR during a laparoscopic cholecystectomy procedure was assessed before and after a training session. The assessment tool used was a validated global score. The authors demonstrated a significant progression outside of the OR in both groups, but a transfer of skills to the OR was only demonstrated in the VR group. One explanation is that training sessions were not supervised and whilst feedback is given to trainees on VR simulators by the metrics, trainees had no feedback on VT apart from time taken (although a rapid hand movement may not necessarily be a correct one). However, a limitation to that study is that all trainees were not assessed by the same observer and one candidate was not always assessed by the same observer before and after the training. The last study compared 2 groups training on simulators, the LAP Mentor™ or a VT, the MISTELS (Mac Gill Inanimate System for Training and Evaluation of Laparoscopic Skills), to a control group during a laparoscopic cholecystectomy in the OR. Both intervention groups demonstrated a significant improvement compared to the control group, but there were no differences between the VT and VR groups.[8]

In total, there may not be a superiority of VR simulators over VT for teaching laparoscopic basic skills. However, VR systems present 2 advantages over VT. First, they provide automatic feedback at the completion of each task, allowing deliberate practice. This deliberate practice has recently demonstrated a positive impact on STS in the porcine model.[116] Second, VR provides more diversity than VT: indeed it comprises not only training for basic skills but also more advanced training, including multiple scenarios for one given procedure.

2.2.7 BEYOND TRAINING FOR BASIC LAPAROSCOPIC SKILLS

Until now, training out of the OR involved mostly basic laparoscopic skills. However, VR simulators of the latest generation provide advanced procedures such as gastric by-pass, sigmoid colectomy, hysterectomy or carotid artery stenting, and forthcoming research in VR should focus on this field. Furthermore, patient-specific models have been designed in VR simulation to answer the “ceiling effect associated with the fixed nature of the anatomy model” described by Essani *et al*.[55] Patient-specific models have been designed on various medical fields such as vascular, craniofacial, rectal surgery, neurosurgery or percutaneous interventions.[82,117] Finally, VR simulators have also been developed and validated in the field of robotic surgery.[118]

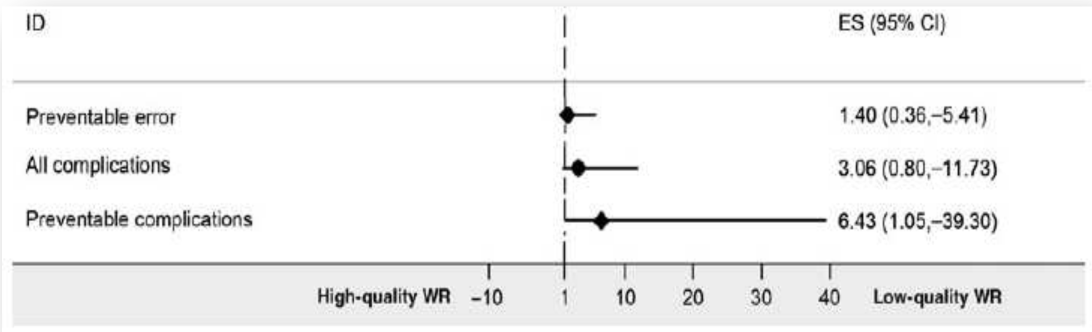
2.2.8 CONCLUSION

Training out of the OR on VR simulators has proven its positive impact on basic skills during real laparoscopic procedures in patients. It also offers an ethical way of assessing the competency of a surgeon in performing a procedure, without risk to a patient. The benefit of VR over VT remains unclear for teaching basic skills. However, VR simulators provide automatic feedback at the completion of each task, unlike VT. This feedback permitted to design structured competency-based curricula and allows deliberate practice. Finally, advanced procedures and patient-specific models have been designed on VR simulators and further investigations are still awaited to appraise their educational value.

2.3 SIMULATION ET PRISE EN CHARGE PÉRIOPÉRATOIRE: VERS LA FORMATION EN PARCOURS DE SOIN SIMULÉ (FPSS)

L'enseignement simulé des compétences chirurgicales a longtemps été restreint aux compétences techniques.[1,2,119] Cependant, les compétences non-techniques sont également essentielles à la formation des chirurgiens.[119] Elles interviennent non seulement au bloc opératoire,[120,121] mais également en amont et en aval d'une intervention chirurgicale. Récemment, Pucher, *et al.* ont mis en évidence que la qualité de la visite en service de chirurgie avait un impact sur les suites opératoires des malades en termes de complications « évitables » (Figure 9).[122]

Figure 9: Impact de la qualité de la visite chirurgicale sur les suites opératoires. D'après Pucher, *et al.*[122] Valeurs indiquées: odd-ratio (IC 95%).



La formation en parcours de soin simulé (FPSS) comprend une formation en compétences techniques sur un simulateur, et une formation en compétences non-techniques sur la prise en charge périopératoire des malades. Le but d'une telle formation est l'amélioration de ces compétences, telles que l'application pratique de connaissances théoriques, la stratégie de prise en charge et la prise de décision. Jusqu'à présent, l'enseignement de la prise en charge périopératoire a été réalisé lors de cours magistraux, dans le système éducatif médical et dans les publications scientifiques. Récemment, le «blended learning» s'est développé, combinant cours magistraux classiques et e-learning basé sur des photos, vidéos, podcasts et questions à choix multiples.[123] Dans leur revue de la littérature, Rowe, *et al.* ont montré que le blended learning avait des résultats intéressants auprès des étudiants en médecine, en particulier pour «combler le fossé entre la théorie et la pratique et améliorer certaines compétences cliniques sélectionnées». Cependant, la plupart des études incluses était de faible qualité méthodologique.[124] De plus, le blended learning n'est pas conçu de manière immersive, avec de «vrais» patients à prendre en charge dans leur globalité. La FPSS est donc une formation supplémentaire, immersive, qui n'a pas vocation à remplacer l'enseignement actuel mais à le compléter.

Plusieurs domaines de recherche ont été développés pour créer des modèles d'enseignement immersifs non-techniques, à la fois pour la prise en charge per- et péri-opératoire : la formation en équipe au bloc opératoire simulé pour le peropératoire (principalement utilisé pour la gestion en équipe des situations de crise);[120,121] le service hospitalier simulé et le patient virtuel pour le périopératoire (Figure 10 & 11).[125–130] Cependant, les formations per- et périopératoires ont toujours été réalisées séparément dans la littérature, et aucune formation n'a jusqu'à présent utilisé la simulation pour combiner enseignement technique et non-technique. Le seul type d'enseignement « combiné » publié a consisté à associé des formations techniques à des cours magistraux sur la prise en charge peropératoire, la plupart du temps auprès de chirurgiens séniors lors de workshops.[50,60,62]

Le modèle le plus fidèle et le plus étudié pour enseigner et évaluer ces compétences est le service hospitalier simulé (SHS),[129,130] qui a démontré son réalisme, sa validité de contenu et sa valeur pédagogique.[131] Le SHS est un espace comprenant de véritables lits hospitaliers avec oxygène et aspiration murale comme dans une véritable chambre hospitalière, occupée par des acteurs qui « jouent » des scenarios de présentation clinique pré-établie et miment des examens cliniques tels que défense abdominale, vomissements, etc... L'étudiant ou interne doit interroger ces « malades », et les examiner. Il a accès à leurs données cliniques et para-cliniques ainsi qu'à

Figure 10: Patient virtuel sur Second Life™.

Figure 11: Service simulé (Hôpital St. Mary's, Imperial College, London).

leurs prescriptions dans un dossier médical et doit effectuer en fin de visite de chaque malade ses propres prescriptions.[129,130] Le SHS comprend en outre des programmes d'entrainement[131] et d'évaluation validés[132] (Ward Non Technical Skills : W-NOTECHS) faisant intervenir le leadership, la coopération avec l'équipe soignante, la communication, la prise de décision, et le prise de conscience de la situation. Cependant, le SHS est onéreux et présente des contraintes de temps et d'accessibilité.

Le patient virtuel est une alternative séduisante car moins onéreuse et plus facile d'accès,[125] qui a également démontré son réalisme, sa validité de contenu et sa valeur pédagogique.[126] Il se définit par un modèle multidimensionnel à travers lequel l'étudiant ou l'interne va communiquer avec le patient, assembler les informations cliniques et paracliniques, émettre un diagnostic et décider d'une prise en charge.[133] Développé dans le monde virtuel de Second Life™, le patient va pouvoir « répondre » aux questions sélectionnées par l'utilisateur par des bulles semblables à celles des bandes dessinées. Pour améliorer le caractère immersif, des outils interactifs ont été créés : le patient est examiné dans l'environnement clinique approprié (service d'urgences, consultation, service de chirurgie, etc…), un bureau est à disposition pour récupérer les résultats des examens paracliniques (biologie et imagerie), un scope permet de récupérer les constantes. Enfin, l'abdomen du patient peut être palpé en cliquant sur la zone à examiner, les auscultations sont audibles, et toute prescription apparaît instantanément à l'écran (perfusion, sonde gastrique, sonde urinaire). Enfin, le patient virtuel est accessible par connexion internet, sur tout ordinateur portable ou tablette, et peut donc être exporté à de larges effectifs.[134] Il est donc un support attractif, utilisé par un nombre croissant d'universités.[135–137]

3 ETUDES PRÉLIMINAIRES – FPSS EN COMPÉTENCES CHIRURGICALES BASIQUES

Le but de ce travail préliminaire était d'abord de développer une FPSS sur une pathologie digestive simple requérant des compétences basiques, étude publiée dans Surgery (Chapitre 3.1) et présentée en Mars 2013 au congrès de l'ACS-AEI à Chicago. Dans un second temps, nous avons évalué la faisabilité de mise en place d'une telle formation dans un service de chirurgie, et l'éventuel impact de cette FPSS sur la prise en charge des patients (Chapitre 3.2). Cette seconde étude a été approuvée par le NRES Committee London – Central. La pathologie choisie était l'appendicite aiguë.

3.1 SURGICAL TRAINING: DESIGN OF A VIRTUAL CARE PATHWAY APPROACH

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3.1.1 ABSTRACT

Background: Both intra- and perioperative care are essential for patients' safety. Training for intraoperative technical skills on simulators and for perioperative care in virtual patients have independently demonstrated educational value. However, no training combining these two approaches has been designed yet. The aim of this study was to design a pathway approach for training in general surgery. A common disease requiring essential skills was chosen: acute appendicitis.

Methods: Preoperative care training was created using virtual patients presenting with acute right iliac fossa (RIF) pain. A competency-based curriculum for laparoscopic appendectomy (LAPP) was designed on a virtual reality simulator: novices (<10 LAPP) and experienced surgeons (>100) were enrolled to perform 2 virtual LAPP for validity evidence assessment; novices performed 8 further LAPP for learning curve analysis. Finally, postoperative virtual patients were reviewed after LAPP.

Results: Four preoperative patient scenarios were designed with different presentations of RIF: not all required surgical treatment. Comments were provided through case progression to allow autonomous practice. Ten novices and 10 experienced surgeons were enrolled for intraoperative training. Time taken (novices: 284.8 *vs.* experienced surgeons: 258.5 s; P = 0.026) and performance score (67% *vs.* 99.5%; $P < 0.0001$) demonstrated evidence for validity, whereas path length did not (916 *vs.* 673 cm; P = 0.113). Proficiency benchmark criteria were defined for measures with validity evidence. Two postoperative virtual patients were created with an uneventful or complicated outcome.

Conclusions: A virtual care pathway approach has been designed for acute appendicitis enabling trainees to follow simulated patients from admission to discharge.

3.1.2 INTRODUCTION

Until now, training out of the operating room (OR) predominantly consisted of improving technical skills using benchtop models and simulators.[1,2,119] This type of training has already demonstrated its positive impact for basic laparoscopic skills in the OR.[5–8] However, both technical and non-technical skills are essential in the training of surgeons.[119] Whilst some studies have described non-technical skills training such as teamwork training,[120,121] no study has evaluated the impact of care pathway training on the healthcare system. Care pathway training implies both technical skills training on a simulator, and training in pre- and postoperative care. The purpose of perioperative training is to improve not only knowledge but mostly decision-making.

The only perioperative care training that has been published so far in the educational system is experiential or via lectures, but not interactive between the trainees and the patients, *i.e.* that the patients themselves (virtual or actors) provide data about their chief complaint, history and exam. The best-known field of research for this type of interactive training is the simulated ward, a high-fidelity model using actors to play patients within an environment pertaining to a real surgical ward.[129,130] However, the simulated ward is expensive and presents both access issues and time constraints.

An attractive field of interactive training is the use of online 3D virtual patients, using pre- and postoperative scenarios.[125] 3D virtual patients are defined as multidimensional model patients through which a user has to simulate communication, information gathering, and apply diagnostic reasoning in support of effective and cost-efficient surgical care.[133] Medical education is continually evolving to use such novel internet-based technologies[138] and 3D virtual patients have demonstrated fidelity and content validity.[126] Moreover, virtual patients are uploaded on a virtual world that is easily accessible through an internet connection.

The aim of this study was to design a curriculum to teach pre, intra, and post-operative surgical care (a care pathway) using virtual patients for the pre and post-operative phases with emphasis on interaction with the patients and decision making required to optimally care for the patient. As a pilot study, a common surgical disease was chosen: acute appendicitis.

3.1.3 METHODS

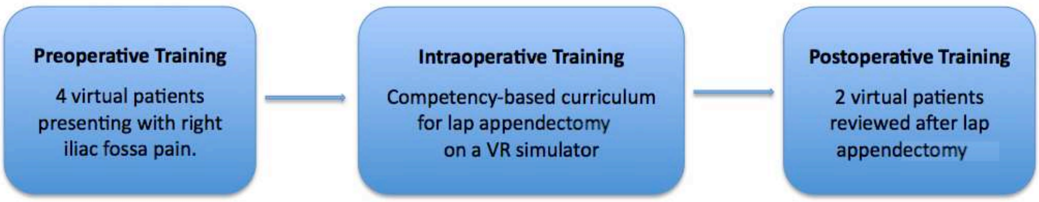
Curricula for pre-, intra- and postoperative training were designed. Preoperative virtual patients presented with acute right iliac fossa (RIF) pain. A competency-based curriculum for laparoscopic appendectomy was created on a virtual reality (VR) simulator, the LapSim® (Surgical Science, Göteborg, Sweden) for intraoperative training. Finally, postoperative patients were created to be virtually assessed in the surgical ward after laparoscopic appendectomy (Figure 12).

3.1.3.1 Preoperative training: design of virtual patients

All preoperative cases were designed and developed according to a similar framework previously employed by our group,[125] according to the guidelines of Posel *et al.*[139] This framework encompassed several steps: determine case content and choose a design model (linear string or branching design model), organize and storyboard the case, manage case

Figure 12: Design of a care pathway training.

lap: laparoscopic; VR: virtual reality.



complexity and match it to the case objectives (as a pilot study using a basic disease, cases were meant to be simple in the present work), develop the case and, finally, tackle interactivity in order to obtain the highest fidelity simulation possible. After testing, the cases were transferred in the virtual world of Second Life™ (Linden Research Inc, San Francisco, CA, USA).

Design model and case content

All cases followed a linear string model of design. Four different preoperative patient scenarios each presenting with RIF pain were designed. Not all of the virtual cases actually had acute appendicitis and thus not all required an operation. The objectives of such cases were to elicit the relevant clinical information from the history and examination, establish the pertinent investigation findings, determine the correct diagnosis and initiate an appropriate management plan, similar to how a resident should perform clinically in an emergency room (ER). Using a screen next to the patient as an interface between the patient and the trainee, the trainee would click on different types of questions regarding chief complaint, history and clinical examination. The patient would answer the trainee via a bubble speech and the trainee could chose the questions he would pick and the ones he would reckon as not relevant. Using the same screen, the trainee would then go to the management plan in order to ask for blood tests, computed tomography (CT) or ultrasound (US) scan, and to select the type of treatment needed. Comments were provided through management plan to allow guidance but otherwise autonomous practice (such as "prescribed", "this is not useful" or "the Consultant / Attending does not agree with your decision"). Once comments were provided, the trainee could either submit another proposition that was written on the screen by clicking on it, if the previous answer was incorrect, or move to another step of the management plan.

Storyboarding the cases

In order to follow a specific framework focusing on information elicitation, processing and decision-making, all cases were designed in the same format with case detail under the categories of history, examination, investigation and management based on case objectives. They were all storyboarded on Word™ (Microsoft, Redmond, WA, USA) by writing down all the potential trainee questions and patient answers (for history and examination) as well as all the trainee possible propositions and comments (for investigation and management) such as "prescribed", "this is not useful" or "the Consultant / Attending does not agree with your decision". All storyboards were written by a junior surgeon (V.P.), and then reviewed by 2 experienced surgeons (L.B., R.A.). Consensus agreement on case content was achieved including input based on recent literature recommendations.[140–142]

Development of the cases

The development phase is about translating the case from a simple storyboard to a virtual interface where the trainee is able to select questions and propositions, the patient can actually "answer" using bubble speeches, and investigations can be obtained. Once storyboarded, case content was transcribed into Eclipse® editor (The Eclipse Foundation, Ottawa, ON, Canada), which is an open-source multi-language development environment. Its purposes are to produce XML files of data and to store them within a retrievable database. XML stands for eXtensible Markup Language, which is a computer-specific language. Case content was then uploaded onto a webplayer, which was hosted on an Imperial College server. This webplayer was formatted to communicate with the editor, and to enable recently developed cases to be uploaded from the developer's computer (V.P.). It also allowed the cases to be run through in a logical sequence.

Subsequently, cases were transferred to a user interface in Second Life™ through a message broker (Figure 13). This message broker was able to relay information from the user to the interface. After development, all cases were again assessed by 2 experienced surgeons (L.B., R.A.).

Interactivity

In order to provide a high fidelity simulated experience between the patient and the physician and heighten the trainee's sense of participation, interactivity tools were built into each scenario. Preoperative virtual patients were reviewed in the appropriate clinical environment, *i.e.* in the ER. An additional room, which would provide the blood requests and retrieval service, was located next to the ER. Patients' observations were displayed on a monitor and their abdomen could be palpated. Audio for breath sounds was also included. Cannulae, a urinary catheter and/or nasogastric tube would appear on the virtual patient when prescribed and appropriate. Finally, as described above, CT and US scan could be requested to assist in diagnosis, with the appropriate results retrievable by the user.

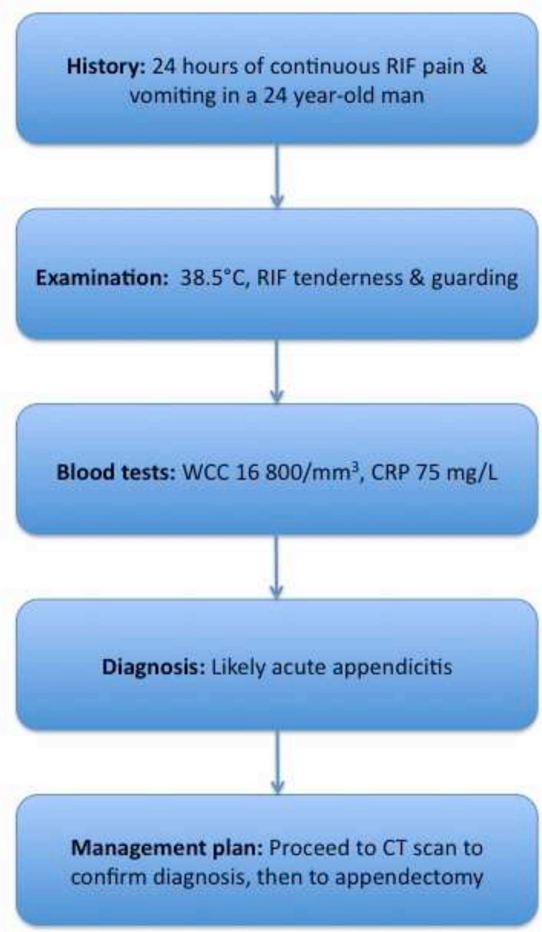


Figure 13: Linear string design of virtual patients (example: patient 1).

RIF: right iliac fossa, WCC: white cell count, CRP: C-reactive protein.

3.1.3.2 Intraoperative training: design of a virtual competency-based curriculum

Subjects

Novices (residents who had performed less than 10 laparoscopic appendectomies) and experienced surgeons (more than 100) were enrolled in the validation study to design a virtual curriculum for laparoscopic appendectomy on the LapSim®. Novices first completed a 1-day didactic seminar introducing them to the basics of laparoscopic surgery based upon material amended from the Royal College of Surgeons, as most of them had no previous laparoscopy experience.

Tasks & procedure performed

The first steps of a curriculum previously shown to have evidence for validity (Figure 8) were used for basic tasks at the easy, medium and difficult levels.[77] They encompassed 7 basic tasks, that aimed to teach instrument navigation, grasping tissues and clip application skills. The last step of the latter curriculum, a laparoscopic cholecystectomy, was replaced by a simulated laparoscopic appendectomy. Indeed, the LapSim® comprises a full laparoscopic appendectomy during which the trainee has to dissect the mesoappendix, apply 3 endoloops, then cut the appendix and insert it in an endoscopic bag. Scissors, graspers and a hook are available for use and instrument use is constrained by the presence of adjacent structures such as the caecum.

Performance assessment

Novices completed the first steps of the curriculum (all except the cholecystectomy) until proficiency at the difficult level as specified in Figure 8, and then performed 10 appendectomies for learning curve analysis. Experienced surgeons performed 2 repetitions of the laparoscopic appendectomy. The second performance of novices and experienced surgeons was compared for assessment of validity evidence, based on simulator-derived metrics on the LapSim®. These metrics were time taken, path length and performance score, the latter a composite score up to 100 based on successful placement of endoloops, tissue damage, sufficient dissection and removal of the appendix. Proficiency measures were based on the performance of experienced surgeons, as trainees are supposed to reach levels of proficiency on a VR model after training.[95]

Statistical analysis

The objective was to include 10 subjects in each group, based upon power calculations from previous studies on VR simulation.[77] The data were analyzed with the Statistical Package for the Social Sciences version 20 (SPSS, Chicago, IL) using nonparametric tests. Data on learning curves were analyzed by the Friedman test and multiple comparisons were then made to identify when the plateau of skills occurred. Comparison of performance between the experienced and the novice group was undertaken using the Mann-Whitney *U* Test. A level of $P < 0.05$ was considered statistically significant.

3.1.3.3 Postoperative training: design of virtual patients

The design of postoperative virtual patients followed the same framework as the preoperative patients'. Two postoperative cases were created representing 2 differing outcomes after laparoscopic appendectomy. Patients were reviewed in the surgical ward. The aim was to identify the patient's postoperative progression and initiate an appropriate management plan, according to literature.[143]

3.1.4 RESULTS

3.1.4.1 Preoperative training scenarios

Four preoperative virtual patient scenarios were designed, all presenting with acute RIF pain in the ER. The four cases were the following (the presentation of virtual patient 1 describes the interactive component of the case as an example; all cases have similar interactivity):

Virtual Patient 1

A 24 year-old man with a 24-hour history of RIF pain and vomiting. He had a temperature of 38.5 °C. Examination revealed RIF tenderness and guarding. His white cell count (WCC) was 16 800/mm^3 and C-reactive protein (CRP) 75 mg/L. The suspected diagnosis was acute appendicitis. Management plan was fasting, intravenous (IV) fluids, analgesia, antiemetics and antibiotics, proceed to abdominal CT scan to confirm diagnosis, and then proceed to appendectomy.

In practice, after being introduced by a nurse (please would you see this 24 year-old man) the patient "tells" the trainee by a bubble speech: "Doctor, I have pain in my tummy". The trainee then has the choice to click on history or examination. If he clicks on history, he can interrogate the patient on the type of pain, its localization and intensity, or if he has nausea/vomiting, if he passes flatus, etc… The patients will then "answer" each question, about the type of pain, when it started, etc… and his other symptoms if these are asked by the trainee. When the trainee clicks on examination, he can then palpate the abdomen or ask if bowel sounds are present. He can also make a pulmonary examination if he judges it necessary. A monitor, placed next to the patients indicates a temperature of 38.5 °C, as well as normal blood pressure and pulse. The trainee can then ask for investigations (blood tests, CT scan or US scan) and chose his management as described above.

Virtual Patient 2

A 28 year-old man with a 2-day history of continuous RIF pain. He reported 10 bowel movements over the last day. He presented with mild tenderness in his RIF. His WCC was 14 800/mm^3 and CRP 108 mg/L. His suspected diagnosis was terminal ileitis from Crohn's disease. Management plan was fasting, IV fluids, analgesia and antibiotics, proceed to abdominal CT scan and, after confirmation, ask for gastroenterology consultation.

Virtual Patient 3

A 22 year-old woman with a 24-hour history of continuous RIF pain. She had a background gynaecological history of heavy menstruation with irregular cycles. She presented with mild tenderness in her RIF. Her urine dipstick was ß-HCG negative, WCC was 12 200/mm^3 and CRP 38 mg/L. Management plan was analgesia and proceed to pelvic US scan. Her diagnosis was a haemorrhagic ovarian cyst: she was addressed to the gynaecological team.

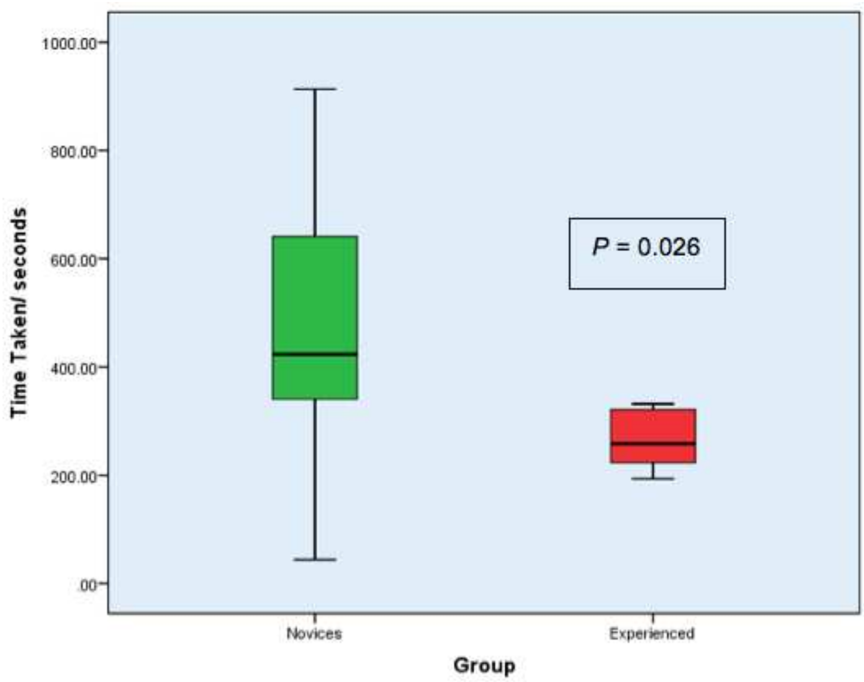
Virtual Patient 4

A 58 year-old man with a 2-day history of intermittent, cramping RIF pain without nausea or vomiting. He had had an increased frequency of defecation over the last 4 months with associated weight and appetite loss. He presented with mild tenderness in the RIF and the presence of bowel sounds. Haemoglobin level was 9.6 g/dL. His suspected diagnosis was caecal cancer. Management plan was to prescribe analgesia, proceed to abdominal CT scan to confirm the diagnosis, and then discuss his case with the multidisciplinary team (MDT).

3.1.4.2 Intraoperative training

Ten novices and 10 experienced surgeons were enrolled. Both time taken (285s for novices *vs.* 259s for experienced surgeons; P = 0.026) (Figure 14) and performance score (67% *vs.* 99%; P < 0.0001) demonstrated evidence for validity whilst path length did not (916 *vs.* 673 cm; $P = 0.113$). A significant learning curve was found for performance score ($P < 0.0001$) with plateau reached at the eighth repetition (Figure 15), whereas no significant learning curves were found for time taken ($P = 0.192$) and path length ($P = 0.117$). There were no differences between novices' tenth attempt and experienced surgeons' second attempt for time taken ($P = 0.814$) and performance score ($P = 0.711$). Experienced surgeons' time and performance score were therefore chosen for proficiency benchmark criteria (Figure 16).

Figure 14: Comparison of 10 experienced surgeons and 10 novices for time taken during a virtual laparoscopic appendectomy.



3.1.4.3 Postoperative training scenarios

The 2 postoperative cases were the following:

Virtual Patient 5

A 26 year-old man, who had a laparoscopic appendectomy 24 hours ago for non-perforated appendicitis. He had an uneventful recovery with little post-operative pain. Management plan was to discharge him with oral analgesia and no postoperative antibiotics.

Virtual Patient 6

A 26 year-old man who had a laparoscopic appendectomy 7 days ago. He had worsening lower abdominal pain for the last 5 days with associated vomiting. His temperature was 38.5 °C and he presented with guarding in his lower abdomen. WCC was 19 300/mm^3 and CRP 158 mg/L. Management plan was to prescribe fasting, IV fluids, analgesia, antiemetics and antibiotics, and proceed to abdominal CT scan. His diagnosis was a postoperative intra-abdominal abscess.

3.1.5 DISCUSSION

This study designed a pathway approach for surgical training, combining for the first time pre-, intra- and postoperative care in a published study. The acute appendicitis model was chosen because it is a common disease requiring elementary surgical skills. It was therefore a good “pilot” for this new approach of training. Moreover, laparoscopic appendectomy has shown a learning curve for technical skills[19] and residents’ participation was shown to be an independent risk factor for major postoperative complications after appendectomy.[140] Interactive pre- and postoperative care training was designed using 3D virtual patients. A competency-based curriculum with validity evidence was created on a VR simulator, while pre- and postoperative training still need support for validity. This type of training enables residents to follow a whole simulated care pathway from the ER to discharge.

Simulation has already demonstrated its positive impact for laparoscopic basic skills in the OR.[5–8] A major advance in technical skills training was the implementation of competency-based curricula on VR simulators, using proficiency goals based on measures with validity evidence[76,77] (automatic metrics such as time taken or number of movements).[94] One of these curricula was designed on the LapSim®,[77] a VR simulator that now provides a virtual laparoscopic appendectomy. We therefore decided to use that curriculum to build our care

Figure 15: Novice performance scores out of 10 attempts of virtual laparoscopic appendectomy compared to experienced surgeons. Performance score: out of 100 composite score based on successful placement of endoloops, tissue damage, sufficient dissection and removal of the appendix; novices: residents who have performed less than 10 laparoscopic appendectomies; experienced: surgeons who have performed more than 100 laparoscopic appendectomies. Whiskers stand for the 5th and 95th percentile, points stand for outliers within the 1st and the 99th percentile, and stars for outliers beyond these percentiles. 1, 11 and 12 stand for trainee 1 (who was an experienced surgeon), and trainees 11 and 12 (who were novices).

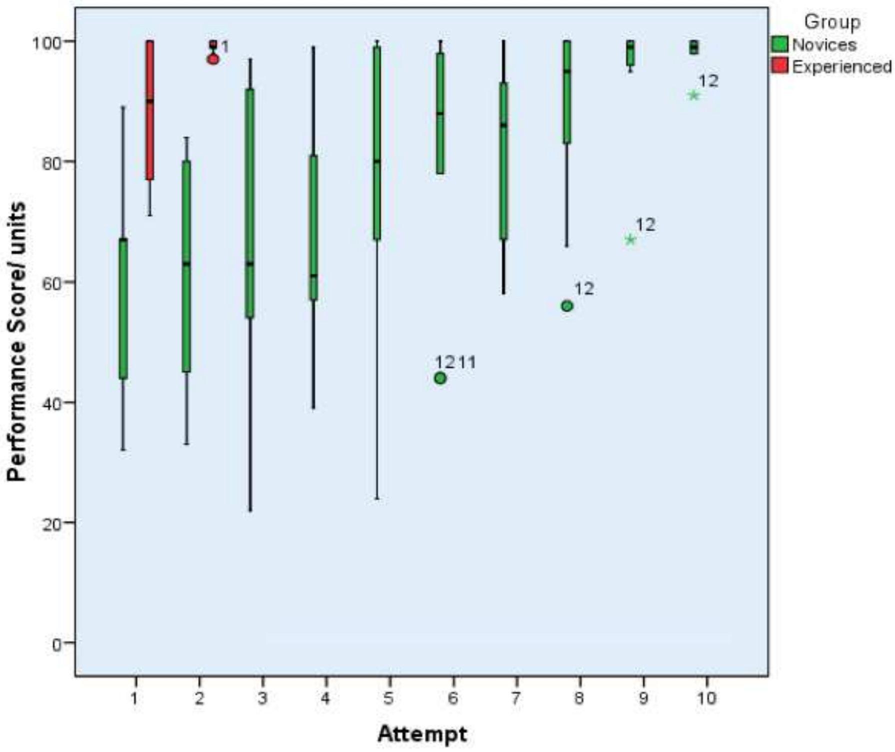
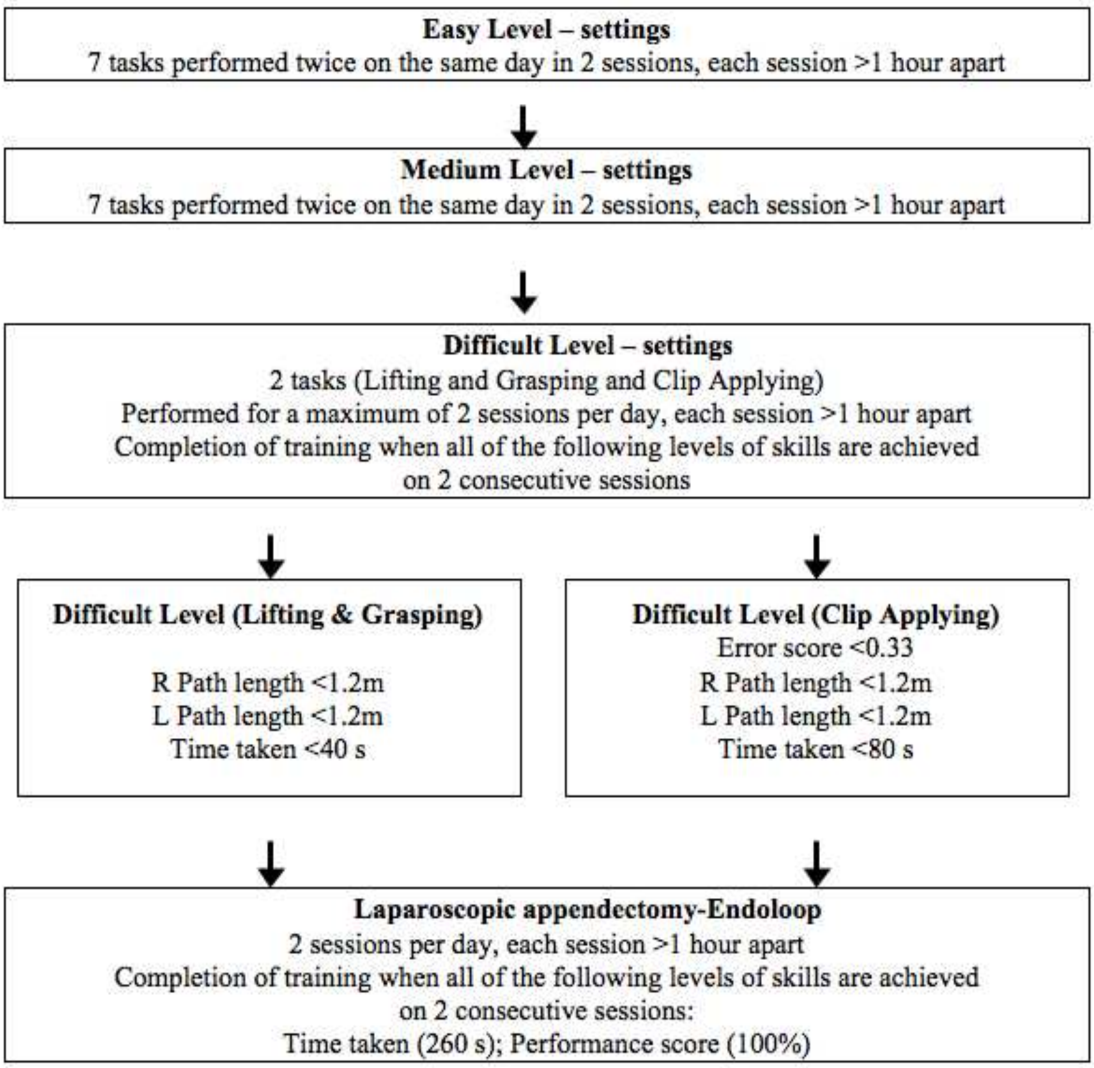


Figure 16: A virtual competency-based curriculum for laparoscopic appendectomy.



pathway training, replacing the cholecystectomy by the appendectomy module. However, such curriculum aims to train only in technical skills, and the purpose of our pathway approach was to train also in non-technical skills through pre- and postoperative care.

Experiential lectures are currently used in the educational system for non-technical skills training, without interaction or any notion of problem-based learning and pathway approach. Several fields of research have been developed to design interactive training models for non-technical skills. These models have been developed for intraoperative as well as pre- and postoperative care. Teamwork training has been designed in the simulated OR,[120,121] mainly for crisis scenarios. As for pre- and postoperative care, training models have already been designed in the simulated ward[129,130] and in the virtual world.[125–128] However, intra- and perioperative care training have always been performed apart form each other. Furthermore, no combination of training in technical and non-technical skills has been designed as a curriculum in literature. The only type of “combined” training published so far has associated technical skills training and formal lectures on intraoperative care, most of the time during workshops in advanced surgery.[50,60,62] This study is therefore the first of its kind, combining perioperative decision-making and intraoperative technical skills training in a structured care pathway manner. Support for validity has not been sought for virtual patients in literature so far, whereas seeking support for validity on intraoperative simulators is well known. The purpose of the present study was the design of the care pathway training. The validation of the pre- and post-operative phase is the purpose of a forthcoming study.

As mentioned above, interactive training for pre- and postoperative care can be performed either in the simulated ward or in virtual patients. Both have demonstrated fidelity, content validity and educational value.[126,144] The simulated ward has the advantage to be highly immersive, using actors that can perfectly mimic patients’ examination (such as abdominal tenderness, guarding or vomiting) within an environment looking very much like a real surgical ward, including drug charts and patient notes.[129,130] However, the simulated ward is expensive and presents both access issues and time constraints. In contrast virtual patients, designed in the virtual world of Second Life™, are free for end-users and easily accessible for everyone from a personal computer, hence easily disseminated to large groups.[134] Virtual patients are therefore an attractive tool for training in non-technical skills, and a growing number of academic institutions are exploring the methods through which virtual world technologies may be used in medical education.[135–137] However, interactivity and decision-making still need to be assessed, as the goal of the present study was only the design of the care pathway training. As mentioned above, a forthcoming research, currently performed in our department, should address this issue.

In the present study, virtual patients were designed and developed according to a framework published by our group,[125] according to the guidelines of Posel *et al.*[139] Previous design methods have been described for virtual patients. They include the linear string and the branching design method.[145] Whilst the branching method provides higher fidelity[139] it is much more complex in terms of design. We therefore chose the linear string method so that if the trainee chose the correct clinical decision then the case would end accordingly. Furthermore, the process of using a similar methodology to storyboard all the cases (history, examination, investigation and management) ensured that information could easily be transferred between cases, therefore reducing the time and cost for development of further variations of a case.[125]

Assessment tools have been designed for non-technical skills, such as the Non Technical Skills for Surgeons (NOTSS), the Non Technical Skills (NOTECHS) and the Observational Teamwork Assessment for Surgery (OTAS), but all have been grounded to the intraoperative care.[146] The skills assessed in NOTSS and NOTECHS are situation awareness, decision-making, task management, leadership, communication and teamwork. Our design of virtual patients did not aim to assess residents explicitly; the primary intention was to train them. Indeed, it did not appear relevant to assess trainees while comments were provided through case progression, giving the trainees feedback on their management outcomes.

Whilst training independently on either a VR simulator or virtual patients has demonstrated its positive impact on trainees' technical and non-technical skills, [5–8,144] the care pathway approach still needs to be implemented on real patients to demonstrate its educational value. Its cost-effectiveness has to be assessed compared to traditional training, taking into account the cost of both VR simulator acquisition and virtual patient development. Moreover, forthcoming research could design a care pathway approach for more complex laparoscopic surgery (such as gastric or colorectal) where decision-making and strategy are paramount. Finally, this type of training could be applied to new procedures (such as robotics or single port surgery) and new pathways of care, especially in the field of enhanced recovery. It could also be designed for non-surgical care: indeed, a pathway approach would be a suitable training in primary angioplasty for myocardial infarction.

A care pathway approach has been designed to train residents in general surgery. A common disease requiring basic skills was chosen as a pilot: acute appendicitis. Unlike previous curricula, the new training type will hopefully not only improve intraoperative skills but also pre- and postoperative care. However, future research still needs to appraise its educational value. A study currently performed in our department should address this issue.

3.2 IMPLEMENTATION OF A SURGICAL SIMULATION CARE PATHWAY APPROACH TO TRAINING IN EMERGENCY ABDOMINAL SURGERY

[Soumis à Annals of Surgery avec les auteurs suivants : Beyer-Berjot L, Patel V, Sirimanna P, Hashimoto DA, Berdah S, Darzi A, Aggarwal R.]

3.2.1 ABSTRACT

Objective: To determine whether a simulation-based care pathway approach (CPA) is feasible for training surgical residents, and could improve efficiency in patients' management.

Summary Background Data: So far, no study has assessed CPA training. A common disease was chosen: acute appendicitis.

Methods: All junior residents of our department were trained in CPA: preoperative CPA consisted in virtual patients (VP) presenting with acute right iliac fossa pain; intraoperative CPA involved a virtual competency-based curriculum for laparoscopic appendectomy (LAPP); finally, postoperative VP were reviewed after LAPP. Thirty-eight patients undergoing appendectomy were prospectively included before (n=21) and after (n=17) the training. All demographic and perioperative data were prospectively collected from their medical records, and time taken from admission to management was measured.

Results: Five residents were enrolled ranging from PGY 2 to 4. All had performed less than 10 LAPP as primary operator. Overall satisfaction was rated 3/5 for VP and 4/5 for intraoperative training; usefulness of preoperative, postoperative and intraoperative training was rated 3.5/5, 3/5 and 4.5/5, respectively. Pre- and intraoperative data were comparable between pre-training and post-training patients. Times to liquid and solid diet were significantly reduced after training (7 hours (2-20) *vs.* 4 (4-6); *P*=0.004, and 17 hours (4-48) *vs.* 6 (4-24); *P*=0.005) without changing postoperative morbidity (4 (19%) *vs.* 0 (0); *P*=0.11) and length of stay (48 hours (30-264) *vs.* 44 (21-145); *P*=0.22).

Conclusion: CPA training is feasible in abdominal surgery. In the current study, it improved patients' management in terms of earlier oral intake.

3.2.2 INTRODUCTION

Both technical and non-technical skills are essential in the training of surgeons.[119] Until now, training out of the operating room (OR) predominantly consisted of improving intraoperative technical skills using benchtop models and simulators.[1,2,119] This type of training has already demonstrated its positive impact for basic laparoscopic skills in the OR.[5–8] Non-technical skills are needed not only in the OR, but also in pre- and postoperative care:

indeed, Pucher, et al. recently showed that ward round quality had some impact on patients' outcomes in surgery.[122]

Most perioperative care training that have been published so far are experiential or via lectures, but not interactive between the trainees and the patients, *i.e.* that the patients themselves (virtual or actors) provide data about their chief complaint, history and exam. The best-known field of research for this type of interactive training is the simulated ward, a high-fidelity model using actors to play patients within an environment pertaining to a real surgical ward.[129,130] However, the simulated ward is expensive and presents both access issues and time constraints. An attractive field of interactive training is the use of online 3D virtual patients (VP), using pre- and postoperative scenarios.[125] VP have demonstrated fidelity and content validity.[126] Moreover, they are uploaded on a virtual world that is easily accessible through an Internet connection.

Ideally, training out of the OR should therefore imply training in the intra- and perioperative care. Care pathway approach implies both technical skills training on a simulator, and training in pre- and postoperative care: the purpose of perioperative training is to improve both decision-making and knowledge. So far, no study has evaluated the impact of care pathway training on the healthcare system.

In a previous study, we designed a curriculum to teach pre, intra, and post-operative surgical care (a care pathway) for acute appendicitis.[147] We used VP for the pre and post-operative phases, and a virtual simulator for the intraoperative phase, which demonstrated validity evidence. The objectives of the present study were to implement such simulation-based curriculum, assessing its feasibility in a department of surgery, and its impact on the healthcare system.

3.2.3 METHODS

3.2.3.1 Study population

This was a prospective one-center study, performed in the department of digestive surgery of St. Mary's Hospital, Imperial College Healthcare NHS Trust, London. The study was approved by the NRES Committee London – Central. Thirty-eight consecutive patients undergoing appendectomy were included before (n=21) and after (n=17) the training of residents, after giving informed consent.

The data included the following: demographic data, such as age, gender and American Society of Anesthesiology score (ASA score);[148] preoperative data, such as Alvarado score,[149] rebound tenderness, fever, hyperleukocytosis, performance of ultrasound (US) or computed tomography (CT) scan, time from admission to: see the resident in surgery, get US- or CT-scan, get antibiotics; intraoperative data, such as time from admission to surgery, type of approach (*i.e.,* laparoscopic or open), conversion to open surgery, rate of difficulty (on a 1 to 5 scale), Objective Structured Assessment of Technical Skills (OSATS) self rating[150], intraoperative findings (*i.e.,* normal, inflamed or perforated appendix, abscess, other diagnosis), intraoperative complications, and operative time; and postoperative data, such as postoperative morbidity (according to Dindo's classification)[151], including gastrointestinal complications, additional surgery and mortality, appropriate duration of antibiotics, type of analgesia, postoperative pain at Day 1 (according to an analogue visual scale (AVS) from 1 to 10), time to liquid and solid diet, length of stay, and confirmation of appendicitis on histopathological analysis.

3.2.3.2 Care pathway curriculum

The curriculum design was previously published (Figure 1).[147] In summary, 4 preoperative VP were designed in the virtual world of Second Life™ (Linden Research Inc, San Francisco, CA, USA). All presented with acute right iliac fossa (RIF) pain in the emergency room (ER): not all of the VP actually had acute appendicitis and thus not all required an operation; the objectives of such cases were to elicit the relevant clinical information from the history and examination, establish the pertinent investigation findings, determine the correct diagnosis and initiate an appropriate management plan, according to literature.[141,142] Intraoperative training consisted in a competency-based curriculum for laparoscopic appendectomy (LAPP) on a virtual reality (VR) simulator: the LapSim® (Surgical Science, Göteborg, Sweden). This curriculum encompassed 7 basic tasks at different levels of difficulty and a full LAPP. It has demonstrated validity evidence.[147] Finally, trainees reviewed 2 VP after LAPP, with uneventful and complicated outcomes. The aim was to identify the patient's postoperative progression and initiate an appropriate management plan, according to literature.[143]

3.2.3.3 Trainees

All junior residents (foundation year and core trainees) of the department were trained in a care pathway approach. Before entering the study, all residents gave informed consent and fulfilled a questionnaire about their seniority and surgical experience. Each session lasted one hour, and consisted in training on one preoperative VP, then on one step of the intraoperative curriculum, and finally on one postoperative VP. Two sessions per day were performed. Training was completed when correct management was achieved for all VP and proficiency goals were reached at every steps of the competency-based curriculum. All residents gave informed consent. At the end of the training, they responded to a satisfaction questionnaire (Annex 1).

3.2.3.4 Definitions

Fever was defined as an elevation of temperature over 37,3°C, according to the Alvarado score.[149] Hyperleukocytosis was defined as > 10,000 /mm³. Conversion to open surgery was defined as any unplanned incision or a planned incision longer than 6 cm. Appropriate duration of antibiotics was defined as pre- or intraoperative, and no postoperative antibiotics in case of non perforated appendix, and 3 to 5 days of postoperative antibiotics in case of perforation.[143,152] Mortality was defined as death occurring in the hospital or within 30 days. Postoperative morbidity was defined as complications occurring in the hospital or within 30 days after surgery. Major complications were defined as those requiring surgical, radiological or endoscopic intervention (Dindo III), life-threatening complications requiring intensive care management (Dindo IV) and death (Dindo V).[151]

3.2.3.5 Statistical analysis

The quantitative data were reported as the medians and range. Normally distributed quantitative data were analyzed with Student's *t* test, and the Mann-Whitney test was used otherwise. The qualitative data were reported as the number of patients (percentage of patients) and were compared using the Pearson's χ^2 test or the Fisher's exact test, as appropriate. The tests were always 2-sided, and the level of statistical significance was set at $p < 0.05$. As this study was the first of its kind, data was lacking to formulate formal power calculations to determine the number of included patients: a convenience sample was therefore chosen. The analysis was performed using the Statistical Package for the Social Sciences software (SPSS, version 20, Chicago, IL, USA).

3.2.4 RESULTS

Five residents were enrolled, ranging from PGY 2 to 4. They were 3 women and 2 men, aged 27 (26-32). All had performed less than 10 LAPP as primary operator, and 3 had performed none. Four residents had performed less than 5 open appendectomies, and one had performed between 5 and 10. Finally, 3 residents had performed no laparoscopic procedures as primary operator, and 2 had operated between 10 and 20 laparoscopic cases. Overall satisfaction was rated 3/5 for VP and 4/5 for intraoperative training; usefulness of preoperative, postoperative and intraoperative training was rated 3.5/5, 3/5 and 4.5/5, respectively.

Preoperative data of pre-training and post-training patients are reported in Table 1. Demographic data and clinical presentations were comparable between groups, and preoperative management did not differ after the training.

Intraoperative data were comparable between pre-training and post-training patients (Table 2). Laparoscopy was performed in 37 patients (97,4%), with a conversion rate of 5,3%. Appendix was mostly inflamed (20 patients, 52,6%) and found normal in 6 patients (15,8%). In the latter case, it was removed in 2 patients (33,3%). In the other 4 patients, another diagnosis was made intraoperatively (1 terminal ileitis, 1 tubo-ovarian abscess, 1 retrograde menstruation, and 1 free fluid of unknown origin). Abscess only occurred as a subset of the patients with perforated appendix. Procedures were performed by senior residents (registrars) in all patients except one in the post-training group, who was operated by a trainee. Trainees were primary assistants otherwise.

Postoperative data are reported in Table 3. Times to liquid (7 hours (2-20) *vs.* 4 (4-6); $P = 0.004$) and solid diet (17 hours (4-48) *vs.* 6 (4-24); $P = 0.005$) were significantly reduced after training. There was also a trend toward less post-operative pain (1 (0-3) *vs.* 0 (0-2); $P = 0.07$), and fewer complications (4 (19%) *vs.* 0 (0); $P = 0.11$), though not significant. Finally, length of stay was not modified (48 hours (30-264) *vs.* 44 (21-145); $P = 0.22$). No patients were readmitted or reoperated within 30 days.

3.2.5 DISCUSSION

This study implemented for the first time a pathway care approach to training in abdominal surgery, combining VP with competency-based curriculum on a VR simulator. We chose a common disease requiring essential skills: acute appendicitis. All junior residents of our department of digestive surgery were trained, with good feedback on satisfaction and usefulness. Even if the number of trainees was low (5), the purpose was to train all the junior residents of the department, which was achieved. The training did not have any impact on junior residents' participation in the OR, but improved patients' management in the surgical ward in terms of earlier oral intake, solid and liquid. There was also a trend toward less post-operative pain and fewer complications, though not significant. Such pathway care approach to training is therefore feasible, with positive impact on the healthcare system.

Lectures were traditionally used in the educational system for non-technical skills training. Recently, blended learning has spread, combining face-to-face courses with e-learning to improve interaction and problem-based learning, by resorting to videos, pictures, podcasts, and multiple choice questions.[123] In their review, Rowe, *et al.* found that blended learning had shown interesting results for healthcare students, especially in "bridg(ing) the gap between theory and practice and improv(ing) a range of selected clinical competencies among students". However, most studies had methodological flaws and their average quality was low.[124] Moreover, blended learning is not structured in a pathway care manner, and has not been designed in an immersive way. Pathway care training is therefore an additional, immersive training, which has not been designed to replace blended learning or classical companionship, but to complete them.

Table III: Preoperative data of 38 patients undergoing appendectomy before (pre-training group) and after (post-training group) pathway care training of residents.

	Pre-training Group, n = 21	Post-training Group, n = 17	*P*
Age (years)	27 (17-68)	25 (16-48)	0.64
Gender: male, n (%)	12 (57)	7 (41)	0.33
ASA score (1-4)	1 (1-3)	1 (1-2)	0.71
Alvarado score (0-10)	8 (4-10)	9 (4-10)	0.68
Rebound, n (%)	18 (86)	11 (65)	0.25
Fever, n (%)	10 (48)	5 (29)	0.33
Hyperleukocytosis, n (%)	17 (81)	12 (81)	0.71
Time to see the resident (minutes)	180 (70-445)	187 (110-450)	0.71
Time to get antibiotics (hours)	11 (1-23)	11 (4-26)	0.89
Clinical diagnosis only, n (%)	12 (57)	7 (41)	0.33
US scan, n (%)	7 (33)	8 (47)	0.51
Time to get US scan (hours)	8 (5-13)	10 (4-23)	0.27
CT scan, n (%)	2 (10)	2 (12)	1
Time to get CT scan (hours)	13 (9-16)	19 (9-29)	0.67

ASA: American Society of Anaesthesiology; US: Ultrasound; CT: Computed Tomography. The data are reported as the median and range.

Table IV: Intraoperative data of 38 patients undergoing appendectomy before (pre-training group) and after (post-training group) pathway care training of residents.

	Pre-training Group, n = 21	Post-training Group, n = 17	*P*
Time to operation (hours)	20 (7-58)	20 (4-35)	0.96
Laparoscopy, n (%)	21 (100)	16 (94)	0.45
Conversion into open surgery, n (%)	2 (10)	0 (0)	0.49
Rate of difficulty (1-5)	3 (1-5)	3 (1-4)	0.97
Self OSATS (7-35)	25 (13-33)	28 (24-33)	0.16
Operative time (minutes)	60 (45-135)	60 (30-150)	0.50
Inflamed appendix, n (%)	12 (57)	8 (47)	0.75
Perforated appendix, n (%)	6 (29)	6 (35)	0.49
Abscess, n (%)	3 (14)	4 (24)	0.68
Normal appendix, n (%)	3 (14)	3 (18)	1
Other diagnosis, n (%)	3 (14)	1 (6)	0.61
Intraoperative complication, n (%)	1 (5)	0 (0)	1

OSATS: Objective Structured Assessment of Technical Skills. The data are reported as the median and range.

Table V: Postoperative data of 38 patients undergoing appendectomy before (pre-training group) and after (post-training group) pathway care training of residents.

	Pre-training Group, n = 21	Post-training Group, n = 17	*P*
Appropriate duration of antibiotics, n (%)	18 (86)	17 (100)	0.24
Time to liquid diet (minutes)	7 (2-20)	4 (4-6)	0.004
Time to solid diet (minutes)	17 (4-48)	6 (4-24)	0.005
Postoperative pain (0-10)	1 (0-3)	0 (0-2)	0.07
IV analgesics at Day 1*	5 (25)	0 (0)	0.13
Oral opioid at Day 1*	11 (55)	11 (85)	0.13
Complications, n (%)	4 (19)	0 (0)	0.11
Major complications, n (%)	0 (0)	0 (0)	ns
GI complications, n (%)	4 (19)	0 (0)	0.11
Length of stay (hours)	48 (30-264)	44 (21-145)	0.22
Appendicitis on histology, n (%)	16 (76)	10 (59)	0.37

IV: Intravenous; GI: Gastrointestinal. The data are reported as the median and range. * Based on available charts, i.e. 20 in the pre-training and 13 in the post- training group.

Several fields of research have been developed to design immersive training models for non-technical skills, both for intra- and perioperative care: teamwork training in the simulated OR for intraoperative care (mainly for crisis scenarios);[120,121] simulated ward and VP for perioperative care. [125–130] However, intra- and perioperative care training have always been performed apart form each other. Furthermore, no combination of training in technical and non-technical skills has been designed as a curriculum in literature. The only type of "combined" training published so far has associated technical skills training and formal lectures on intraoperative care, most of the time during workshops in advanced surgery.[50,60,62] This study is therefore the first of its kind, combining perioperative decision-making and intraoperative technical skills training in a structured care pathway manner.

Both simulated ward and VP have demonstrated fidelity, content validity and educational value.[126,144] The simulated ward is highly immersive, using actors that can perfectly mimic patients' examination (such as abdominal tenderness, guarding or vomiting) within an environment looking very much like a real surgical ward, including drug charts and patient notes.[129,130] Moreover, it comprises a validated simulation-based curriculum[131] and the Ward Non Technical Skills (W-NOTECHS) assessment tool.[132] However, the simulated ward is expensive and presents both access issues and time constraints. In contrast VP, designed in the virtual world of Second Life™, are free for end-users and easily accessible for everyone from a personal computer, hence easily disseminated to large groups.[134] VP are therefore an attractive tool for training in non-technical skills, and a growing number of academic institutions are exploring this field.[135–137] Our design of VP did not aim to assess residents explicitly; the primary intention was to train them through a simulation-based curriculum.[147] Indeed, it did not appear relevant to assess trainees while comments were provided through case progression, giving the trainees feedback on their management outcomes. Hence, educational value of VP was measured by their impact on the healthcare system, which was positive.

Simulation has already demonstrated its positive impact for laparoscopic basic skills in the OR.[5–8] A major advance in technical skills training was the implementation of competency-based curricula on VR simulators, using proficiency goals based on measures with validity evidence.[76,77] One of these curricula was designed on the LapSim®, a VR simulator that provides a virtual laparoscopic appendectomy.[147] Indeed, laparoscopic appendectomy has shown a learning curve for technical skills,[142] and residents' participation appeared to be an independent risk factor for major postoperative complications after appendectomy.[140] However, such a curriculum aims to train only in technical skills, and the purpose of our pathway approach was to train also in non-technical skills through pre- and postoperative care. In the present study, training on technical skills did not improve junior residents' participation in the OR. Hence, OSATS rating was not relevant and was unsurprisingly comparable before and after the training. This finding shows that trainees' participation as primary operator does not only depend on their own skills, but also relies on their seniors' ability and confidence. Training out of the OR seems all the more crucial that OR access is scarce as primary operator.

Whilst training independently on either a VR simulator or VP had demonstrated its positive impact on trainees' technical and non-technical skills,[5–8,144] the care pathway approach still needed to be implemented on real patients to demonstrate its educational value. This was done in the present study, both confirming the feasibility of such training, and showing its positive impact on patients' management. Forthcoming research should design care pathway to training in more complex surgery, where decision-making and strategy are paramount. Finally, this type of training could be applied to new procedures (such as robotics or single port surgery) and new pathways of care, especially in the field of enhanced recovery.

It could also be designed for non-surgical care: indeed, a pathway approach would be, for example, a suitable training in primary angioplasty for myocardial infarction.

A care pathway approach to training in emergency abdominal surgery has been implemented for acute appendicitis. It both demonstrated its feasibility in a surgical department, and its positive impact on patients' management. Forthcoming studies should focus on more complex surgery, where intraoperative skills, strategy, and decision-making are paramount, and new pathways of care.

4 A VIRTUAL REALITY TRAINING CURRICULUM FOR LAPAROSCOPIC COLORECTAL SURGERY

Devant les résultats encourageants de ces travaux préliminaires, nous avons développé une FPSS en chirurgie colorectale. La première étape, ci-dessous, a consisté à valider un programme d'entrainement virtuel (PEV). Cette étude a été présentée en 2012 au London Surgical Symposium, Imperial College, et au 8ème Congrès Francophone de Chirurgie Digestive et Hépatobiliaire. Elle est actuellement soumise au Journal of the American College of Surgeons avec les auteurs suivants: Beyer-Berjot L, Berdah S, Hashimoto DA, Darzi A, Aggarwal R.

4.1 ABSTRACT

Background: Training within a competency-based curriculum outside the operating room (OR) enhances performance during real basic surgical procedures. This study aimed to design a virtual reality (VR) competency-based curriculum for an advanced laparoscopic procedure: a sigmoid colectomy.

Methods: Novices (surgeons who had performed <5 laparoscopic colorectal resections as primary operator), intermediate (between 10 and 20) and experienced surgeons (>50) were enrolled. Construct validity was based on metrics given by a VR simulator, the Lap Mentor™, during the second attempt of each task in between groups. The tasks assessed were 3 modules of a laparoscopic sigmoid colectomy (medial dissection, lateral dissection, anastomosis) and the full procedure. Novices were randomly assigned to one of two groups to perform 8 further attempts of all 3 modules or the full procedure, for learning curve analysis.

Results: Twenty novices, 7 intermediate and 6 experienced surgeons were enrolled. Medial and lateral dissection tasks, as well as the full procedure, demonstrated construct validity for time (*P*=0.005, *P*=0.003 and *P*=0.001 respectively), number of movements (*P*=0.013,

P=0.005 and P=0.001) and path length (P=0.03, P=0.017 and P=0.001), whereas the anastomosis did only for time (P=0.03) and path length (P=0.013). Significant learning curves were found for time, movements and path length in the medial and lateral dissection tasks, and also for the full procedure. Experienced surgeons' benchmark criteria were defined for all construct valid metrics.

Conclusions: A competency-based training curriculum in laparoscopic colorectal surgery has been designed. Such training may reduce the learning curve during real colorectal resections in the OR.

4.2 INTRODUCTION

Surgical training outside the operating room (OR) using simulation has widely spread this last decade, especially in laparoscopic surgery[1,2]. Many studies have assessed simulation for basic laparoscopic skills (such as basic drills, laparoscopic cholecystectomy, appendectomy and hernia repair)[3,4], and training out of the OR has proven its positive impact in basic skills during real laparoscopic procedures in patients[5–8]. Virtual reality (VR) simulators have the advantage to provide automatic and instantaneous measures of performance: these metrics can serve to monitor progress while learning a technical skill, aid in the provision of structured feedback, and ultimately ensure that proficiency criteria have been reached[94,95]. By drawing attention to only the most educationally valuable tasks and performance metrics, curricula can make an important contribution to the effectiveness of VR training. Such curricula were implemented in basic laparoscopic surgery and endoscopy[76–78].

A further step in education would be to design competency-based curricula for advanced training in laparoscopic abdominal surgery (ATLAS). Such training may reduce learning curves and improve patients' safety in the OR. Indeed, junior surgeons have limited access to these complex procedures as primary operator[11] while, for example, the learning curve in laparoscopic colorectal surgery (LCS) is estimated between 30 and 60 cases[71–73]. However, this field of research is still quite poor, as most studies appraising education in ATLAS are purely descriptive. In their systematic review, Miskovic *et al.* found only 6 studies assessing simulation in LCS: they concluded that there was a "notable lack of available data on the educational value of simulated training"[11]. The aim of the present study was to design a VR competency-based curriculum for an advanced laparoscopic procedure: a sigmoid colectomy.

4.3 METHODS

4.3.1 Participants

This was a multi-site project. Surgeons of 3 different levels of experience (novices, intermediate, and experienced surgeons) were recruited to participate in the study, in the United Kingdom and in France. Residents in surgery who had performed more than 5 basic laparoscopic procedures (*i.e.* cholecystectomy, appendectomy, hernia repair) and less than 5 laparoscopic colorectal resections (LCR) as primary operator were eligible for recruitment to the novice group. Surgeons who had performed between 10 and 20 LCR as primary operator were eligible for the intermediate group, and surgeons who had performed more than 50 LCR were eligible for the experienced group.

All participants completed a questionnaire (Annex 2) concerning their age, gender and seniority, their experience in laparoscopic and colorectal surgery (as primary operator and assistant), their dominant hand and their video games practice. Participation was based on voluntary basis.

4.3.2 Simulation tool

The Lap-Mentor™ (Simbionix, Cleveland, OH, USA) is the latest generation VR simulator, incorporating haptic feedback. It comprises basic tasks, suturing tasks, procedural tasks or modules, and full procedures that range from basic (cholecystectomy, hernia repair) to advanced laparoscopic surgery (gastric by-pass, hysterectomy, sigmoid colectomy). The VR images are based on MRI and *in vivo* laparoscopy for procedural tasks and full procedures.

4.3.3 Procedural tasks and metrics

Colorectal training encompasses 2 items on the Lap-Mentor™: a full laparoscopic sigmoid colectomy (LSC) performed for carcinoma of the sigmoid colon, which comprises the whole dissection (Figure 17) and an anastomotic module. Procedural tasks of medial and lateral dissection were defined within the full sigmoid colectomy. Hence, 3 procedural tasks (medial and lateral dissection, anastomosis) and a full procedure were assessed (Table VI).

Figure 17: Laparoscopic sigmoid colectomy performed on the Lap-Mentor™.

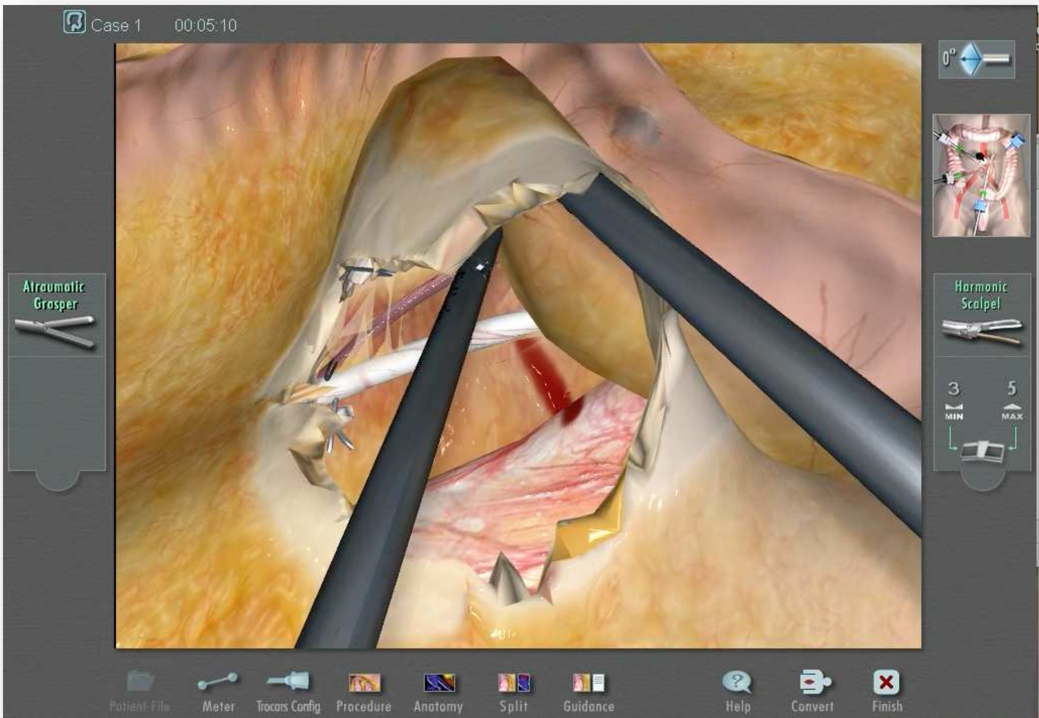


Table VI: Procedural tasks and full procedure (laparoscopic sigmoid colectomy).

Procedural tasks	**Description**
Medial Dissection	Module completed when: • Peritoneal incision is performed from the promontory to 1 cm above the inferior mesenteric vein • Left ureter and genital vein are identified • Inferior mesenteric artery and vein are dissected, clipped (x2) and cut • Colon is mobilized from medial to lateral
Lateral Dissection	Module completed when: • Peritoneal incision is performed from the promontory to the end of the drawn white line of the Toldt's fascia (no mobilization of the splenic flexure) • Left ureter and genital vein are identified • Colon is mobilized from lateral to medial
Anastomosis	Module completed when: • Stapled colorectal anastomosis is performed laparoscopically (an anvil has already been positioned at the colonic end at the beginning of the module)
Full procedure: LSC (dissection)	Procedure completed when: • Medial dissection is performed first • Peritoneal incision is performed medially from 1 cm above the inferior mesenteric vein and laterally from the end of the drawn white line of the Toldt's fascia (no mobilization of the splenic flexure) to 5 cm below the promontory, with a complete mobilization of the colon • Left ureter and genital vein are identified • Inferior mesenteric artery and vein are dissected, clipped (x2) and cut • Rectum is dissected, stapled and cut

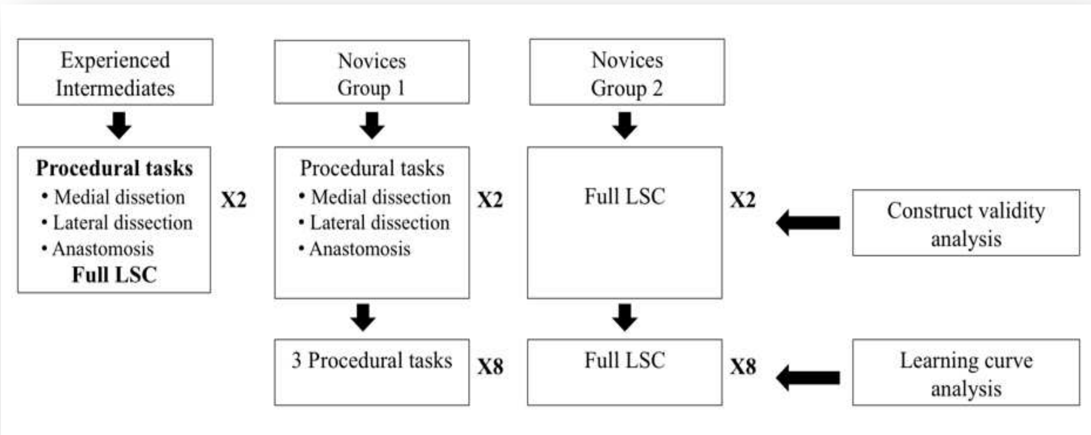
4.3.4 Definitions

The qualities of procedural tasks and full LSC were assessed according to standard definitions[14]. Construct validity was defined as the simulator ability to distinguish between groups of individuals with different levels of experience. Fidelity was defined as the extent to which the examination resembled real life situations, and content validity was defined as the extent to which the domain that was being measured was measured by the assessment tool.

4.3.5 Study design (Figure 18)

Figure 18: Study design.

LSC: Laparoscopic Sigmoid Colectomy.



Intermediate and experienced candidates performed 2 repetitions of all procedural tasks and the full procedure. Novices were randomized (sealed envelopes) into 2 groups to performed 10 repetitions of all 3 procedural tasks, or the full procedure. Beforehand, all novices performed 2 basic tasks that previously demonstrated construct validity on the Lap-Mentor™ (task 5: clipping and grasping; task 6: two-handed maneuvers)[76]. All sessions were completed at least 1 hour apart, and those in the novice groups completed no more than 2 sessions per day. Novices had no specific training between sessions, but received only classic apprenticeship.

The second attempt of each task / procedure was compared in between groups for construct validity analysis, and benchmark criteria were based on the median performance of the experienced group. Novices' 8 further attempts were performed for learning curve analysis, and to ensure that novices' performance could meet benchmark criteria.

After completion, all candidates rated their satisfaction and the training overall usefulness on a Likert scale ranging from 1 to 5. Intermediate and experienced candidates also rated overall realism, ergonomy, force feedback, as well as realism of Toldt fascia dissection, colonic mobilization, vessels dissection, left ureter and genital vein identification, rectal dissection, rectal stapling and anastomosis, for fidelity and content validity analysis (Annex 3).

4.3.6 Statistical analysis

The number of subjects per group was based on a two-tailed test, with $\alpha = 0{\cdot}05$ and power $(1 - \beta) = 0{\cdot}80$, and an intended reduction of 30 per cent in time taken to complete procedures for experienced versus novice surgeons, based on data from previous studies of VR simulation.[11,12] The quantitative data were reported as median and range, and were analyzed using the Mann-Whitney test. Learning curves and plateaus were analysed using the Skillings-Mack test, on STATA. The other analyses were performed using the Statistical Package for the Social Sciences software (SPSS, version 19.0, Chicago, IL, USA). Tests were always 2-sided, and the level of statistical significance was set as $P < 0.05$.

4.4 RESULTS

4.4.1 Participants

Thirty-three candidates participated in the study, including 20 novices, 7 intermediate and 6 experienced surgeons. Median age was 31 ± 5 years (range, 26-49). Nineteen candidates (57,6%) were men, 29 (87,9%) were right-handed, and 9 (27,3%) were video game players, comprising 5 novice, 2 intermediate and 2 experienced surgeons.

Among novices, median seniority was 3 years. Eleven novices (55%) had performed less than 20 laparoscopic procedures, and 14 (70%) had never performed any LCR as primary operator: the other 6 (30%) had performed between 1 and 5 LCR and were at least PGY4. No residents were excluded from the novice groups for having performed more than 5 LCR as primary operator. Eight novices (40%) had attended at least 20 LCS as first assistant. Sixteen (80%) had performed less than 10 open colorectal resections as primary operator, including 6 (30%) who had performed none. Novices were randomized in 2 groups of 10 to perform either the 3 procedural tasks (Group 1) or the full procedure (Group 2). There were no differences of performance between Group 1 and Group 2 during initial assessment of basic tasks 5 and 6 (Table VII).

4.4.1 Construct Validity (Table VIII)

Medial dissection, lateral dissection and full LSC demonstrated construct validity between novices and experienced surgeons for time (*P*=0.005, *P*=0.003, and *P*=0.001), number of movements (*P*=0.013, *P*=0.005, and *P*=0.001) and path length (*P*=0.03, *P*=0.017 and *P*=0.001). Only time (*P*=0.03) and path length (*P*=0.013) were construct-valid for the anastomosis module. All metrics were construct-valid between novices and intermediate surgeons. On the other hand, no metrics demonstrated construct validity between intermediate and experienced surgeons, except time in the full LSC (*P*=0.037) (Figure 19).

Table VII: Initial assessment of novices during laparoscopic basic tasks.

No.: number. Group 1 is to train on procedural tasks and Group 2 on the full procedure. Values are median, with inter-quartile range in parentheses.

Basic Tasks	**Group 1**	**Group 2**	***P***
Task 5: Clipping & Grasping			
Time (seconds)	114 (70-175)	112 (96-144)	0,74
Task 6: Two-handed Maneuvers			
Time (seconds)	116 (85-183)	146 (75-179)	0,5
No. of Movements	126 (79-228)	158 (119-218)	0,082
Path Length (cm)	436 (352-778)	497 (387-628)	0,33

Figure 19: Construct validity: Time taken during the full laparoscopic sigmoid colectomy.

Horizontal lines within boxes, boxes and whiskers represent the 50^{th}, $25^{th}/75^{th}$, and $5^{th}/95^{th}$ percentile, respectively. Outliers are represented by solid dots.

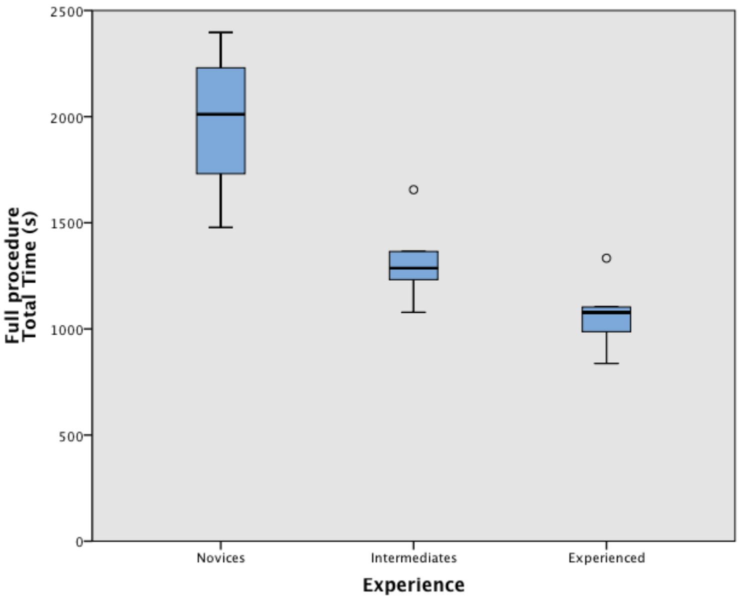


Table VIII: Construct validity of procedural tasks and full laparoscopic sigmoid colectomy.

No.: number. LSC: Laparoscopic Sigmoid Colectomy. Construct-valid metrics are highlighted in grey. Values are median, with inter-quartile range in parentheses.

	Novices	Intermediates	Experienced	*P* Novices *vs* Experienced	*P* Novices *vs* Intermediates	*P* Experienced *vs* Intermediates
Medial Dissection						
Time (s)	870 (556-1407)	618 (429-854)	527 (270-701)	0,005	0,015	0,39
No. of movements	1784 (899-3119)	1108 (707-1653)	1104 (449-1425)	0,013	0,015	0,72
Path Length (cm)	3436 (1453-5181)	1947 (1338-3010)	2056 (992-2716)	0,03	0,025	0,89
Lateral Dissection						
Time (s)	540 (339-867)	336 (199-399)	327 (215-375)	0,003	0,002	1
No. of movements	1102 (893-2240)	735 (410-891)	654 (517-1056)	0,005	0,001	0,89
Path Length (cm)	1813 (1590-4564)	1425 (816-1678)	1371 (939-2188)	0,017	0,002	0,89
Anastomosis						
Time (s)	287 (101-983)	114 (103-227)	119 (81-227)	0,03	0,015	0,83
No. of movements	243 (54-1273)	90 (59-169)	66 (23-296)	0,057	0,019	0,57
Path Length (cm)	427 (148-1483)	188 (85-347)	141 (55-407)	0,013	0,019	0,48
Full LSC						
Time (s)	2011 (1478-2397)	1287 (1078-1656)	1078 (837-1333)	0,001	0,002	0,037
No. of movements	4158 (3268-5007)	2581 (2166-2843)	2103 (1842-2792)	0,001	0,001	0,055
Path Length (cm)	8059 (6380-9630)	4759 (4665-5945)	4535 (3339-5157)	0,001	0,002	0,26

4.4.2 Learning curves and benchmark criteria (Table IX, Figures 20a & 20b)

Learning curve analysis found significant improvements in the 3 assessed metrics (time, movements, path length) for medial and lateral dissection, as well as full LSC. Learning was consistently found to plateau at or beyond the 6th attempt for full LSC. Importantly, there were no differences between novices' 10th attempt and experienced surgeons' performance (*i.e.* 2nd attempt) in any metric. Hence, choosing experienced surgeons' performances as benchmark criteria seemed relevant. Finally, no significant learning curves were found for the anastomosis module.

Table IX: Significance of learning curves. Evolution of performances across the 10 attempts is compared using the Skillings-Mack test. *No.: number. LSC: Laparoscopic Sigmoid Colectomy. N/A: not applicable. Significant learning curves are highlighted in grey. Values in the right column correspond to the number of attempts to reach a plateau.*

	P **Learning curve**	**Plateau**
Medial Dissection		
Time	0,008	2
No. of movements	0,019	3
Path Length	0,024	2
Lateral Dissection		
Time	0,009	3
No. of movements	0,021	2
Path Length	0,029	3
Anastomosis		
Time	0,099	N/A
No. of movements	0,27	N/A
Path Length	0,15	N/A
Full LSC		
Time	0,0001	6
No. of movements	< 0,0001	7
Path Length	0,0002	6

Figure 20a: Learning curve: Time taken for the medial dissection module across the novices' 10 attempts. *Horizontal lines within boxes, and boxes represent the 50th and 25th/75th percentile, respectively. Outliers are represented by solid dots.*

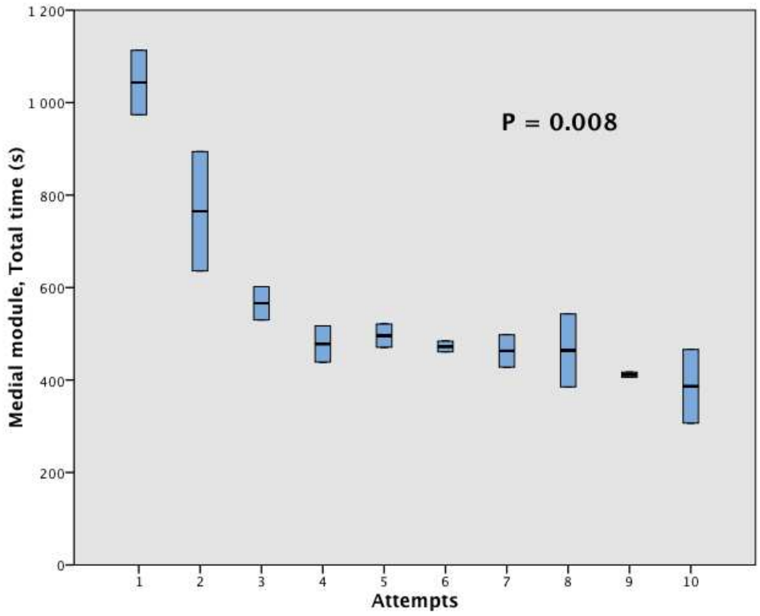
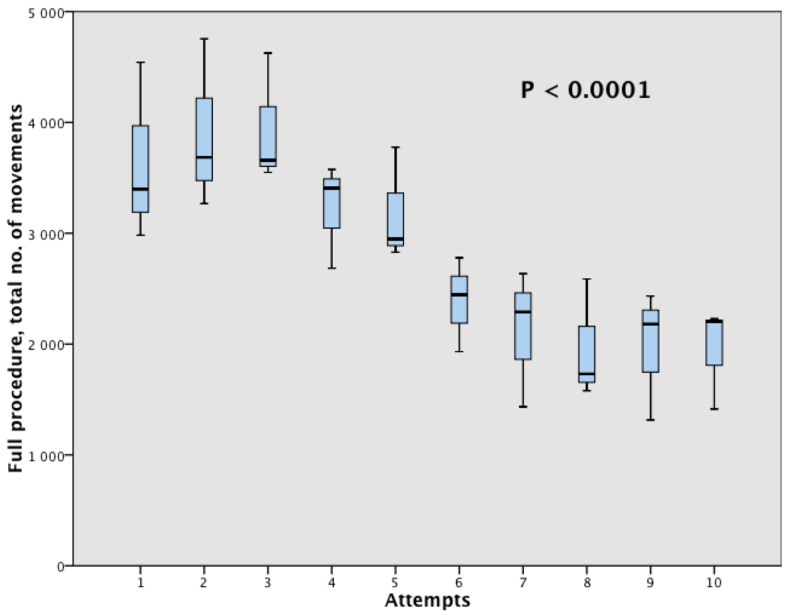


Figure 20b: Learning curve: Number of movements for the full laparoscopic sigmoid colectomy across the novices' 10 attempts. *Horizontal lines within boxes, boxes and whiskers represent the 50th, 25th/75th, and 5th/95th percentile, respectively. Outliers are represented by solid dots.*



4.4.3 Fidelity and content validity

All candidates were satisfied with their training on the simulator, with a median rate of 4/5 (3-5). Novices rated the training overall usefulness 4,5/5 (3-5), and intermediate and experienced surgeons, 4/5 (2-5). Fidelity and content validity are reported in Table X. Overall realism was rated 3/5 (2-4), and experienced surgeons rated all items higher than intermediates. The less realistic item was the inferior mesenteric vein dissection, rated 2/5 (1-4) due to a lack of fidelity for clipping; the most realistic item was the rectal stapling, rated 4/5 (1-5). Ergonomy was rated 4/5 (2-5), and force feedback, 3/5 (2-4).

Table X: Fidelity and content validity assessed by intermediate and experienced surgeons on a Likert scale (1 to 5).

IMA = inferior mesenteric artery; IMV = inferior mesenteric vein. Values are median, with inter-quartile range in parentheses.

Fidelity	**Experienced alone**	**Experienced + Intermediates**
Global realism	3,5 (2-4)	3 (2-4)
Content Validity		
Toldt Dissection	4 (2-5)	3 (2-5)
Colonic Mobilization	3 (2-5)	3 (2-5)
IMA Dissection	3 (2-4)	3 (2-4)
IMV Dissection	2 (1-4)	2 (1-4)
Ureter Identification	3,5 (2-4)	3 (1-4)
Rectal Dissection	3 (2-4)	3,5 (2-4)
Rectal Stapling	3,5 (1-5)	4 (1-5)
Anastomosis	4 (2-5)	3 (1-5)

4.4.4 Construction of the Curriculum (Figure 21)

All construct-valid metrics were included in the training curriculum. Only one metric was excluded: number of movements for the anastomosis module, as it did not show construct validity. Benchmark criteria were based on experienced surgeons' performance (*i.e.* 2nd attempt). Each step of the curriculum was completed when level of proficiency was achieved on 2 consecutive sessions, with a maximum of 2 sessions per day performed at least one hour apart, according to previously published curricula[76–78]. As this training curriculum involved advanced laparoscopic skills, its first step required to achieve proficiency in basic laparoscopic skills, during a cholecystectomy: indeed, cholecystectomy is a standard training procedure for laparoscopic skills, and a pre-requisite of general surgery training in the USA[153]. Chosen benchmark criteria corresponded to the last step of a previously validated curriculum for basic skills, designed on the same simulator[76].

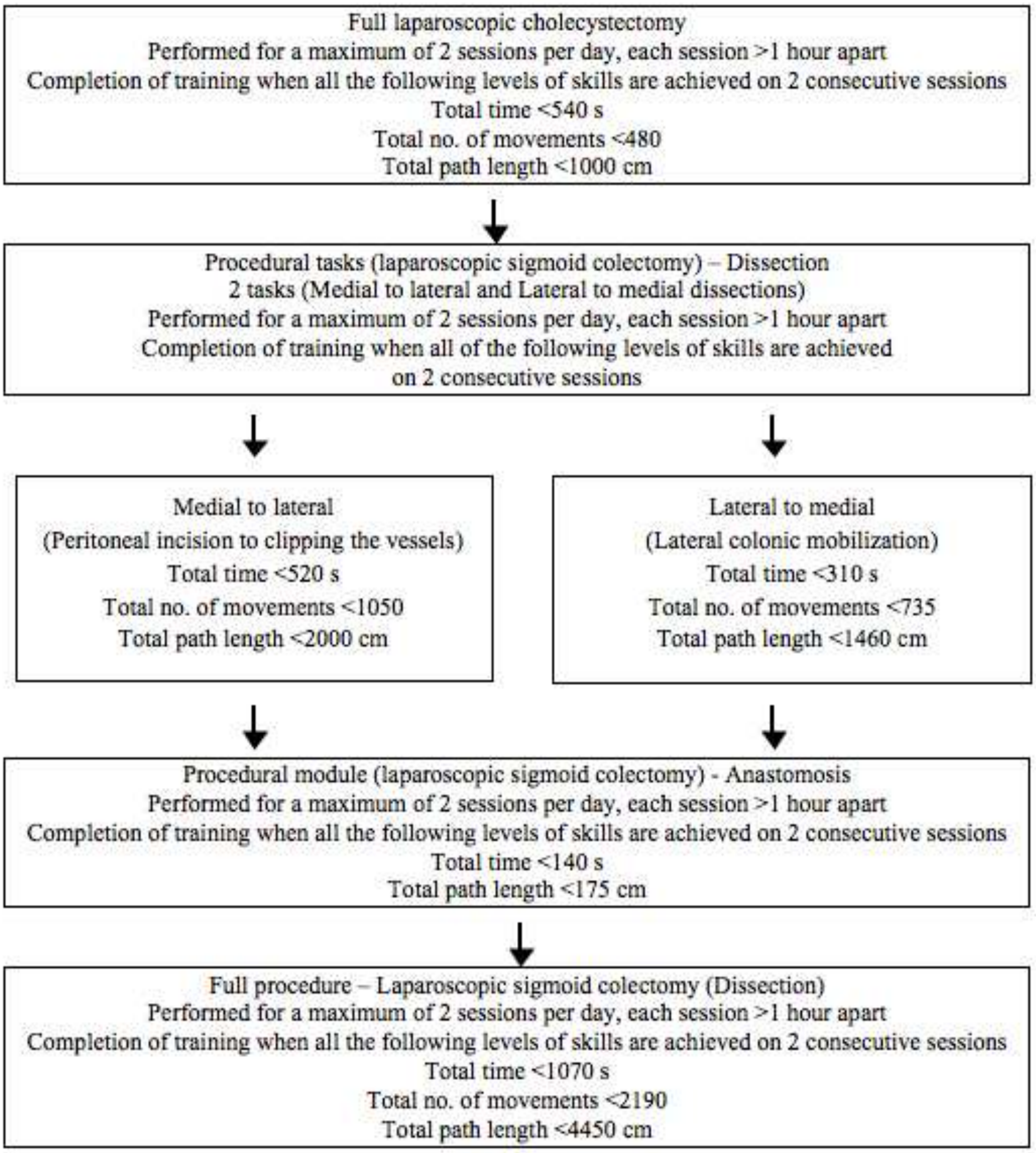
4.5 DISCUSSION

Thirty-three surgeons of various levels of expertise participated in this prospective study. The 3 metrics already validated in basic laparoscopic surgery (*i.e.* time, number of movements and path length)[76,77] showed construct validity during a virtual LSC, except for number of movements in the anastomosis module. These metrics helped design a competency-based virtual curriculum in advanced laparoscopic surgery. Moreover, both procedural tasks and full LSC demonstrated fidelity and content validity, and were thought to be useful as training tools.

At present only limited structured guidelines exist for the training of LCS, that seem difficult to implement in terms of budget, time and equipment (*i.e.* didactic courses associated with porcine and cadaver lab)[69]. While the learning curve in LCS is estimated between 30 and

Figure 21: Virtual curriculum for laparoscopic colorectal surgery.

Proficiency levels for laparoscopic cholecystectomy are based upon Aggarwal et al.[76]*; No. = number.*



60 cases, and even if such expertise is not to be expected at the end of residency, surgical access remains very poor for residents in LCS, as primary operator[71–73]. In the Canadian series of Palter *et al.,* more than one third of PGY3-5 had no experience in LCS as primary operator[42]. Rattner *et al.* interviewed 85 residents who were at least PGY4: 81% had performed less than 3 laparoscopic colectomies[74]. Our study showed similar findings, as 70% of residents had never performed any LCR, and the other 30%, all at least PGY4, had done less than 5 LCR. This gap between expected level and actual practice has prompted Essani *et al.*[55] to write that "the adequacy of Dr. Halsted's one-century-old apprenticeship model is questionable in LCS", and to promote the use of simulation in this field. Moreover, Lin *et al.* found that simulation in advanced surgery favored residents' participation in the OR without altering patients' outcomes[68].

Though expensive (108 000 USD for the Lap-Mentor™), VR simulators allow more advanced training than video-trainers without presenting the ethical issue of live animals and cadavers. Moreover, traditional training is not without its cost. Bridges and Diamond estimated this cost to be approximately 47,970 USD per graduating resident[90], based on the time "lost" by primary operator residents in the OR. In addition, the application of faculty costs leads to approximately 84,870 USD to 233,352 USD per resident[92]. VR simulators are therefore an increasingly attractive option: once bought, they require little running cost, are easily available for use and allow iterative skills training. Moreover, VR simulators provide feedback on performance, which permitted to design competency-based curricula in basic laparoscopic skills[154].

These VR curricula used proficiency goals on construct-valid measures[76,77]. The aim of such competency-based curriculum was to acquire a basic level of proficiency prior to entering the OR, and to reduce the learning curve on real patients: predefined benchmark criteria could ensure that skills acquisition had been successful. However, these curricula could be enhanced through use of quality-based outcome measures, such as global and procedural rating scales. Training sessions were short and iterative (a maximum of 2 sessions per day, performed at least one hour apart) in order to ensure a distributed rather than massed approach to skills training. Indeed, distributed training has demonstrated higher impact on technical skills in VR[104]. Finally, retention of technical skills has been shown up to 7 months after training to proficiency on VR simulators[105].

Twenty-two studies assessed simulation in LCS, mostly during a sigmoid colectomy. The majority were purely descriptive, and only 2 involved VR simulators[57,58]. Only one study assessed the impact of LCS training in the OR: it was a randomized controlled trial in which training in LCS on cadavers was the last step of a whole training curriculum involving also a VR competency-based curriculum in basic skills and cognitive courses. Then, trainees were assessed during a real laparoscopic right hemi-colectomy, using validated rating scales. Curricular-trained residents demonstrated higher performance in the OR than controls, who followed only classical apprenticeship (P=0.03)[10]. Our study is the first to implement a competency-based VR curriculum in ATLAS. However, a forthcoming randomized study should assess its impact in the OR, during a real LSC, to appraise its educational value.

As a short duration of training may produce better results, advanced procedures could be split into modules (*i.e.* procedural tasks) to strengthen the impact of training[3]. Such modules have been implemented in vascular surgery and endoscopy. Willaert *et al.*[79] demonstrated that training on a carotid stenting module was as effective as training on a full procedure, whilst Sugden *et al.*[78] developed a VR curriculum in colonoscopy, progressing from basic modules (intubating the sigmoid and descending colon) to advanced modules (intubating the splenic flexure), and then to the full procedure (a full colonoscopy). The same kind of progression was designed in our curriculum: training in basic laparoscopic skills (cholecystectomy), then advanced procedural tasks (medial and lateral dissection, anastomosis) and finally full LSC. In ATLAS, a few studies set a workflow analysis with specific steps[32,44], but no study had dichotomized a full procedure into modules so far.

As for learning curves in VR simulation, most studies showed that novices reached expert proficiency after approximately 10 trials in basic skills, with individual variations[101,102]. The same type of learning curve is observed in ATLAS: indeed, in the present study, novices reached experienced surgeons' level of proficiency after 10 attempts. This result justified using experienced surgeons' performances as benchmark criteria: this choice was not empirical any more, but demonstrated its feasibility. This gap between learning curves in VR and real colorectal resections (10 attempts *vs.* 30 to 60 cases) is explained by the simplified (no small bowel to recline, no mobilization of splenic flexure) and fixed nature of the procedure in VR. Indeed, both tumor localization and patient are the same every time. This also explains the absence of differences between intermediate and experienced surgeons in almost every metric, and confirms that such curriculum is not supposed to replace classical companionship. As in basic skills training, these 2 fields of education complete each other.

In conclusion, a competency-based VR curriculum was validated in LCS. Such training may reduce learning curves and improve patients' safety in the OR, as junior surgeons have limited access to these complex procedures as primary operator. A forthcoming study assessing the impact of such VR curriculum in the OR is awaited to fully appraise its educational value.

5 ENHANCED RECOVERY SIMULATION IN COLORECTAL SURGERY: DESIGN OF VIRTUAL ONLINE PATIENTS

Ce chapitre traite du design de la formation périopératoire, utilisant le patient virtuel et se basant sur les recommandations de réhabilitation précoce en CCL.

[Précédemment publié sous la référence : Beyer-Berjot L, Patel V, Ziprin P, Taylor D, Berdah S, Darzi A, Aggarwal R. Surgical training: Design of a virtual care pathway approach. Surg Endosc DOI: 10.1007/s00464-014-3941-8.]

5.1 ABSTRACT

Background: The aim of the present study was to design virtual patients (VP) involving enhanced recovery programs (ERP) in colorectal surgery, in order to train surgical residents in peri-operative care. Indeed, ERP have changed perioperative care and improved patients' outcomes in colorectal surgery. Training, using online VP with different pre- and post-operative cases, may increase implementation of ERP.

Methods: Pre- and post-operative cases were built in the virtual world of Second-Life™ according to a linear string design method. All pre- and post-operative cases were storyboarded by a colorectal surgeon in accordance with guidelines in both ERP and colorectal surgery, and reviewed by an expert in colorectal surgery.

Results: Four pre-operative and five post-operative cases of VP undergoing colorectal surgery were designed, including both simple and complex cases. Comments were provided through case progression to allow autonomic practice (such as "prescribed", "this is not useful" or "the consultant does not agree with your decision"). Pre-operative cases involved knowledge in colorectal diseases and ERP such as pre-operative counseling, medical review,

absence of bowel preparation in colonic surgery, absence of fasting, minimal length incision and discharge plan. Post-operative cases involved uneventful and complicated outcomes in order to train in both simple implementation of ERP (absence of nasogastric tube, epidural analgesia, early use of oral analgesia, perioperative nutrition, early mobilization) and decision making for more complex cases.

Conclusion: Virtual colorectal patients have been developed to train in ERP through pre- and post-operative cases. Such patients could be included in a whole pathway care training involving technical and non-technical skills.

5.2 INTRODUCTION

Enhanced recovery programs (ERP) include perioperative multimodal interventions that when used together have led to decreased length of stay and post-operative complications while increasing patient recovery and satisfaction.[155,156] Despite the known benefits of ERP, uptake remains slow: compliance to colorectal ERP would only be 60 to 70%,[157,158] and tends to decrease with time, even in reference centers.[159] Recently, a Delphi consensus stated that continuing education of new team members was one of the three most important leads to sustain success in ERP, along with regular staff update sessions and positive feedback to team.[160] Moreover, surgical residents make many decisions in the post-operative care[156] and should therefore be explicitly trained in ERP.

Models for interactive training in the pre- and post-operative care have already been designed in the simulated ward[129,130,161] and in the virtual world.[125,126,147] Both settings have demonstrated fidelity, content validity and educational value.[126,144] The purpose of such training is to improve not only knowledge, but also decision making during patient assessment and management.

The simulated ward is a high-fidelity model, that uses actors to play patients within an environment pertaining to a real surgical ward.[129,130] It has been the best-known field of research so far. However, the simulated ward is expensive and presents both access issues and time constraints.

An attractive field of interactive training is the use of online virtual patients (VP), using pre- and post-operative scenarios.[125] VP are defined as multidimensional model patients through which a user has to simulate communication, information gathering, and apply diagnostic reasoning in support of effective and cost-efficient surgical care.[133] Medical education is continually evolving to use such novel internet-based technologies[138] and VP have demonstrated fidelity and content validity.[126] Moreover, VP are uploaded on a virtual world that is easily accessible through an internet connection.

The aim of the present study was to design VP involving ERP in colorectal surgery, in order to train surgical residents in perioperative care.

5.3 MATERIAL AND METHODS

Pre- and post-operative VP were designed: pre-operative VP presented in clinics with various colorectal diseases, and post-operative patients were created to be virtually assessed in the surgical ward after laparoscopic colorectal surgery. All cases were designed and developed according to a similar framework previously employed by our group,[125] according to the guidelines of Posel *et al.*[139] This framework encompassed several steps: determine case content and choose a design model (linear string or branching design model), organize and storyboard the case, manage case complexity and match it to the case objectives, develop the case and, finally, tackle interactivity in order to obtain the highest fidelity simulation possible. After testing, the cases were transferred in the virtual world of Second Life™ (Linden Research Inc, San Francisco, CA, USA).

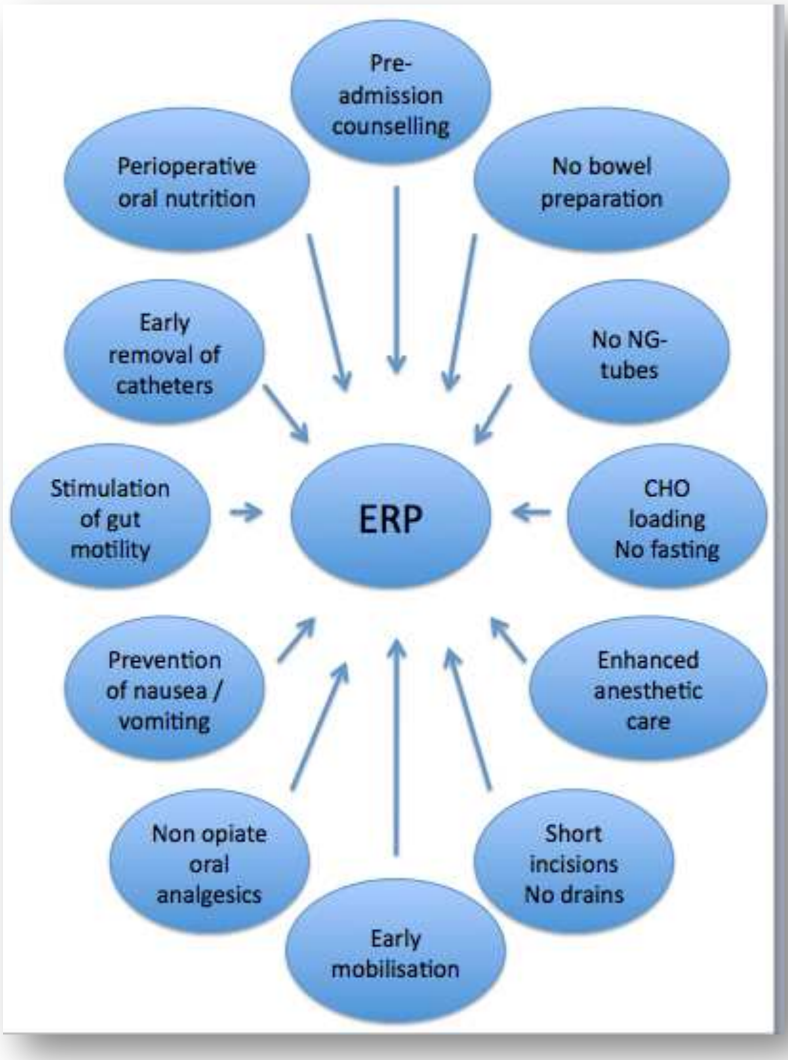
5.3.1 Pre-operative VP

5.3.1.1 Design model and case content

All cases followed a linear string model of design. Four pre-operative VP presenting with colorectal diseases were designed, including both simple and complex cases. The objectives of pre-operative cases were to elicit the relevant clinical information from the history and examination, establish the pertinent investigation findings, determine the correct diagnosis and initiate an appropriate management plan, similar to how a surgeon should perform in clinics. The cases involved knowledge in colorectal diseases and ERP such as pre-operative counseling, preoperative identification of high-risk patients for ERP failure (in particular, social assessment), medical review, absence of bowel preparation in colonic surgery, absence of fasting, minimal length incision and discharge plan (Figure 22).[162] Using a screen next to the patient as an interface between the patient and the trainee, the trainee would click on different types of questions regarding chief complaint, history and clinical examination. The patient would answer the trainee via a bubble speech and the trainee could choose the questions to pick and the ones which were not relevant. Using the same screen, the trainee would go to previous investigations to review blood tests, computed tomography (CT) scan, MRI, colonoscopy, and endorectal ultrasound (US). Then, the trainee would proceed to the management plan in order to ask for further investigations, anesthetic review, and select the needed treatment: whether surgery or further medical treatment. If surgery was scheduled, the trainee was asked to specify the type of operation, pre-operative counseling and discharge plan according to ERP. Comments were provided through the management plan to allow guidance but otherwise autonomous practice (such as “prescribed”, “this is not useful” or “the Consultant / Attending does not agree with your decision”). Once comments were provided, the trainee could either submit another proposition that was written on the screen by clicking on it, if the previous answer was incorrect, or move to another step of the management plan.

Figure 22: Main items of enhanced recovery programs (ERP), based upon Fearon *et al.*[163]

NG: nasogastric, CHO: carbohydrate.



5.3.1.2 Storyboarding the cases

In order to follow a specific framework focusing on information elicitation, processing and decision making, all cases were designed in the same format with case detail under the categories of history, examination, previous investigations, management plan (require further medical treatment, further investigations, or anesthetic review, schedule the operation, plan for ERP) based on case objectives. They were all storyboarded on Word™ (Microsoft, Redmond, WA, USA) by writing down all the potential trainee questions and patient answers (for history and examination), trainee questions and available information (for previous investigations) as well as all the trainee possible propositions and comments (for management) such as “prescribed”, “this is not useful” or “the Consultant / Attending does not agree with your decision”. All storyboards were written by a colorectal surgeon (LB) in accordance with guidelines in both ERP and colorectal surgery, and reviewed by an expert in colorectal surgery (PZ). Consensus agreement on case content was achieved including input based on literature recommendations.[162–164]

5.3.1.3 Development of the cases

The development phase is about translating the case from a simple storyboard to a virtual interface where the trainee is able to select questions and propositions, the patient can actually “answer” using bubble speeches, and investigations can be obtained. Once storyboarded, case content was transcribed into Eclipse® editor (The Eclipse Foundation, Ottawa, ON, Canada), which is an open-source multi-language development environment. Its purposes are to produce XML files of data and to store them within a retrievable database. XML stands for eXtensible Markup Language, which is a computer-specific language. Case content was then uploaded onto a webplayer, which was hosted on an Imperial College server. This webplayer was formatted to communicate with the editor, and to enable recently developed cases to be uploaded from the developer’s computer (ViP). It also allowed the cases to be run through in a logical sequence.

Subsequently, cases were transferred to a user interface in Second Life™ through a message broker. This message broker was able to relay information from the user to the interface. After development, all cases were again assessed by 2 experienced gastrointestinal surgeons (PZ, RA).

5.3.1.4 Interactivity

In order to provide a high fidelity simulated experience between the patient and the physician and heighten the trainee's sense of participation, interactivity tools were built into each scenario. Pre-operative VP were reviewed in the appropriate clinical environment, *i.e.* in the clinics. An additional room, which would provide the blood requests and retrieval service, was located next to the clinics. Patients' observations were displayed on a monitor and their abdomen could be palpated. Audio for breath sounds was also included. Finally, as described above, CT scan, MRI, colonoscopy, and endorectal US could be requested to assist in diagnosis, with the appropriate results retrievable by the user.

5.3.2 Post-operative VP

The design of post-operative VP followed the same framework as the pre-operative patients'. Post-operative cases were created involving uneventful and complicated outcomes after colorectal surgery, in order to train in both simple implementation of ERP (absence of NG tube, epidural analgesia in case of open surgery, early use of oral analgesia, perioperative nutrition, early mobilization)[165] and decision making for more complex cases. Their objectives were to identify the patient's post-operative progression and initiate an appropriate management plan according to ERP, similar to how a surgeon should perform in the surgical ward.

5.4 RESULTS

5.4.1 Pre-operative training scenarios

Four pre-operative VP scenarios were designed, all presenting with colorectal diseases. The four cases were the following (the presentation of VP1 describes the interactive component of the case as an example; all cases have similar interactivity):

VP1

VP1 was a 45 year-old male who had experienced a second episode of diverticulitis two months before. He had no medical history and no addictions. His first episode of diverticulitis was uncomplicated, and treated by antibiotics. The second episode was complicated with a 60 mm abscess, and treated by drainage under CT scan, and parenteral antibiotics. Abdominal examination was normal. A CT scan performed one week before was normal. Management plan was to require a colonoscopy first, then discuss the benefits and risks of a laparoscopic sigmoid colectomy. After discussion, VP1 wished to be operated and was scheduled in ERP.

In practice, a nurse introduced VP1. The trainee then had the choice to click on history, examination or previous investigations. If the trainee clicked on history, they could interrogate VP1 on his medical history and presenting complaint (if he had pain, its localization and intensity, if he had nausea/vomiting, etc…). The patients would then "answer" each question if these were asked. By clicking on examination, the trainee could palpate the abdomen, ask if rectal examination was normal or if bowel sounds were present. The trainee could ask for previous investigations (blood tests, CT scan, colonoscopy or MRI): VP1 had normal blood tests, and a CT scan. The trainee could then: require anesthetic review; schedule the operation (and would be told that "the consultant requires a colonoscopy first"); require further medical treatment ("this is not useful"); or require further investigations: for colonoscopy, results are available ("there are some diverticula in the sigmoid colon"), and the trainee was asked to discuss the benefits and risks of surgery. A new screen opened showing "the patient wants to be operated" and the trainee could plan for ERP, according to the following items: type of operation (laparoscopic sigmoid colectomy with colorectal anastomosis), information concerning the operation and its risks (conversion into open surgery, stoma, anastomotic leak), bowel preparation ("the consultant does not agree with your decision"), pre-operative fasting (6 hours solid, 2 hours clear fluids and carbohydrate loading), no anesthetic premedication, and discharge plan (home at Day 4, telephone call after 24 hours and clinical review at Day 8 and 30).

VP2

VP2 was a 65 year-old woman, who was diagnosed a left colon carcinoma (Figure 23). She had chronic obstructive lung disease, was a smoker. She had no pre-operative CT scan, and colonoscopy showed an impassable left colonic tumor. Medical review, CT scan and discussion with the multidisciplinary team (MDT) were required before surgery, according to ERP. Discharge plan included a full colonoscopy at Day 30.

VP3

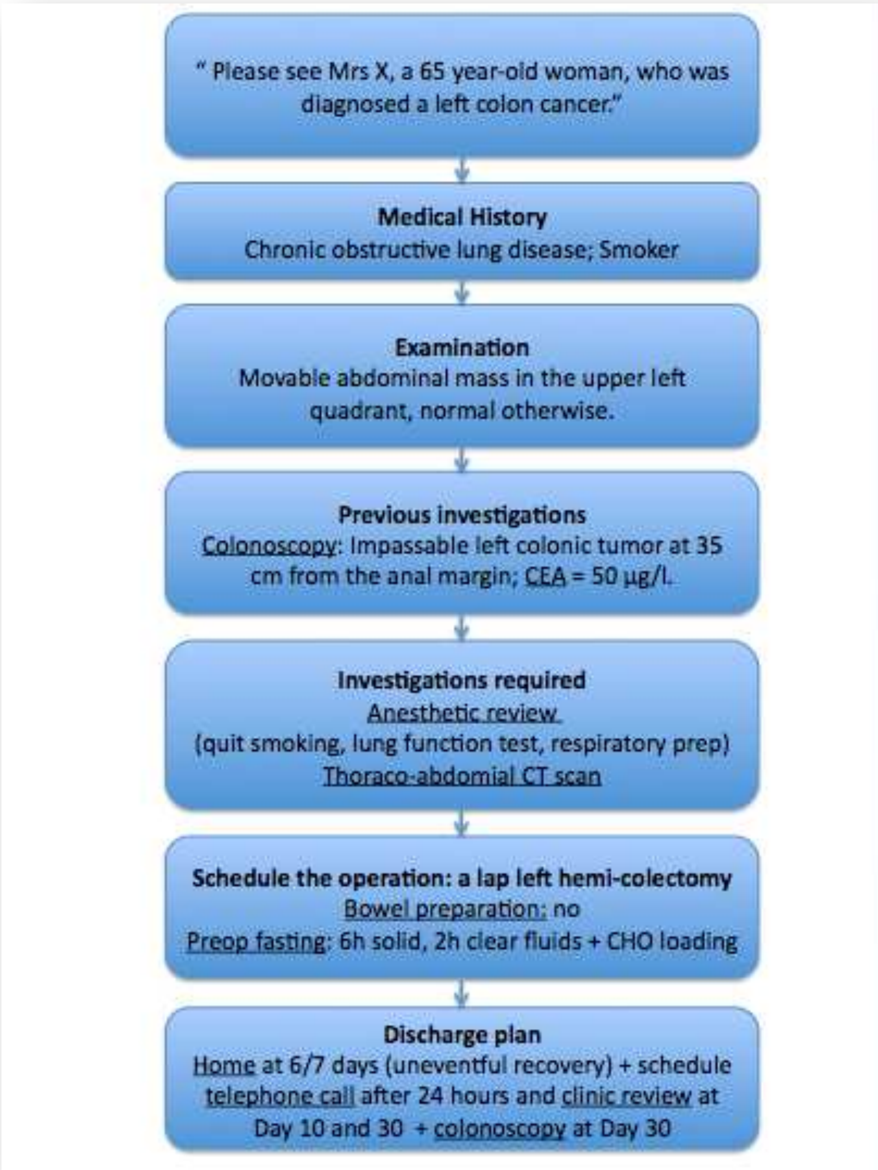
VP3 was a 50 year-old male, diabetic, who was diagnosed a low-rectum carcinoma. Rectal examination showed an anterior rectal mass located 3 cm from the anal sphincter, mobile. On previous investigations, CT scan showed pelvic lymph nodes; colonoscopy was performed, and both MRI and endo rectal US showed a tumor classified T3N+. Management plan was to require neoadjuvant radiochemotherapy (RCT) after discussion with MDT.

VP4

VP4 was VP3, 8 weeks after RCT. Abdominal and rectal examinations were unchanged, except the tumor volume had decreased since last examination. Investigations, performed after RCT, were the following: CT scan still only showed pelvic lymph nodes, and both MRI and endo rectal US showed a tumor still classified T3N+, with a circumferential rectal margin (CRM) of 25 mm. Medical review was required and an ultra-low anterior resection with coloanal anastomosis and covering loop ileostomy was scheduled, according to ERP. Both surgical approaches, laparoscopic or open, were suitable for fulfilling the case.

Figure 23: Linear string design of virtual patients (example: virtual patient 2).

CT: computed tomography, CHO: carbohydrate, prep: preparation, preop: pre-operative.



5.4.2 Post-operative training scenarios

The 5 post-operative cases were the following:

VP5

VP5 was a 52 year-old male, who had an uneventful laparoscopic sigmoid colectomy after 3 episodes of diverticulitis, with no drain. The trainee was asked to review VP5 2 hours after surgery and at Day 2. At Day 0, analgesia given was efficient (intravenous (IV) paracetamol) and palpation found a slightly tender abdomen. Correct management consisted in starting oral paracetamol (instead of IV) and oral fluids, and asking for early mobilization. At Day 2, examination and blood tests were normal. Correct management consisted in removing urinary drainage ~~and epidural catheter~~, discontinuing IV fluids, starting normal diet, increasing mobilization, and planning discharge in 2 days.

VP6

VP6 was a 43 year-old male, who had an uneventful laparoscopic left hemi-colectomy for carcinoma 5 days before, with stapled colorectal anastomosis and no drainage. The tumor was impassable on pre-operative colonoscopy. He had no pain, had passed flatus but had not opened his bowels. Post-operative course was uneventful. Correct management consisted in discharging the patient, and scheduling telephone call at 24 hours, clinical review, as well as post-operative colonoscopy.

VP7

VP7 was a 65 year-old male, who had an uneventful open low anterior resection with coloanal anastomosis for mid-rectal adenocarcinoma, with covering loop ileostomy and pelvic drainage. The trainee was asked to review the patient at Day 4 and Day 7. At Day 4, he presented with high stoma output, tachycardia, and slight renal failure. The trainee had to put a urinary drainage, continue IV fluids and antithrombotic prophylaxis, prescribe oral potassium, loperamide, low-residue diet, and correct mobilization. At Day 7, examination and blood tests were normal, and outputs had decreased around 250 ml per day. The trainee had to stop IV fluids, remove urinary drainage and discharge the patient, scheduling clinical review and water-soluble contrast enema at 30 days, for planning of stoma closure.

VP8

VP8 was a 45 year-old male, who had a converted left hemi-colectomy with stapled colorectal anastomosis for carcinoma 4 days before. He presented with small bowel obstruction that needed medical treatment: NG tube, IV analgesia, antiemetics, and 100 ml of gastrograffin via NG tube.

VP9

VP9 was a 38 year-old male, who had an uneventful laparoscopic left hemi-colectomy for carcinoma 6 days before. He presented with clinical peritonitis, confirmed on CT scan. Correct management was the following: reoperate the patient and proceed to laparoscopy first, with either lavage, covering loop ileostomy and drainage, or conversion into open surgery, Hartmann's procedure, lavage and abdominal drainage given the local conditions.

5.5 DISCUSSION

This study, following a pilot study based on a pathway approach for acute appendicitis,[147] designed 4 pre-operative and 5 post-operative VP presenting with various colorectal diseases. The aim was to manage VP according to ERP guidelines,[162,163] and scenarios ranged from trivial to more complex cases, from uneventful to complicated courses. Cases involved knowledge in colorectal diseases and ERP, as well as decision-making. They also took into account "real life" practice with both laparoscopic and open cases, as well as conversions into open surgery. Such patients could be included in a whole simulated pathway care training, involving technical and non-technical skills: this pathway care training would enable residents to follow virtual colorectal patients from initial clinical review to discharge.

The key concepts of ERP in colorectal surgery include patient education and preparation, preservation of gut function, minimization of organ dysfunction, minimization of pain and discomfort, and promotion of patient autonomy.[166] Several meta-analyses, through 13 randomized controlled trials, found that ERP decreased length of hospital stay and global morbidity, despite no differences were found in mortality and surgical morbidity.[167–169] A recent series of 541 colorectal procedures, performed according to ERP, showed that compliance with oral intake and fluid management in the first 48 hours significantly decreased post-operative morbidity.[170] Moreover, Aarts *et al.* found that pre-operative counseling, laparoscopy, reintroduction of clear fluids at Day 0 and early discontinuation of urinary catheter were significantly associated with length of stay < 5 days in multivariate analysis.[171] In the LAFA-trial, Vlug *et al.* demonstrated that laparoscopy associated with ERP decreased total hospital stay.[172] Despite these benefits, compliance to ERP remains an issue in everyday practice.

Indeed, compliance to colorectal ERP would only be 60-70%,[157,158] and tends to decrease with time, even in reference centers.[159] An audit, comparing consecutive colorectal patients with patients included in a trial, found that ERP observance was significantly lower outside the trial (for example, 61% *vs.* 96%, $P<0.001$, for carbohydrate loading).[158] This led Cakir *et al.* to write that "embedding ERP into an organization and repetitive education are vital to sustain its beneficial effects on length of stay and outcome".[159] Likewise, a recent Delphi consensus stated that continuing education of new team members was one of the 3 most important leads to sustain success in ERP, along with regular staff update sessions and positive feedback to team.[160]

Pearsall *et al.* interviewed 55 surgeons, anesthetists and nurses: they found that surgeons cited themselves and residents as barriers to ERP. With regard to residents, some surgeons were concerned that they might not follow ERP because of lack of awareness.[155] Nadler *et al.* interrogated 77 residents in surgery on ERP: they stated that fluid diet would be ordered on Day 0 and regular diet on Day 1 by 68% and 49%, respectively, after laparoscopic colectomy, but only by 50% and 26% following open colectomy; in patients with an epidural, approximately 50% of residents stated that they would wait until it was removed to discontinue urinary catheter. Overall, they had a reasonable approach to the management of patients who underwent laparoscopic colectomy, but there were gaps in their management, especially following open colectomy and laparoscopic anterior resection.[156] Education and training are therefore needed for residents in ERP. Moreover, though designed for residents in first intent, our VP may also be useful for practicing surgeons to increase implementation to ERP.

Experiential lectures are currently used in the educational system for non-technical skills training, mostly without interaction or any notion of problem-based learning. Several fields of research have been developed to design interactive training models for non-technical skills. These models have been developed for intraoperative as well as pre- and post-operative care. Teamwork training has been designed in the simulated OR, mainly for crisis scenarios.[120,121] As for pre- and post-operative care, training models have already been designed in the simulated ward[129,130,161] and in the virtual world.[125–128,147] Both have demonstrated fidelity, content validity and educational value.[126,144] The simulated ward has the advantage to be highly immersive, using actors that can perfectly mimic patients' examination (such as abdominal tenderness, guarding or vomiting) within an environment looking very much like a real surgical ward, including drug charts and patient notes.[129,130] However, simulated ward is expensive and presents both access issues and time constraints. In contrast, VP, designed in the virtual world of Second Life™, are free for end-users and easily accessible for everyone from a personal computer, hence easily disseminated to large groups.[134] VP are therefore an attractive tool for training in clinical skills, for a growing number of academic institutions.[135–137]

In the present study, VP were designed and developed using a framework published by our group,[125] according to the guidelines of Posel *et al.*[135–137] Previous design methods have been described for VP. They include the linear string and the branching design method.[145] Whilst the branching method provides higher fidelity[139] it is more complex in terms of design. We therefore chose the linear string method so that if the trainee chose the correct clinical decision then the case would end accordingly. The chosen scenarios corresponded to standard ERP pathway. However, ERP are continuously evolving,[22] and the designed VP could be found somehow rigid, in terms of "real-life" situations. The present project was proof of practice: in the future, modules could be modified according to ERP evolution and/or local practice, and additional sub-modules (management of epidural failure; pre-operative optimization of high risk ERP patients…) could be added.

Furthermore, the process of using a similar methodology to storyboard all the cases (history, examination, previous investigations, management plan: further medical treatment, further investigations, anesthetic review, schedule the operation, plan for ERP) ensured that information could easily be transferred between cases, therefore reducing time and cost for development of further variations of a case. In the present study, the cost for developing the project corresponded to the design of VP (1600 USD) and the 6-month rental of an island on Second-Life™ (1770 USD): total cost was 3370 USD. The original cost (100 000 USD) was spent during the first design of VP, in a previous study, and will not be needed in further projects.[173]

Assessment tools have been designed for non-technical skills in perioperative care, such as the ward round non-technical skills (W-NOTECHS) scale, implemented in the simulated ward.[132] The skills assessed were leadership, cooperation, communication, assessment/decision making, and situation awareness. Our design of VP did not aim to assess residents explicitly: the primary intention was to develop a tool to train them. Indeed, it did not appear relevant to assess trainees while comments were provided through case progression, giving the trainees feedback on their management outcomes. However, interactivity and quality of decision making still need to be assessed, as the goal of the present study was only the design of pre- and post-operative cases. A forthcoming research, currently performed in our department, should address this issue.

Virtual cases have been designed to train residents in pre- and post-operative care for colorectal surgery, according to ERP. The aim of such training is to improve resident knowledge and decision making, but these VP may also help increase compliance to ERP. However, future research still needs to appraise their educational value: a study currently performed in our department should address this issue. Finally, colorectal VP could be included in a whole pathway care training involving technical and non-technical skills, enabling residents to follow virtual colorectal patients from pre-operative review to discharge.

6 COLORECTAL SURGERY AND ENHANCED RECOVERY: IMPACT OF A SIMULATION-BASED CARE PATHWAY TRAINING CURRICULUM

Il s'agit de l'étude finale de cette thèse, étudiant l'impact de notre FPSS en chirurgie colorectale. Cette etude a été approuvée par le NRES Committee London – Central (référence REC: 12/LO/1215). Elle est actuellement soumise à Annals of Surgery avec les auteurs suivants: Beyer-Berjot L, Pucher P, Hashimoto DA, Ziprin P, Berdah S, Darzi A, Aggarwal R.

6.1 ABSTRACT

Introduction: The aim was to determine whether a surgical simulation pathway curriculum could improve compliance for enhanced recovery programs (ERP), and residents' participation in laparoscopic colorectal surgery (LCS). Indeed, junior surgeons have limited access to LCS as primary operator, and ERP have improved patients' outcomes in colorectal surgery (CS).

Methods: All residents of our department of CS were trained in a simulation-based pathway care approach: pre- and postoperative training consisted in virtual patients built in accordance with guidelines in both ERP and colorectal surgery, whilst intraoperative training involved a virtual reality simulator curriculum. Twenty patients undergoing CS were prospectively included before (n = 10) and after (n = 10) the training. All demographic and perioperative data were prospectively collected from their medical records, including compliance for ERP. Residents' participation in LCS was measured as the percentage of time during which they were primary operator.

Results: Five residents were enrolled ranging from PGY 4 to 7. All had performed over 50 laparoscopic procedures, but none had performed LCS as primary operator. Overall

satisfaction and usefulness were both rated 4.5/5, usefulness of preoperative, postoperative and intraoperative training was rated 5/5, 4.5/5 and 4/5, respectively. Residents' participation in LCS significantly improved after the training (0% (0-100) *vs.* 82.5% (10-100); $P = 0.006$). Pre- and intraoperative data were comparable between pre-training and post-training patients. Postoperative morbidity was also comparable, with a trend to less major morbidity (5 (50%) *vs.* 1 (10%); $P = 0.07$). Compliance for ERP improved at day 2 in post-training patients (3 (30%) *vs.* 8 (80%); $P = 0.035$). Length of stay was not modified (9,5 days (4-26) vs. 6,5 (5-30); $P = 0.74$).

Conclusion: A surgical simulation pathway curriculum for training in CS improved compliance for ERP and residents' participation as primary operator without adversely altering patients' outcomes.

6.2 INTRODUCTION

Surgical skills have long been grounded to technical abilities: training out of the operating room (OR) predominantly consisted of improving intraoperative technical skills using benchtop models and simulators.[1,2,119] However, both technical and non-technical skills are essential in the training of surgeons.[119] Non-technical skills are needed not only in the OR,[120,121] but also in pre- and postoperative care. Indeed, Pucher, *et al.* recently showed that ward round quality had some impact on patients' outcomes in surgery.[122]

Care pathway approach implies both technical skills training on a simulator, and training in pre- and postoperative care: the purpose of perioperative training is to improve both decision-making and knowledge. Most perioperative care training that have been published so far are experiential or via lectures, but not interactive between the trainees and the patients, *i.e.* that 3D virtual patients (VP) or actors in a simulated ward provide data about their chief complaint, history and exam. In a pilot study, we demonstrated that simulation-based care pathway training (using VP and a virtual reality (VR) intraoperative curriculum) had a positive impact on the healthcare system for acute appendicitis, a common disease requiring basic skills.

A further step in education would be to implement simulation-based care pathway for advanced training in laparoscopic abdominal surgery (ATLAS), where intraoperative skills, strategy, and decision-making are paramount. Indeed, advanced technical skills training may reduce learning curves and improve patients' safety in the OR. Advanced non-technical skills training should encompass enhanced recovery programs (ERP). Despite the known benefits of ERP,[155,156] uptake remains slow: compliance to colorectal ERP would only be 60 to 70%,[157,158] and tends to decrease with time, even in reference centers.[159]

We previously designed VP in colorectal surgery to train in ERP through pre- and post-operative cases,[174] and an intraoperative VR competency-based curriculum for sigmoid colectomy, which demonstrated validity evidence.[175] The objectives of the present study were to implement such simulation-based care pathway training curriculum, and to assess its impact on compliance for ERP.

6.3 METHODS

6.3.1 Study population

This was a prospective one-center study, performed in the department of colorectal surgery of St. Mary's Hospital, Imperial College Healthcare NHS Trust, London. The study was approved by the NRES Committee London – Central under the REC reference: 12/LO/1215. Twenty consecutive patients undergoing colorectal surgery were prospectively included before (n = 10) and after (n = 10) the training of residents, after giving informed consent.

The data included the following: demographic data, such as age, gender, body mass index (BMI) and American Society of Anesthesiology score (ASA score);[148] preoperative data, such as indication for surgery, disease location, cancer (and in case of rectal cancer, preoperative radiochemotherapy), type of operation scheduled, preoperative counseling, respiratory preparation, bowel preparation, admission at the day of surgery; intraoperative data, such as type of approach (*i.e.,* laparoscopic or open), type of operation actually performed, stoma creation, drainage, conversion to open surgery, self rating of difficulty (on a 1 to 5 scale), Objective Structured Assessment of Technical Skills (OSATS) self rating,[150] intraoperative complications, operative time, percentage of time during which residents were primary operator; and postoperative data, such as compliance for ERP at Day 1 and Day 2 (including appropriate diet and mobilization, and discontinuation of IV fluids at Day 2), time to liquid and solid diet, type of analgesia, postoperative pain at Day 1 (according to an analogue visual scale (AVS) from 1 to 10), postoperative morbidity (according to Dindo's classification),[151] including gastrointestinal complications, additional surgery and mortality, and length of stay.

6.3.2 Care pathway curriculum

The curriculum was designed in a previous study.[174] In summary, 4 preoperative VP were designed in the virtual world of Second Life™ (Linden Research Inc, San Francisco, CA, USA). They presented in clinics with various colorectal diseases, including both simple and complex cases. The objectives of pre-operative cases were to elicit the relevant clinical information from the history and examination, establish the pertinent investigation findings, determine the correct diagnosis and initiate an appropriate management plan, similar to how a surgeon should perform in clinics. The cases involved knowledge in colorectal diseases and ERP such as pre-operative counseling, medical review, absence of bowel preparation in colonic surgery, absence of fasting, minimal length incision and discharge plan (Figure 1).[162] Intraoperative training consisted in a competency-based curriculum for laparoscopic sigmoid colectomy on a virtual reality (VR) simulator: the Lap-Mentor™ (Simbionix, Cleveland, OH, USA). This curriculum encompassed procedural modules (medial and lateral colonic dissection, colorectal anastomosis) and a full sigmoid colectomy (Figure 2). It has demonstrated validity evidence in a preliminary study currently under review.[175] Finally, 5 post-operative VP were virtually assessed in the surgical ward after laparoscopic colorectal surgery, with uneventful and complicated outcomes, in order to train in both simple implementation of ERP (absence of NG tube, early use of oral analgesia, perioperative nutrition, early mobilization) and decision making for more complex cases. Their objectives were to identify the patient's post-operative progression and initiate an appropriate management plan according to ERP, similar to how a surgeon should perform in the surgical ward (Figure 3).

6.3.3 Trainees

All senior residents (registrars) of the department were trained in a simulation-based pathway care approach. Before entering the study, all residents gave informed consent and fulfilled a questionnaire about their seniority and surgical experience (Annex 4). Each session lasted one hour, and consisted in training on one preoperative VP, then on one step of the intraoperative curriculum, and finally on one postoperative VP. Two sessions per day were performed. Training was completed when correct management was achieved for all VP and proficiency goals were reached at every steps of the competency-based curriculum. At the end of the training, they responded to a satisfaction questionnaire (Annex 5).

6.3.4 Definitions

Conversion to open surgery was defined as any unplanned incision or a planned incision longer than 6 cm. Postoperative morbidity was defined as complications occurring in the hospital or within 30 days after surgery. Major complications were defined as those requiring surgical, radiological or endoscopic intervention (Dindo III), life-threatening complications requiring intensive care management (Dindo IV) and death (Dindo V).[151] Mortality was defined as death occurring in the hospital or within 30 days.

6.3.5 Statistical analysis

The quantitative data were reported as the medians and range. Normally distributed quantitative data were analyzed with Student's *t* test, and the Mann-Whitney test was used otherwise. The qualitative data were reported as the number of patients (percentage of patients) and were compared using the Pearson's χ^2 test or the Fisher's exact test, as appropriate. As worse results were not expected after training, the tests were one-sided, and the level of statistical significance was set at $p < 0.05$. As this study was the first of its kind, data was lacking to formulate formal power calculations to determine the number of included patients: a convenience sample was therefore chosen. The analysis was performed using the Statistical Package for the Social Sciences software (SPSS, version 20, Chicago, IL, USA).

6.4 RESULTS

Five residents were enrolled ranging from PGY 4 to 7. All had performed over 50 laparoscopic procedures, but none had performed any laparoscopic colorectal surgery (LCS) as primary operator. Overall satisfaction and usefulness of training were both rated 4.5/5, whereas usefulness of preoperative, postoperative and intraoperative training was rated 5/5, 4.5/5 and 4/5, respectively.

Preoperative data of pre-training and post-training patients are reported in Table XI. Demographic data and clinical presentations were comparable between groups, and preoperative management did not differ after the training. All but one patient (pre-training group) had preoperative counseling. Most patients presented with cancer (17; 85%), located in the right colon in 8 cases, left colon in 2 cases, rectum in 7 cases (2 high-, 3 mid-, and 2 low-rectum). The other 3 patients presented with inflammatory bowel disease in 2 cases (one Crohn's disease, one ulcerative rectocolitis) and unresectable polyp in one case. No patients scheduled for colonic surgery had bowel preparation, whereas all patients undergoing rectal surgery did. No patients needed respiratory preparation.

Intraoperative data were comparable between pre-training and post-training patients (Table XII) except for residents' participation in LCS, which significantly improved after the training (0% (0-100) *vs.* 82.5% (10-100); $P = 0.006$) and OSATS self-rating, which was better in the pre-training group (35 (27-35) *vs.* 27 (23-35); $P = 0.011$). Fifteen patients were admitted the day of surgery (75%). Laparoscopy was performed in 18 patients (90%), with 8 conversions into open surgery. Conversion was not modified after the training: it was performed for adhesions in 3 cases, difficulties of exposure in 3 cases, technical failure of laparoscopic stack in one case, and vascular injury in one case. Two intra-operative complications occurred, both in pre-training group: one vascular injury, and one port-site bleeding.

Compliance for ERP (Table XIII) was not modified at day 1, but improved at day 2 in post-training patients in terms of overall objectives (3 (30%) *vs.* 8 (80%); $P = 0.035$) and mobilization (3 (30%) *vs.* 8 (80%); $P = 0.035$). There was a trend toward shorter time to solid diet, though not significant (72 hours (24-192) *vs.* 42 (20-192); $P = 0.18$). Postoperative morbidity (Table XIV) was comparable, with a trend to less major morbidity in post-training patients (5 (50%) *vs.* 1 (10%); $P = 0.07$). In the pre-training group, the 5 major complications were 3 reoperations (2 peritonitis, one pelvic abscess with no radiological access), 1 collection drained under CT scan associated with pulmonary embolism requiring intensive care, and 1 cardiac failure requiring intensive care. In the post-training group, the one major complication was a reoperation for peritonitis. Overall, there were 9 ileus, and 7 medical complications (one pulmonary embolism and one cardiac failure, cited above, one urinary retention, one slight renal failure, 3 slight cardiac failure, and one chest infection), some patients having both major complications and ileus or medical complications. There were no deaths. Length of stay was not modified (9,5 days (4-26) *vs.* 6,5 (5-30); $P = 0.74$).

Table XI: Preoperative data of 20 patients undergoing colorectal surgery before (pre-training group) and after (post-training group) pathway care training of residents. BMI: Body Mass Index; ASA: American Society of Anaesthesiology. The data are reported as the median and range.

	Pre-training Group, n = 10	**Post-training Group, n = 10**	***P***
Age (years)	79 (37-93)	75 (34-85)	0.32
BMI (kg/m^2)	24 (17-39)	26 (23-35)	0.24
Gender: male, n (%)	5 (50)	6 (60)	0.5
ASA score	3 (2-3)	3 (1-4)	0.68
Cancer, n (%)	9 (90)	8 (80)	0.5
Preoperative Radiochemotherapy, n (%)	0 (0)	1 (10)	0.5
Preoperative counseling, n (%)	9 (90)	10 (100)	0.5

Table XII: Intraoperative data of 20 patients undergoing colorectal surgery before (pre-training group) and after (post-training group) pathway care training of residents.
The data are reported as the median and range.

	Pre-training Group, n = 10	Post-training Group, n = 10	*P*
Right Hemicolectomy, n (%)	4 (40)	6 (60)	0.33
Left Hemicolectomy, n (%)	2 (20)	0 (0)	0.24
Anterior Resection, n (%)	4 (40)	4 (40)	0.68
Difficulty (1-5)	3 (1-5)	4 (3-4)	0.09
% Laparoscopic Trainee time	0 (0-100)	82.5 (10-100)	0.006
Laparoscopy, n (%)	9 (90)	9 (90)	0.76
Primary open surgery, n (%)	1 (10)	1 (10)	0.76
Conversion into open surgery, n (%)	3 (30)	5 (50)	0.33
Intraoperative complication, n (%)	2 (20)	0 (0)	0.47
Ileostomy / colostomy, n (%)	2 (20)	3 (30)	0.5
Drain, n (%)	4 (40)	3 (30)	0.5

Table XIII: Postoperative data of 20 patients undergoing colorectal surgery before (pre-training group) and after (post-training group) pathway care training of residents: compliance for ERP. ERP: Enhanced Recovery Program; Goals Day 1 and Day 2 stand for goals of ERP at postoperative day 1 and 2. The data are reported as the median and range.

	Pre-training Group, n = 10	**Post-training Group, n = 10**	***P***
Goals Day 1 achieved, n (%)	3 (30)	5 (50)	0.33
Walk x4 on Day 1, n (%)	3 (30)	5 (50)	0.33
Out of bed 8 hours on Day 1, n (%)	6 (60)	7(70)	0.5
Goals Day 2 achieved, n (%)	3 (30)	8 (80)	0.035
Walk x4 on Day 2, n (%)	3 (30)	8 (80)	0.035
Out of bed 8 hours on Day 2, n (%)	4 (40)	8 (80)	0.09
Time to resume liquid diet (hours)	6 (4-72)	6 (4-18)	0.45
Time to resume solid diet (hours)	72 (24-192)	42 (20-192)	0.18
Time to remove drain (hours)	96 (96-168)	96 (72-144)	0.70
Length of hospital stay (days)	9,5 (4-26)	6,5 (5-30)	0.74

Table XIV: Postoperative data of 20 patients undergoing colorectal surgery before (pre-training group) and after (post-training group) pathway care training of residents: morbidity. The data are reported as the median and range.

	Pre-training Group, n = 10	Post-training Group, n = 10	*P*
Overall morbidity, n (%)	8 (80)	7 (70)	0.5
Major morbidity, n (%)	5 (50)	1 (10)	0.07
Surgical complication, n (%)	7 (70)	5 (50)	0.33
Medical complication, n (%)	4 (40)	3 (30)	0.5
Reoperation, n (%)	3 (30)	1 (10)	0.29
Intensive Care Unit admission, n (%)	4 (40)	2 (20)	0.31
Death, n (%)	0 (0)	0 (0)	1

6.5 DISCUSSION

This study implemented a simulation-based care pathway approach to training in ERP and laparoscopic colorectal surgery (LCS), combining virtual patients with a competency-based curriculum on a VR simulator. All senior residents of our department of colorectal surgery were trained, with good feedback on satisfaction and usefulness. Even if the number of trainees was low (5), the purpose was to train all the senior residents of the department, which was achieved. Compliance for ERP improved in post-training patients. Moreover, residents' participation in LCS as primary operator significantly improved after the training, without adversely altering patients' outcomes: postoperative morbidity of pre- and post-training patients was comparable, with a trend to less major morbidity after the training (P = 0.07).

Whilst training independently on either a VR simulator or VP has demonstrated its positive impact on trainees' technical and non-technical skills,[5–8,144] intra- and perioperative care training have always been performed apart form each other. Furthermore, no combination of training in technical and non-technical skills has been designed as a curriculum in literature. The type of "combined" training published so far has associated technical skills training and formal lectures on intraoperative care, most of the time during workshops in advanced surgery.[50,60,62] We previously designed a pilot simulation-based care pathway approach to training in acute appendicitis,[147] which was implemented on real patients: both feasibility of such training and positive impact on patients' management were found. The present research was designed to train in more complex surgery, LCS, where decision-making and strategy are paramount.

Lectures were traditionally used in the educational system for non-technical skills training. Recently, blended learning has spread, combining face-to-face courses with e-learning to improve interaction and problem-based learning.[123] In their review, Rowe, *et al.* found that blended learning had shown interesting results for healthcare students, especially in "bridg(ing) the gap between theory and practice and improv(ing) a range of selected clinical competencies among students". However, most studies had methodological flaws and their average quality was low.[124] Moreover, blended learning is not structured in a pathway care manner, and has not been designed in an immersive way, with VP or actors in a simulated ward, to take care of. Pathway care training is therefore an additional, immersive training, which has not been designed to replace blended learning or classical companionship, but to complete them.

The key concepts of ERP in colorectal surgery include patient education and preparation, preservation of gut function, minimization of organ dysfunction, minimization of pain and discomfort, and promotion of patient autonomy.[166] Several meta-analyses, through 13 randomized controlled trials, found that ERP decreased length of hospital stay and global morbidity, despite no differences were found in mortality and surgical morbidity.[68,167,169] A recent series of 541 colorectal procedures, performed according to ERP, showed that compliance with oral intake and fluid management in the first 48 hours significantly decreased post-operative morbidity.[170] In the present study, simulation-based care pathway training improved compliance for ERP in the first 48 hours. Neither length of stay nor global morbidity was modified. However, the objective of our study was to assess compliance for ERP and not patients' outcomes, which would have needed much larger samples.

Despite its benefits, compliance for ERP remains an issue in everyday practice. Indeed, compliance to colorectal ERP would only be 60-70%,[157,158] and tends to decrease with time, even in reference centers.[159] An audit, comparing consecutive colorectal patients with patients included in a trial, found that ERP observance was significantly lower outside the trial.[158] This led Cakir *et al.* to write that "embedding ERP into (…) repetitive education (is) vital to sustain its beneficial effects".[159] Likewise, a recent Delphi consensus stated that continuing education of new team members was one of the 3 most important leads to sustain success in ERP, along with regular staff update sessions and positive feedback to team.[160] In their interview study, Pearsall *et al.* found that surgeons were concerned that residents might not follow ERP because of lack of awareness.[155] Nadler *et al.* interrogated 77 residents in surgery on ERP: overall, they had a reasonable approach to the management of patients who underwent laparoscopic colectomy, but there were gaps in their management, especially following open colectomy and laparoscopic anterior resection.[156] Education and training are therefore needed in ERP for residents, who make many decisions in the post-operative care.

Advanced technical skills training may reduce learning curves and improve patients' safety in the OR. Indeed, junior surgeons have limited access to these complex procedures as primary operator, while the learning curve in LCS is estimated between 30 and 60 cases.[71–73] In the series of Palter *et al.,* more than one third of PGY3-5 had no experience in LCS as primary operator[42]. Rattner *et al.* interviewed 85 residents who were at least PGY4: 81% had performed less than 3 laparoscopic colectomies[74]. This is in accordance with our own results, where none of the PGY 4-7 residents had performed LCS before the training. For now, only limited structured guidelines exist for the training of LCS, that seem difficult to implement in terms of budget, time and equipment (*i.e.* didactic courses associated with porcine and cadaver lab).[69] This gap between expected level and actual practice has prompted Essani *et al.*[55] to write that "the adequacy of Dr. Halsted's one-century-old apprenticeship model is questionable in LCS", and to promote the use of simulation.

However, this field of research is still quite poor, as most studies appraising education in ATLAS are purely descriptive. In their systematic review, Miskovic *et al.* found only 6 studies assessing simulation in LCS: they concluded that there was a "notable lack of available data on the educational value of simulated training".[11] However, 2 studies found interesting results. Palter *et al.* assessed the impact of LCS training in the OR in a randomized controlled trial: training in LCS on cadavers was the last step of a whole training curriculum involving also a VR competency-based curriculum in basic skills and cognitive courses. Then, trainees were assessed during a real laparoscopic right hemi-colectomy, using validated rating scales. Curricular-trained residents demonstrated higher performance in the OR than controls, who followed only classical apprenticeship (P=0.03).[10] Lin *et al.* found that simulation in LCS favored residents' participation in the OR without altering patients' outcomes.[68] The present study found the same results, as residents' participation in LCS as primary operator significantly improved after the training, without adversely altering patients' outcomes.

A care pathway approach to training in ATLAS has been implemented for colorectal surgery: it demonstrated its positive impact on residents' participation in the OR and on compliance for ERP. This type of training could be applied to new procedures (such as robotics or single port surgery), new pathways of care, especially in the field of enhanced recovery, and non-surgical care (for example, primary angioplasty for myocardial infarction).

7 DISCUSSION ET PERSPECTIVES FUTURES

7.1 INTERET D'UNE FPSS

Les compétences non-techniques périopératoires sont aussi importantes que les compétences techniques opératoires pour les chirurgiens,[119,176] comme l'illustre le travail de Pucher, *et al.*, démontrant que la qualité de la visite en service de chirurgie a un impact direct sur les suites opératoires des malades en termes de complications « évitables ».[122]

La FPSS comprend une formation en compétences techniques sur un simulateur, et une formation en compétences non-techniques sur la prise en charge périopératoire des malades. Le but d'une telle formation est l'amélioration de ces compétences, telles que l'application pratique de connaissances théoriques, la stratégie de prise en charge et la prise de décision. C'est la première fois qu'une telle formation est développée : les enseignements per- et périopératoires ont toujours été réalisés séparément dans la littérature, et aucune formation n'a jusqu'à présent utilisé la simulation pour combiner enseignement technique et non-technique. Le seul type d'enseignement « combiné » publié a consisté à associer des formations techniques à des cours magistraux sur la prise en charge peropératoire, la plupart du temps auprès de chirurgiens séniors lors de workshops.[50,60,62] La prise en charge périopératoire a longtemps été enseignée exclusivement lors de cours magistraux et dans le cadre du compagnonnage, au lit du malade. Cependant, cet enseignement « au lit du malade » est grevé d'une importante hétérogénéité de prise en charge, comme le montre la grande variabilité du nombre de complications évitables d'un service de chirurgie à l'autre.[179] Le «blended learning», approche plus récente de cet enseignement, combine cours magistraux classiques et e-learning.[123] Cependant la plupart des études portant sur ce type d'enseignement sont de faible qualité méthodologique.[124] De plus, le blended learning n'est pas conçu de manière immersive, avec de «vrais» patients à prendre en charge dans leur globalité. La FPSS est une formation supplémentaire, immersive, qui n'a pas vocation à remplacer le compagnonnage ou le blended learning mais à les compléter.

Deux types de support étaient envisageables pour réaliser la formation périopératoire de manière immersive. Le modèle le plus fidèle et le plus étudié était le SHS,[129,130] qui a démontré son réalisme, sa validité de contenu et sa valeur pédagogique.[131] Cependant, il s'agissait d'un support onéreux et présentant des contraintes de temps et d'accessibilité. En effet, l'utilisation du SHS n'est possible que dans les facultés disposant d'un tel environnement, et en présence d'acteurs rémunérés à chaque séance. A l'inverse, le patient virtuel est un outil certes moins fidèle, mais également moins onéreux et plus facile d'accès,[125] qui a aussi démontré son réalisme, sa validité de contenu et sa valeur pédagogique.[126] En effet, le patient virtuel est accessible par connexion internet, sur tout ordinateur portable ou tablette, et peut donc être exporté à de larges effectifs.[134] Dans notre étude, le coût de développement du patient virtuel était de 1600 $, et la location d'une « île » sur Second-Life™ pour 6 mois de 1770 $. Le coût originel nécessaire au développement du tout premier patient virtuel à l'Imperial College s'élevait à 100 000 $US, et ne sera plus nécessaire pour le développement de projets ultérieurs.[173]

Dans notre travail préliminaire (Chapitre 3), nous avons développé la première FPSS, faisant appel au patient virtuel et à un simulateur de réalité virtuelle. Nous avons volontairement choisi une pathologie simple et fréquente faisant intervenir des compétences fondamentales : l'appendicite aiguë. La mise en place d'une telle formation dans un service de chirurgie a démontré sa faisabilité. Il s'agissait de l'objectif principal de cette étude, avant de développer une FPSS plus complexe. Cependant, cette formation a également eu un impact positif sur la prise en charge des malades, en termes de réalimentation plus précoce, liquide (7 heures (2-20) *vs.* 4 (4-6); P=0.004) et solide (17 heures (4-48) *vs.* 6 (4-24); P=0.005). Elle a, en outre, reçu un bon accueil des internes qui l'ont jugée utile et satisfaisante.

Dans le travail final (Chapitre 6), nous avons mis en place une FPSS en chirurgie colorectale laparoscopique. Cette formation, plus complexe, était adressée à des internes plus avancés dans leur formation, qui l'ont également jugée utile et satisfaisante (4,5/5 pour les 2 items). Le respect des objectifs de réhabilitation précoce (ORP), qui était l'objectif principal de l'étude, était amélioré à 48 heures (3 (30%) *vs.* 8 (80%); P = 0.035). La participation des internes comme opérateur était significativement augmentée après formation (0% (0-100) *vs.* 82.5% (10-100); P = 0.006) sans altérer les suites opératoires des patients, avec une tendance vers une diminution des complications majeures (P = 0.07). La recherche d'un impact sur la morbi-mortalité postopératoire aurait nécessité de bien plus larges effectifs et n'était donc pas l'objectif de l'étude. Le respect des ORP étant associé une diminution de la morbidité dans plusieurs méta-analyses,[167–169] et étant un objectif de la FPSS, c'est ce critère que nous avons étudié.

Au total, nous avons montré la faisabilité d'une FPSS, que celle-ci porte sur une pathologie basique ou plus complexe, et son impact positif sur la prise en charge des malades et la participation des internes. Des études futures pourraient appliquer cette FPSS à de nouvelles approches chirurgicales (robotique, mono-trocart,…), voire à des disciplines interventionnelles non chirurgicales, comme la prise en charge d'un syndrome coronarien aiguë avec réalisation d'une angioplastie, ou le traitement d'une hémorragie digestive en endoscopie.

7.2 INTERET DE LA SIMULATION EN CHIRURGIE COLORECTALE LAPAROSCOPIQUE

Dans le Chapitre 1, nous avons mis en évidence que la qualité méthodologique des 54 études traitant de la simulation en chirurgie laparoscopique complexe (ou avancée) était faible, une étude sur 5 étant purement descriptive. Seules 8 études randomisées étaient recensées, toutes présentant des biais potentiels. Cependant, ces études montraient des résultats encourageants en termes d'HTC avancée et de satisfaction. Vingt-deux études ont évalué la simulation en CCL, majoritairement lors d'une sigmoïdectomie.[177] Une seule de ces études a évalué l'impact de la simulation sur l'HTC au bloc opératoire. Il s'agissait d'une étude randomisée durant laquelle des internes étaient soumis à un PEV en gestuelle basique puis à un entrainement en CCL sur cadavres. Ils étaient ensuite évalués lors d'une colectomie droite laparoscopique au bloc opératoire : le groupe soumis au programme d'entrainement présentait une meilleure HTC que le groupe contrôle, soumis uniquement à la formation classique.[10] L'étude présentée dans le Chapitre 4 est la première à développer un PEV en gestuelle avancée laparoscopique. Il s'agit néanmoins d'une première étape et une seconde étude, randomisée, devra évaluer l'impact de ce PEV au bloc opératoire, lors d'une sigmoïdectomie réelle (*cf.* ci-dessous, Chapitre 7.4.1).

Dans leur revue parue en 2010, Miskovic *et al.* ne retrouvaient que 6 études évaluant la simulation en chirurgie colorectale laparoscopique (CCL) : leur conclusion était qu'il persistait un « manque notable de données sur la valeur pédagogique de la simulation » dans ce domaine.[11] Il n'existe pas de consensus quant aux objectifs d'apprentissage en CCL durant l'internat de chirurgie.[11] Fleshman *et al.* ont rédigé des recommandations mais cette démarche reste isolée et peu reproductible en termes de temps, d'infrastructure et de budget (cours didactiques associés à des ateliers d'entrainement sur modèle porcin et cadavérique).[69] Si la courbe d'apprentissage a été estimée entre 30 et 60 cas en CCL,[71–73] et même si ce niveau n'est pas attendu à la fin de l'internat (rôle du clinicat), l'expérience chirurgicale des internes est très loin d'atteindre ces objectifs. Dans l'étude canadienne de Palter *et al.*, plus d'un tiers des internes de 3ème à 5ème année n'avait aucune expérience en CCL en tant qu'opérateur.[42] Rattner *et al.* ont interviewé 85 internes qui étaient au moins en 4ème année avec des résultats similaires : 81% d'entre eux avaient réalisé moins de 3 colectomies laparoscopiques.[74] L'étude présentée dans le Chapitre 4 est en accord avec ces données, puisque 70% des internes évalués n'avaient jamais réalisé de résection colorectale laparoscopique et que les 30% restants en avaient effectué moins de 5, et étaient tous au moins en 4ème année d'internat. Cet écart entre le niveau théorique attendu et la pratique a conduit Essani *et al.* à écrire que « la pertinence du seul modèle de compagnonnage (…) est discutable en CCL » et à promouvoir la simulation dans ce domaine.[55] De plus, Lin *et al.*[68] ont montré que la simulation en CCL promouvait la participation des internes au bloc opératoire pour ces procédures, sans augmenter la morbi-mortalité des patients. Nous avons retrouvé les mêmes résultats dans le Chapitre 6, avec une participation des internes en tant qu'opérateur passant de 0% (0-100) à 82.5% (10-100) après FPSS (P = 0.006) sans modification des suites opératoires.

Bien qu'onéreux (60 000 € minimum, 80 000 € pour le Lap-Mentor™) les simulateurs virtuels fournissent un entrainement plus avancé que les simulateurs simples (procédures complexes), sans poser la question éthique que soulèvent les animaux vivants et les cadavres. De plus, l'entrainement « classique » a également un coût propre. Bridges & Diamond ont estimé celui-ci à 40 775 € par interne, sur la base du temps supplémentaire au bloc opératoire lorsque l'interne est l'opérateur.[90] Si l'on ajoute les coûts liés à l'enseignement par la faculté, ce montant s'élève entre 62 810 € et 172 682 € par interne.[92] Les simulateurs virtuels constituent donc une option intéressante : une fois acquis, leur entretien est peu onéreux, ils sont facilement accessibles et permettent des entrainements multiples, au contraire des autres modèles (animaux vivants, cadavres, organes animaux ou synthétiques pour les simulateurs simples). Enfin, les simulateurs virtuels présentent l'avantage de renseigner l'utilisateur sur sa performance, ce qui a permis de développer des PEV en gestuelle laparoscopique basique.[154]

Au total, la simulation en CCL pourrait réduire la courbe d'apprentissage au bloc opératoire, pour des procédures dont l'accès reste limité en tant qu'opérateur au cours de l'internat. Les simulateurs de réalité virtuels semblent être un support adapté dans ce domaine.

7.3 INTERET D'UNE FORMATION EN REHABILITATION PRECOCE

Les principes fondamentaux de la réhabilitation précoce (RP) en chirurgie colorectale sont l'éducation et la préparation du patient, la préservation de la fonction intestinale, une prise en charge optimale de la douleur et de l'inconfort, ainsi que l'autonomisation du patient à travers une réalimentation et une mobilisation précoces.[166] Trois méta-analyses, basées sur 13 études randomisées contrôlées, ont montré que la RP permettait une diminution de la durée d'hospitalisation et de la morbidité globale, sans toutefois diminuer la morbidité chirurgicale ni la mortalité.[167–169] Une étude récente, portant sur 541 procédures colorectales réalisées en accord avec les recommandations de RP, a montré que le respect des règles de réalimentation et de perfusion des malades dans les premières 48 heures diminuait significativement la morbidité postopératoire.[170] De plus, Aarts *et al.* ont montré que l'anticipation de la RP en consultation préopératoire, l'approche laparoscopique, la prise de liquides clairs dès J0, ainsi que le retrait précoce de la sonde urinaire étaient significativement associés à une durée d'hospitalisation < 5 jours en analyse multivariée.[171] Dans le LAFA-trial, Vlug *et al.* ont montré que l'association de la laparoscopie et de la RP diminuait également la durée d'hospitalisation.[172] Malgré ses bénéfices démontrés, le respect des ORP reste problématique dans la pratique quotidienne.

En effet, le taux d'application des ORP en chirurgie colorectale ne serait que de 60-70%,[157,158] et tend à diminuer avec le temps, y compris dans les centres de référence.[159] Un audit, comparant des patients non inclus et inclus dans un essai, a montré que le respect des ORP était significativement diminué hors de l'essai (par exemple, 61% *vs.* 96%, P<0.001, pour la charge préopératoire en hydrates de carbone).[158] Ces observations ont conduit Cakir *et al.* à écrire qu' "associer la RP à (…) une éducation répétée (était) vital pour maintenir un bénéfice sur la durée de séjour et les suites opératoires".[159] De même, un consensus récent d'experts a statué que l'éducation des nouveaux membres d'une équipe était l'un des 3 éléments fondamentaux pour maintenir les bénéfices de la RP, avec des staffs de mise à jour réguliers, et un feed-back de ces bénéfices à l'équipe soignante.[160]

Pearsall *et al.* ont interviewé des chirurgiens, des anesthésistes et des infirmiers : les chirurgiens se citaient eux-mêmes ainsi que leurs internes comme des entraves aux respect des ORP. Concernant les internes, certains chirurgiens pensaient que les ORP n'étaient pas appliqués du fait d'un manque de connaissances pratiques.[155] Nadler *et al.* ont interrogé 77 internes de chirurgie sur les ORP : 68% et 49% d'entre eux ont répondu que les liquides clairs devaient être repris à J0 et l'alimentation solide à J1 en cas de CCL ; ces taux tombaient à 50% and 26% en cas de colectomie par laparotomie; chez les patients présentant un cathéter épidural, 50% des internes auraient attendu son retrait pour enlever la sonde urinaire. Au total, la prise en charge était globalement correcte en cas de colectomie laparoscopique, mais celle-ci était moins bien connue en cas de chirurgie ouverte ou de proctectomie laparoscopique[156]

Une formation à la RP est donc nécessaire pour les internes. Dans l'étude du Chapitre 6, une telle formation à permis une amélioration à 48 heures des ORP (3 (30%) *vs.* 8 (80%); P = 0.035). Bien que développée initialement pour les internes, une telle formation périopératoire pourrait également être utile aux chirurgiens séniors, afin d'augmenter le taux d'application des ORP.

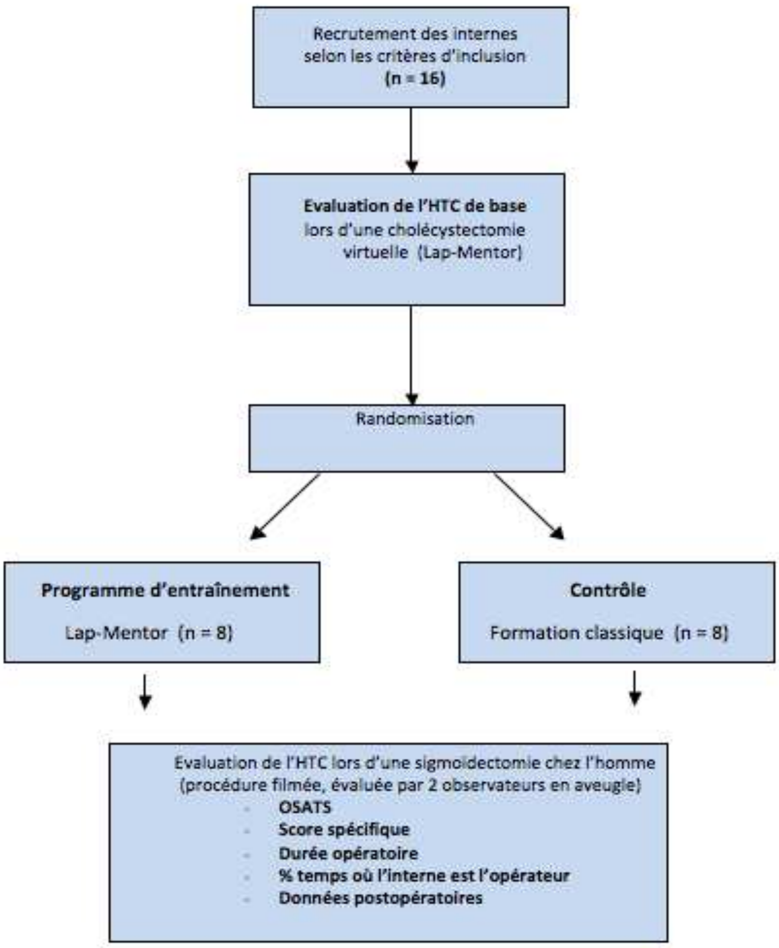
7.4 PERSPECTIVES

7.4.1 Validation de l'impact du Programme d'entrainement virtuel (PEV) sur l'habileté technique en chirurgie colorectale

Une prochaine étude, récemment initiée, vise à évaluer l'impact du PEV que nous avons validé dans le Chapitre 4. Il s'agit d'une étude randomisée contrôlée bi-centrique (Hôpital Nord, Institut Paoli-Calmettes) ayant obtenu l'accord du CIL et inscrite au registre CIL/AP-HM sous le numéro : 2014-10. Les objectifs de cette étude sont les suivants : premièrement, déterminer si ce PEV a un impact positif sur l'habileté technique chirurgicale (HTC) des internes lors d'une sigmoïdectomie laparoscopique ; deuxièmement, déterminer si le PEV modifie le coût de prise en charge des malades. L'objectif primaire sera basé sur la mesure de l'HTC par un score global (OSATS ; Annexe 6)[150] et spécifique à la chirurgie colorectale laparoscopique,[178] sur la durée opératoire, ainsi que sur la morbidité postopératoire (jusqu'à 30 jours postopératoires) selon la classification de Dindo[151] et la durée d'hospitalisation. L'objectif secondaire fera l'objet d'une analyse médico-économique. Pour cela nous inclurons des internes réalisant un semestre en chirurgie digestive et des patients avec sigmoïdectomie laparoscopique programmée. Les critères d'inclusion seront pour les internes, d'être un interne en chirurgie digestive ayant réalisé plus de 5 procédures laparoscopiques « basiques » et moins de 5 résections colorectales laparoscopiques en tant qu'opérateur ; pour les patients d'être âgé de plus de 18 ans et d'être opéré d'une sigmoïdectomie laparoscopique programmée, quelle que soit l'indication (diverticulite, cancer…).

Seize internes seront recrutés et randomisés au moyen d'enveloppes scellées après évaluation de l'HTC initiale lors d'une cholécystectomie virtuelle sur simulateur. Avant randomisation, l'HTC initiale des internes inclus sera évaluée lors d'une cholécystectomie laparoscopique virtuelle sur le Lap-Mentor™. Le premier groupe recevra le PEV en plus de la formation classique (compagnonnage) et le second, la formation classique seule (groupe contrôle). A l'issue de ce programme, tous les internes seront évalués lors d'une sigmoïdectomie laparoscopique (Figure 24).

Figure 24: Design de l'étude randomisée.



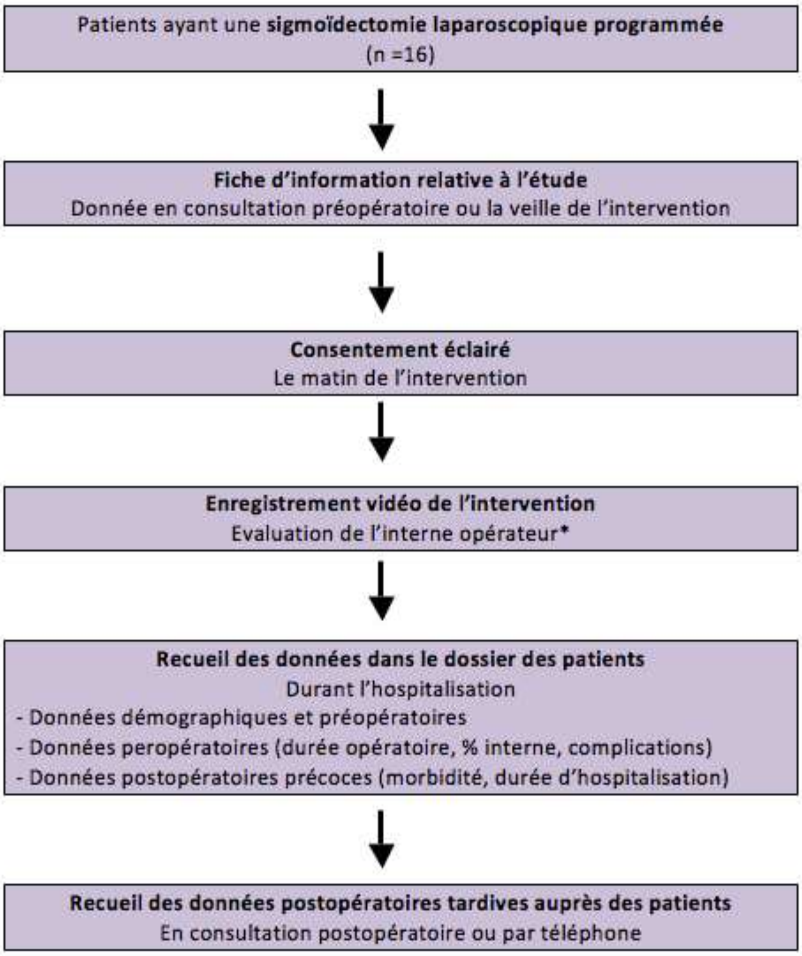
On réalisera un enregistrement vidéo de la procédure. Les temps opératoires imposés et évalués en aveugle par deux observateurs indépendants (LB et SB) seront le décollement colo-épiploïque et la dissection latérale (comportant le décollement colopariétal et le repérage de l'uretère gauche). Lors de ces temps, l'interne évalué sera placé en opérateur et le chirurgien sénior en aide opératoire. Le chirurgien sénior pourra fournir des conseils à l'interne évalué et reprendre sa place d'opérateur à tout moment si il le juge nécessaire pour la sécurité du patient. Cette partie de procédure sera évaluée au moyen des 2 scores d'évaluation sus-cités. Le reste de l'opération sera pratiqué par le chirurgien sénior ou l'interne selon le choix du chirurgien sénior. La durée opératoire et le pourcentage de temps durant lequel l'interne est opérateur seront également quantifiés.

Les patients seront suivis de la veille de l'intervention à 30 jours postopératoires, ou à la fin de leur hospitalisation si cette dernière dépasse 30 jours. Les données démographiques, préopératoires, peropératoires et postopératoires précoces seront collectées à partir des dossiers des patients après leur accord. Les données postopératoires tardives seront obtenues auprès du patient soit lors de la consultation postopératoire, soit par téléphone (Figure 25).

7.4.2 Développement du CERC

Le CERC (Centre d'Enseignement et de Recherche Chirurgicale) dispose de modèles animaux vivants (cochons) et propose depuis 2005 un stage de formation aux nouveaux internes de chirurgie, sur une semaine, avec un très bon retour des participants.[179] Le projet dans lequel nous nous inscrivons avec le Pr Stéphane Berdah et le Pr Gilles Karsenty est de développer ce centre en associant le CERC, le LBA (Laboratoire de Biomécanique Appliquée UMR T24 IFSTTAR/AMU – thématique : développement d'un modèle humain virtuel réaliste) et le Centre de Simulation de l'APHM orienté vers la formation continue et paramédicale. Il vise à créer un centre à vocation européenne d'enseignement et de recherche autour de la simulation en santé.

Figure 25: Protocole de suivi des patients de l'étude randomisée



Les buts de cette nouvelle unité seront les suivants:

- Proposer une formation initiale et continue aux spécialités interventionnelles médicales et paramédicales (chirurgicale, endoscopique, radiologique, réanimatoire) concentrée en un même lieu.
- Structurer une formation et une évaluation des compétences techniques et non techniques aux internes marseillais de DES de chirurgie viscérale et digestive, actuellement inédite en France bien que souhaitée par les tutelles (Rapport HAS ; Figure 26).[180]

- Créer un Master 2 de pédagogie médico-chirurgicale (*cf.* ci-dessous, Chapitre 7.4.3)
- Développer une filière universitaire (Masters, Doctorats) pour les médecins et scientifiques, mais également pour le personnel paramédical.
- Poursuivre et développer le partenariat avec les équipes de recherche de l'Imperial College de Londres, et de l'Université Mc Gill de Montréal, où le Dr Rajesh Aggarwal a récemment pris ses fonctions.

Figure 26: Propositions de l'HAS concernant la simulation en santé.[180]

Simulation en santé : 10 propositions
Proposition 1 → La formation par les méthodes de simulation en santé doit être intégrée dans tous les programmes d'enseignement des professionnels de santé à toutes les étapes de leur cursus (initial et continu). Un objectif éthique devrait être prioritaire : **« jamais la première fois sur le patient ».**
Proposition 2 → L'importance de l'impact de la formation par la simulation sur les facteurs humains et le travail en équipe ainsi que son utilité dans la sécurité des soins doivent être largement étudiés.
Proposition 3 → Une politique nationale doit permettre à la formation par la simulation d'être valorisée et dotée de manière adaptée.
Proposition 4 → La formation initiale et continue par la simulation doit faire l'objet de coopérations entre les universités et les structures de soins ou les instituts de formation (publics ou privés).
Proposition 5 → Les formateurs en matière de simulation doivent bénéficier d'une compétence réelle, validée par l'obtention de diplômes universitaires spécifiques.
Proposition 6 → Chaque société savante doit identifier des programmes de formation par la simulation adaptés aux priorités de leur discipline.
Proposition 7 → L'ensemble des ressources doit faire l'objet d'une mutualisation selon des critères validés (plates-formes équipées accessibles, banque de scénario, programmes de DPC, etc.).
Proposition 8 → Au niveau national ou régional, les accidents les plus graves ou les plus signifiants doivent faire l'objet de reconstitutions en simulation afin d'en analyser les causes et de prévenir leur répétition.
Proposition 9 → La simulation peut être utilisée comme un outil de validation des compétences (ou de transfert de compétences) des professionnels au sein de structures « certifiées ».
Proposition 10 → Les travaux de recherche sur la simulation en santé doivent faire l'objet d'une méthodologie rigoureuse et d'une collaboration en réseau.

7.4.3 Développement d'un Master 2

Le projet est de réaliser au sein du CERC et en collaboration avec les Pr Karsenty et Berdah un Master 2 de pédagogie interventionnelle, pour lequel nous avons obtenu un accord de l'Université d'Aix-Marseille et qui devrait débuter en Septembre 2015. Ce Master 2 sera encadré par une douzaine d'intervenants et fera l'objet d'un enseignement de 5 semaines, à raison de 10 demi-journées par semaine. Il abordera les thématiques suivantes : **Introduction** au Master et aux outils statistiques, **Module 1 : Processus d'apprentissage** (Qu'est ce qu'apprendre ? Processus adaptatif de l'enfant et de l'adulte ; Historique du mode d'apprentissage en médecine et apprentissage actuel ; Processus d'apprentissage du geste en chirurgie et en médecine interventionnelle ; Expérience et expertise : l'expérience fait-elle de nous des experts ? Comment vise-t-on l'excellence ?), **Module 2 : Apprentissage des compétences techniques** (Limites de l'apprentissage exclusif au bloc opératoire ; Apprentissage des gestuelles chirurgicales et interventionnelles basiques (outils et modes d'évaluation, du simulateur au mental practice) ; Apprentissage des gestuelles complexes ou avancées; Innovation technologique), **Module 3 : Apprentissage des compétences non techniques** (Apprentissage du travail en équipe (leadership, gestion du stress) ; Sécurité du patient ; Apprentissage des compétences en service, avant et après le geste : connaissance des indications, stratégie et prise de décision), **Module 4 : Evaluation des nouvelles procédures et nouveaux matériaux en chirurgie /médecine interventionnelle**.

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ANNEXES

Annex 1:

Please rate from 1 to 5 the following questions (1 being poor and 5 excellent)

1/ Second life scenarios

Overall satisfaction:	1	2	3	4	5
Overall usefulness:	1	2	3	4	5
Usefulness of preoperative scenarios:	1	2	3	4	5
Usefulness of postoperative scenarios:	1	2	3	4	5

2/Lapsim curriculum

Overall satisfaction:	1	2	3	4	5
Overall usefulness:	1	2	3	4	5
Usefulness of basic tasks:	1	2	3	4	5
Usefulness of LAPP:	1	2	3	4	5
Overall realism of LAPP:	1	2	3	4	5

Realism of:

- Mesoappendix dissection:	1	2	3	4	5
- Endoloop positioning:	1	2	3	4	5
- Cutting the appendix:	1	2	3	4	5

Realism of ergonomics:	1	2	3	4	5

Comments:

LAPP: laparoscopic appendectomy.

Annex 2:

Date:

Candidate n°:

Age:

Gender:	F / M
Dominant hand:	R / L
Seniority:	PGY1 / 2 / 3 / 4 / 5 / 6 / 7 / Consultant
Video games player:	Y / N

Total number of laparoscopic cases performed as primary operator:

5-10 10-20 20-50 50-100 >100

Number of open colorectal resections performed as primary operator (>50%):

0 1-5 5-10 10-20 20-50 50-100 >100

Number of laparoscopic colorectal resections performed as primary operator (>50%):

0 1-5 5-10 10-20 20-50 50-100 >100

Number of laparoscopic colorectal resections performed as primary assistant:

0 1-5 5-10 10-20 20-50 50-100 >100

Annexe 3:

Date:

Candidate n°:

Please rate from 1 to 5 the following questions (1 being poor and 5 excellent):

Overall satisfaction:	1	2	3	4	5
Overall usefulness as a training tool:	1	2	3	4	5
Overall realism:	1	2	3	4	5
Realism of:					
- Toldt fascia dissection:	1	2	3	4	5
- Colonic mobilization:	1	2	3	4	5
- Vessels dissection:					
o Inferior mesenteric artery:	1	2	3	4	5
o Inferior mesenteric vein:	1	2	3	4	5
- Left ureter and genital vein identification:					
	1	2	3	4	5
- Rectal dissection:	1	2	3	4	5
- Rectal stapling:	1	2	3	4	5
- Anastomosis:	1	2	3	4	5
Ergonomy:	1	2	3	4	5
Force feedback:	1	2	3	4	5

Comments:

Annex 4: Pre-training questionnaire.

Date:

Candidate n°:

Age:

Gender:	F / M
Seniority:	ST3 / ST4 / ST5 / ST6 / ST7

Total number of laparoscopic cases performed as primary operator:

5-10	10-20	20-50	50-100	>100

Number of open colorectal resection performed (>50%) as primary operator:

0	1-5	5-10	10-20	20-50	50-100	>100

Number of laparoscopic colorectal resection performed (>50%) as primary operator:

0	1-5	5-10	10-20	20-50	50-100	>100

Number of laparoscopic colorectal resection performed as primary assistant:

0	1-5	5-10	10-20	20-50	50-100	>100

Annex 5: Post-training questionnaire.

Date:

Candidate n°:

Please rate from 1 to 5 the following questions (1 being poor and 5 excellent)

Overall satisfaction:	1	2	3	4	5
Overall usefulness:	1	2	3	4	5
Usefulness of preoperative scenarios:	1	2	3	4	5
Usefulness of postoperative scenarios:	1	2	3	4	5

Confidence in managing colorectal patients in the ward before the training:

1 2 3 4 5

Confidence in managing colorectal patients in the ward after the training:

1 2 3 4 5

Confidence in assisting laparoscopic colorectal resections before the training:

1 2 3 4 5

Confidence in assisting laparoscopic colorectal resections after the training:

1 2 3 4 5

Confidence in performing laparoscopic colorectal resection (primary operator) before the training:

1 2 3 4 5

Confidence in performing laparoscopic colorectal resection (primary operator) after the training:

1 2 3 4 5

Comments:

Annexe 6: Echelle d'évaluation de l'habileté technique OSATS

(Martin JA, Regehr G, Reznick R, et al. Objective structured assessment of technical skill (OSATS) for surgical residents. Br J Surg. 1997; 84: 273-8.)

	1	2	3	4	5
Respect for tissue	Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments		Careful handling of tissue but occasionally caused inadvertent damage		Consistently handled tissues appropriately with minimal damage
	1	2	3	4	5
Time and motion	Many unnecessary moves		Efficient time/motion but some unnecessary moves		Economy of movement and maximum efficiency
	1	2	3	4	5
Instrument handling	Repeatedly makes tentative or awkward moves with instruments		Competent use of instruments although occasionally appeared stiff or awkward		Fluid moves with instrument and no awkwardness
	1	2	3	4	5
Knowledge of Instruments	Frequently asked for the wrong instrument or used inappropriate instrument		Knew the names of most instruments and used appropriate instrument for the task		Obviously familiar with the instruments required and their names
	1	2	3	4	5
Use of assistants	Consistently placed assistants poorly or failed to use assistants		Good use of assistants most of the time		Strategically used assistant to the best advantage at all times
	1	2	3	4	5
Flow of operation and forward planning	Frequently stopped operating or needed to discuss next move		Demonstrated ability for forward planning with steady progression of operative procedure		Obviously planned course of operation with effortless flow from one move to the next
	1	2	3	4	5
Knowledge of specific procedure	Deficient knowledge. Needed specific instruction at most operative steps		Knew all important aspects of the operation		Demonstrated familiarity with all aspects of the operation

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PRATIQUE DE SOINS / *HEALTHCARE STRATEGIES*

Implication et intérêt du training hors du bloc opératoire dans l'apprentissage chirurgical

Training out of the operating room: Impact in surgical apprenticeship

L. Beyer · G. Karsenty · S. Berdah

« A simulator need not have high fidelity to achieve significant educational value. » [1].

Pourquoi déplacer l'apprentissage hors du bloc opératoire ?

La maîtrise gestuelle indispensable à l'accomplissement d'interventions chirurgicales, que nous appellerons habileté technique chirurgicale (HTC), est une compétence spécifique de la chirurgie. Cette « habileté technique », nécessaire à la bonne pratique d'un examen clinique ou à la réalisation d'actes diagnostiques et thérapeutiques, compte selon Epstein et Hundert parmi les dimensions essentielles de la compétence médicale [2].

C'est William Halsted qui introduisit en 1889 la notion de compagnonnage chirurgical en développant un concept d'enseignement basé sur l'immersion et la responsabilité graduelle [3]. Ce système reste à ce jour le mode principal, et pour beaucoup exclusif, d'apprentissage de la chirurgie en Europe et en Amérique du Nord : au cours de l'internat de spécialité, le futur chirurgien (interne) est invité lors d'interventions réelles à participer en tant qu'aide de plus en plus actif d'un chirurgien sénior. Ainsi, l'apprentissage et l'évaluation de l'HTC ne sont pas formalisés dans le système d'enseignement français de chirurgie. Cette situation a déjà été identifiée depuis environ 15 ans en Angleterre et au Canada [4,5], et ce type d'enseignement connaît aujourd'hui des limitations croissantes liées à la fois à l'évolution de la pratique chirurgicale et au fonctionnement du système hospitalo-universitaire [6]. On peut lister :

- l'accélération de l'innovation technique (en particulier la cœlioscopie) qui augmente les compétences à acquérir, mobilisant ainsi les chirurgiens enseignants à leur propre formation ;
- la question éthique que constitue la réalisation de gestes par un novice, même sous contrôle d'un chirurgien senior et la potentielle perte de chance qui en découle pour le patient ;
- la diminution du temps passé au bloc opératoire par les internes suite à l'instauration, par ailleurs bénéfique, du repos compensateur ;
- la pression économique pour une optimisation du temps d'occupation des salles d'opération ;
- la pression médicolégale croissante en cas de survenue de complications per- ou postopératoires [7,8].

Un moyen de faciliter les acquisitions techniques élémentaires est de déplacer leur apprentissage en dehors du bloc opératoire et de ses contraintes en utilisant des modèles inanimés [9-13]. Cette démarche s'inspire de l'aéronautique, dans laquelle la simulation a trouvé sa place depuis une cinquantaine d'années [14] : quel passager accepterait en effet de monter à bord d'un avion piloté par un commandant qui n'aurait pas été confronté auparavant à différents décollages, atterrissages et pannes sur simulateur ?

Cet engouement pour la simulation a permis de voir se développer de nombreux appareils toujours plus sophistiqués et coûteux. Mais existe-t-il un réel transfert des compétences acquises sur simulateur au bloc opératoire ? La réponse à cette question n'est pas claire et après un engouement important pour les simulateurs dans les écoles de chirurgie, ils sont aujourd'hui sous-utilisés [15]. La littérature sur ce sujet est dense mais fait dire à Champion et Gallagher en 2003 que « la mauvaise qualité des études scientifiques dans le domaine (…) est devenue chose trop commune » [16]. Jusqu'à présent, seules quatre études ont étudié l'impact de la simulation sur les performances lors d'une procédure de cœlioscopie réelle [17-20]. Toutes concluent à un impact positif.

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Malheureusement, pour trois d'entre elles, l'échelle d'évaluation utilisée n'était pas validée et les délais d'évaluation après formation sur simulateur n'étaient pas précisés ou trop courts.

Modèles de simulation cœlioscopique

On peut distinguer cinq types de modèles de simulation (Tableau 1) :

- les modèles inanimés simplifiés ou simulateurs simples (Fig. 1) qui ont pour avantage d'être peu onéreux, transportables et toujours disponibles. On peut citer par exemple le MISTELS (Mac Gill Inanimate System for Training and Evaluation of Laparoscopic Skills), outil d'entraînement et d'évaluation validé, la validation d'un simulateur consistant à prouver son caractère discriminant entre un novice et un expert [21,22]. Ce simulateur issu des travaux de Fried entre dans le programme d'enseignement utilisé dans le cursus de formation proposé par le Collège américain de chirurgie, le FLS Program (Fundamentals of Laparoscopic Surgery). Son coût est de 3 400 euros ;
- les simulateurs virtuels (Fig. 2), plus sophistiqués, qui permettent de réaliser à la fois des gestes de base et des interventions chirurgicales complètes, mais qui sont très coûteux. On distingue les simulateurs de première génération tels que le MIST-VR® (Mentice AB, Göteborg, Suède) et de dernière génération tels que le Lap-Mentor® (Symbionix, Cleveland, OH), tous deux validés dans la littérature [23-25]. Le coût du Lap-Mentor® est par exemple de 80 000 euros, soit environ 20 fois plus cher qu'un simulateur simple. Malgré ce surcoût, les quelques études comparant simulateurs simples et virtuels montrent jusqu'à présent des résultats disparates [26-28]. Une revue récente de la littérature concluait à une supériorité des simulateurs virtuels sur des scores de performance établis hors du bloc opératoire, mais précisait que « le bénéfice de la réalité virtuelle n'est pas clair » [29]. Quant à la satisfaction des utilisateurs, il semble que les simulateurs virtuels obtiennent des scores inférieurs aux simulateurs simples, probablement du fait d'une moins bonne sensation de retour de force et de perception de profondeur ;
- les simulateurs de « réalité amplifiée » qui combinent l'utilisation d'instruments réels de cœlioscopie à des images de réalité virtuelle. Certains ont été validés dans

Tableau 1 Différents modèles de simulation en cœlioscopie

Modèles	Exemples	Avantages	Inconvénients
Simulateurs simples	MISTELS, TowerT, SCMIS GEM	Coût Disponibilité Perception de profondeur Sensation de retour de force	Manque de réalisme Entraînement limité aux exercices basiques (manipulation, suture) Autoévaluation limitée au chronométrage (pas de score d'erreur)
Simulateurs virtuels	Lap-Mentor®, LapSim, MIST-VR®	Réalisme Entraînement varié (exercices basiques, procédures chirurgicales complètes) Autoévaluation (score d'erreur)	Coût Disponibilité Perception de profondeur Sensation de retour de force Pas de supériorité démontrée/ simulateur simple
Simulateurs de réalité amplifiée	LTS2000-ISM60, ProMIS®	Réalisme Entraînement varié Autoévaluation (score d'erreur) Perception de profondeur Sensation de retour de force	Coût Disponibilité Pas de supériorité démontrée/ simulateur simple
Modèle animal	Cochon	Réalisme Perception de profondeur Sensation de retour de force	Coût Disponibilité Éthique
Cadavres		Réalisme Perception de profondeur Sensation de retour de force	Coût Disponibilité Éthique

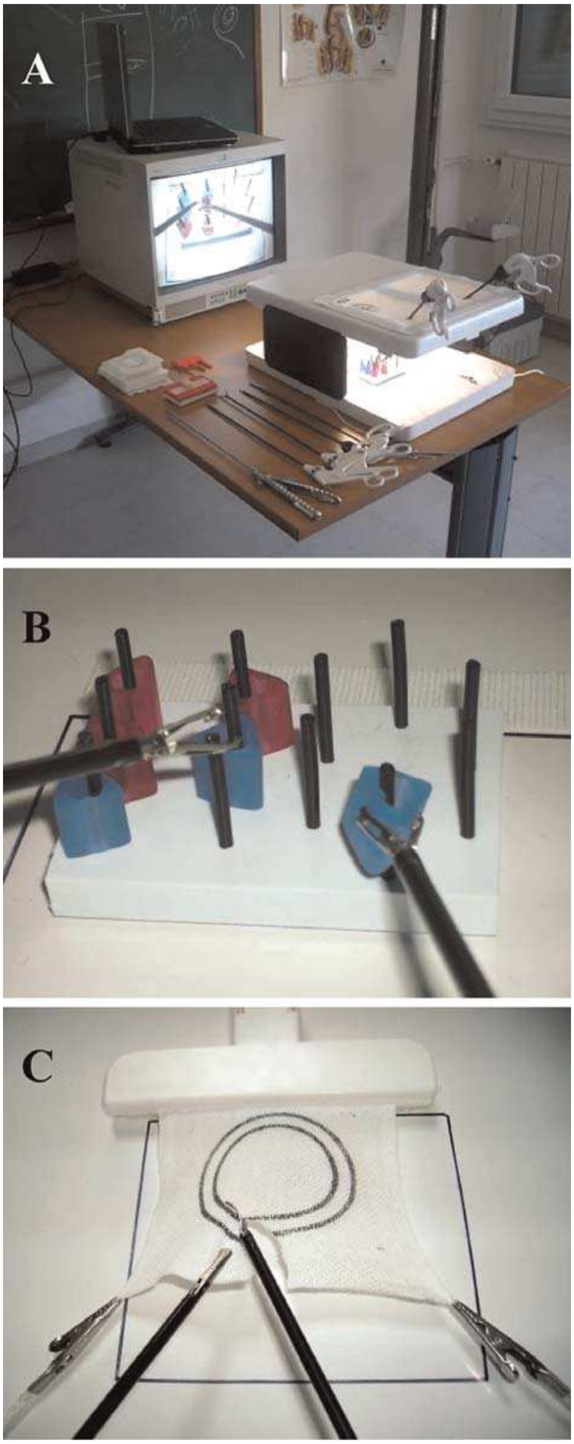

Fig. 1 Un exemple de simulateur simple, le MISTELS. A. La boîte d'entraînement est reliée à un écran vidéo. Les instruments sont ceux utilisés au bloc opératoire. B. Exercice de transferts de boulons. C. Exercice de section d'une compresse sur une marque prédéfinie

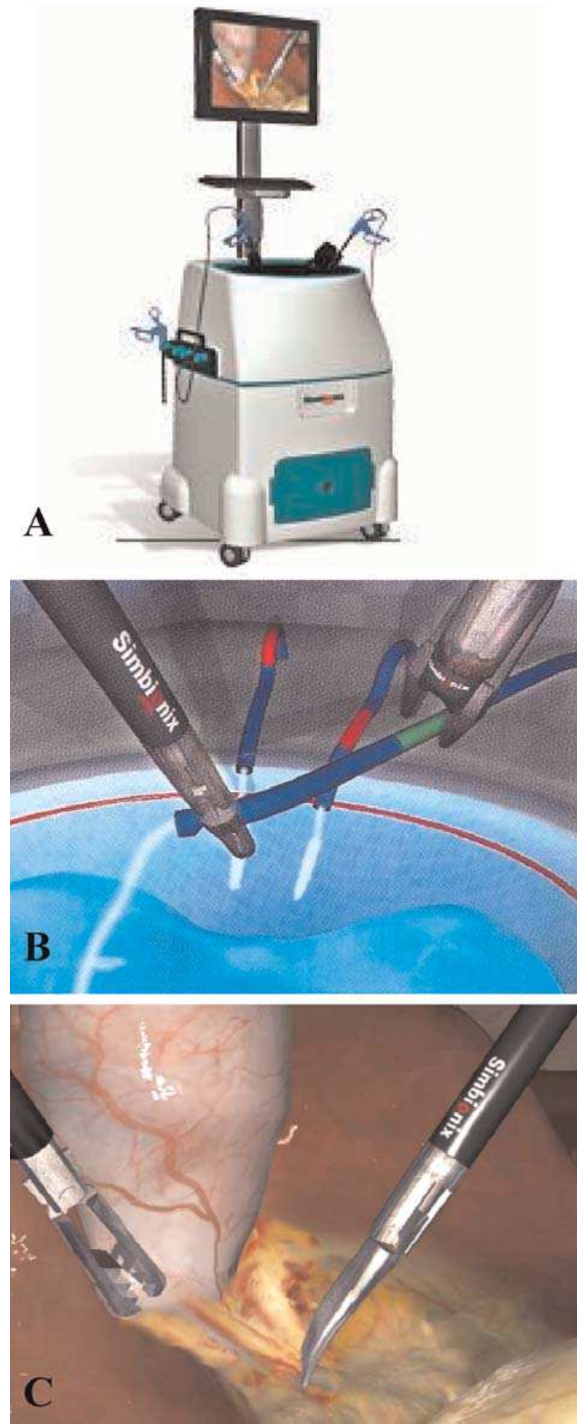

Fig. 2 Un exemple de simulateur virtuel de dernière génération, le Lap-Mentor®. A. Colonne de cœlioscopie mobile. B. Exercice de mise en place de clips. C. Procédure chirurgicale complète (cholécystectomie) réalisée à partir d'images d'IRM et de cœlioscopie in vivo

la littérature et obtiennent des scores de satisfaction par les utilisateurs supérieurs aux simulateurs simples [30,31]. Cependant, leur coût se rapproche de celui des simulateurs virtuels et aucune étude n'a comparé leur impact sur l'HTC par rapport à un simulateur simple. Ce surcoût n'est donc pour le moment pas justifié aux vues de la littérature, mais une étude comparative rigoureuse est nécessaire ;

Tableau 2 Programme du stage d'initiation à la gestuelle chirurgicale proposé au CERC aux internes de premier semestre de chirurgie.

1/2 journée	Programme	Supports utilisés
1	Principes d'asepsie, lavage des mains, habillage, champage, circulation au bloc opératoire	Cours théoriques (1 heure) Travaux pratiques autour d'une table opératoire (2 heures)
2	Ligature et suture	Cours théorique (40 minutes) Pratique sur pieds de porc et stands plastiques (4 heures)
3	Principes en chirurgie digestive et urologique	Cours théorique (1 heure 30 minutes)
4	Initiation à la chirurgie ouverte et cœlioscopique	Pratique sur porcs anesthésiés (5 heures 00 minute)
5	Principes en neurochirurgie	Cours théorique (1 heure) Pratique sur sujet anatomique (2 heures 30 minutes)
6	Principes en chirurgie orthopédique	Cours théorique (1 heure) Pratique sur os sec (3 heures)
7	Principes en chirurgie vasculaire	Cours théorique (1 heure) Pratique sur sujet anatomique (2 heures 30 minutes)
8	Principes en chirurgie thoracique	Cours théorique (1 heure) Pratique sur sujet anatomique (2 heures 30 minutes)
9	Principes en réanimation et gestes d'urgence	Cours théorique (1 heure) Pratique sur mannequins (3 heures)
10	Bilan et perspective	Discussion ouverte Scores de satisfaction anonymes

- le modèle animal vivant qui est coûteux, moins disponible et pose un problème éthique. Par exemple, le coût global d'une seule séance de cœlioscopie sur un cochon est de 1 000 euros ;
- les cadavres qui présentent les mêmes limites que le modèle animal [6].

Place du compagnonnage

Dans le modèle de Fitts et Posner d'acquisition d'une compétence gestuelle, la première étape dite cognitive consiste à comprendre chaque étape élémentaire du geste. À ce stade, les performances sont médiocres et la réalisation du geste requiert toute l'attention de l'apprenant. La deuxième phase dite d'assimilation permet de passer de la connaissance des étapes élémentaires à un comportement moteur adapté permettant d'enchaîner les étapes élémentaires au prix d'une concentration suffisante. La troisième étape dite d'automatisation, atteinte par l'entraînement, voit l'apprenant automatiser la séquence des étapes élémentaires du geste tout en allouant ses ressources attentionnelles à un autre objet [32].

La simulation en dehors du bloc opératoire permet d'amorcer les deux premières étapes du processus d'acquisition (cognition, assimilation) et de sensibiliser l'interne à la nécessité de la troisième (automatisation) qui ne pourra se faire qu'avec un enseignement de type compagnonnage, indispensable à l'apprentissage de la chirurgie. Ainsi, l'apprentissage hors du bloc opératoire trouve sa place privilégiée auprès des internes en début de cursus et ne saurait en aucun cas se substituer au compagnonnage classique, mais le précède et le complète.

Exemple d'enseignement et de recherche

À titre expérimental à Paris, Marseille et Toulouse, les internes nouvellement admis en chirurgie bénéficient avant leur prise de fonction d'un stage d'initiation à la gestuelle chirurgicale. À Marseille, ce stage est proposé au Centre d'enseignement et de recherche chirurgicale (CERC) sur le mode du volontariat et dure une semaine. Des bases d'HTC sont dispensées sur différents types de modèles et la forte satisfaction des étudiants témoigne d'une attente réelle pour ce type d'enseignement. Dans chaque discipline, un enseignant PUPH est aidé d'un ou de plusieurs juniors (le Tableau 2 résume les objectifs du stage et les moyens mis à disposition). Il apparaît que ce type d'enseignement permet une acquisition de l'HTC de base plus rapide [33].

Une structure telle que le CERC permet également la réalisation de masters dans le domaine de la pédagogie chirurgicale. Un projet de recherche comparant l'impact sur l'HTC au bloc opératoire d'un training sur simulateur par rapport au compagnonnage seul a ainsi pu être réalisé, mettant en évidence un bénéfice de ce training (évaluation avant–après au bloc opératoire basée sur un score validé) [34]. Utilisant la même méthodologie, un second projet a montré une équivalence d'impact significative entre simulateur simple (MISTELS) et simulateur virtuel (Lap-Mentor®).

Conclusion

L'évolution des pratiques chirurgicales et du fonctionnement hospitalo-universitaire impose un déplacement de l'enseignement des gestes de base hors du bloc opératoire. Cette formation prend toute son importance chez les internes en début de cursus et ne remplace aucunement le compagnonnage mais le complète. De nombreux outils d'entraînement ont été développés dans ce domaine, plus ou moins sophistiqués et plus ou moins coûteux : des études rigoureuses évaluant l'impact de ces outils en situation réelle à l'aide de scores validés sont encore nécessaires pour démontrer l'intérêt de chaque appareil et les comparer entre eux. À l'heure où un programme hospitalier de recherche clinique national est sur le point d'évaluer le Lap-Mentor® comme outil d'enseignement de chirurgie digestive, il convient de se demander si un simulateur simple n'a pas un impact aussi efficace sur l'HTC. En effet, il serait plus facile pour les facultés de médecine françaises de s'équiper d'un simulateur simple tel que le MISTELS, environ 20 fois moins onéreux qu'un simulateur virtuel.

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Clinical Science

Impact of laparoscopy simulator training on the technical skills of future surgeons in the operating room: a prospective study

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KEYWORDS:
Simulator;
Training;
Laparoscopy;
MISTELS;
LAP Mentor

Abstract

BACKGROUND: The efficacy of laparoscopy simulators remains controversial.

METHODS: This was a comparative prospective study that evaluated the impact of simulator training on technical competence during a real surgical procedure. Residents were divided into 3 groups: the Mcgill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS) group, training on a simple simulator; LAP Mentor group, training on a virtual simulator; and control group. An initial evaluation was made by a validated score during a laparoscopic cholecystectomy. Each resident was then trained for 1 month. A second evaluation was then performed.

RESULTS: Before/after scores were significantly improved in the MISTELS ($P = .042$) and LAP Mentor ($P = .026$) groups. It was not the case in the control group. There was a better progression in the MISTELS ($P = .026$) and LAP Mentor ($P = .007$) groups than in the control group. There was no significant difference between the MISTELS and LAP Mentor groups.

CONCLUSIONS: Simulator training provides a more rapid acquisition of competence in surgical technique.

Epstein and Hundert[1] consider that technical skill in the practice of diagnostic and therapeutic procedures is one of the essential dimensions in medical competence. The mastery of manual skills that is indispensable for the performance of surgical tasks, which we call "surgical technical skill" (STS), is a competence that is specific to surgery, as there are technical skills specific to anesthesia, interventional radiology, or cardiology. Paradoxically, its training and evaluation are not formalized in the French surgical education system. The same situation was identified in England and Canada 15 years ago.[2,3] In France, the acquisition of STS occurs almost exclusively in real operations during residency. This transmission of knowledge through gradual immersion and responsibility or "mentorship" is becoming increasingly limited because of both the development of surgical practice[4] and the functioning of the university hospital system. We can cite the following: (1) the ethical question of surgery performed by a novice; (2) the acceleration of technical innovation (particularly laparoscopy), which increases the number of skills to be acquired and mobilizes teaching surgeons to acquire new skills too; (3) the reduction in the time residents spend in the operating room

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(compensatory rest); (4) the economic pressure to optimize the use of operating rooms; and, finally, (5) increasing medicolegal pressure.[5,6] One way to facilitate the acquisition of elementary techniques is to move such training out of the operating room and its constraints[7] by using inanimate models.[8–11] But is there a real transfer of skills from the model to the operating room? The answer to this question is not clear, and after the craze for simulators in schools of surgery, they are underused.[12] The aim of this study was to evaluate the impact of simulator training on resident STS in the operating room.

Materials and Methods

Between May 2007 and July 2008, we performed a monocenter prospective study over a period of 3 residency rotations. The impact of the 3 training rotations on STS was estimated in a single blind comparison with a validated tool: the Global Operative Assessment of Laparoscopic Skills (GOALS) score.

The participants in the study were general surgery or gynecology-obstetrics residents joining the general and digestive surgery Department at the North Hospital in Marseille for 1 rotation. They were not randomized. Three groups of residents were formed, each corresponding to a different rotation; all of them benefitted from surgical mentorship as the principal means of training from a team of 8 teaching surgeons. The groups only differed according to the complementary training they received: group 1 underwent training on a Mcgill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS) Simulator, group 2 trained on the LAP Mentor Virtual Simulator (Symbionix, Cleveland, OH), and group 3 was the control group and was trained by classic mentorship only. Participation was on a volunteer basis. Our institution does not have a local ethics committee for medical pedagogy work. However, the residents were informed that the results obtained from the various evaluations would not influence the grade they received for the residency rotation.

Study agenda

Each resident was submitted to an initial STS evaluation during the first 2 months of the rotation in a real situation during a laparoscopic cholecystectomy in which the resident was aided by a teaching surgeon (the GOALS score was based on dissection of the vesicular bed). The resident then received the training scheduled for his/her group (Fig. 1). The second evaluation was made in a real situation after 4 months. All laparoscopic procedures the resident performed during the 4-month period were retrieved, as operator or assistant operator.

Evaluation of STS in a real situation (operating room)

During a laparoscopic cholecystectomy, the resident was the operator for dissection of the vesicular bed under the supervision of a senior surgeon acting as assistant. The senior surgeon could give some oral advice but could not provide any operative assistance (it was an excluding criterion of the performance). STS evaluation of each resident for both evaluations (before and after) was blind and performed independently by 2 observers watching every video recording of the procedures. Both observers were experts in laparoscopy (ie, over 100 laparoscopic cholecystectomies performed) and properly trained in how to assess videos using the GOALS score. A random video montage ensured the anonymity of the resident and the surgical assistant. Thus, the observers could not know the name of the resident, his/her group, or if it was the first or second evaluation cholecystectomy.

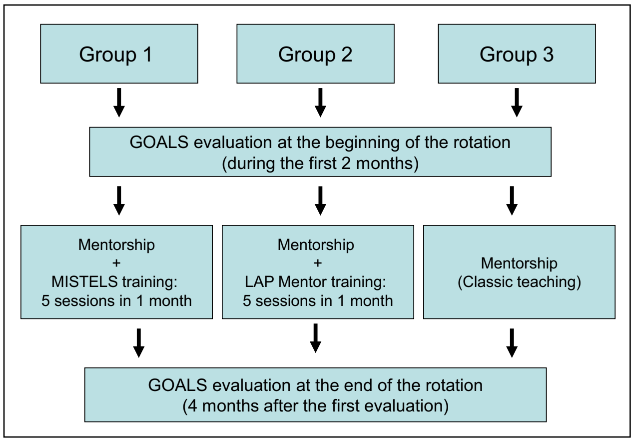

Figure 1 Study agenda.

The GOALS assessment tool developed by Vassiliou et al[13] in 2005 was used to evaluate STS (Appendix 1). GOALS is a validated evaluation scale that is specific to laparoscopy. It has proven itself by distinguishing a beginner from a trained operator and by its superiority when compared with an evaluation by a list of errors.[14] The GOALS score is composed of 5 items and a visual analog scale (VAS) for the difficulty of the surgery. Each item is ranked from 1 to 5 for dissection of the vesicular bed during laparoscopic cholecystectomy: item 1: perception of depth (passage from a 3-dimensional space to a 2-dimensional space, item 2: bimanual dexterity (complementary use of both hands for optimal exposition), item 3: efficiency (measurement of fluidity and the progression of the procedure), item 4: tissue handling (the overall ability of the operator to properly handle tissue without damaging it through the right choice of laparoscopic instruments and the adapted force of the operator), and item 5: autonomy. Item 5 depends not only on the level of the operator but also on the difficulty linked to the local conditions of the cholecystectomy. Because the evaluation was blind thanks to video support, it was difficult to evaluate the degree of assistance and counseling provided by the senior surgeon to the resident. In the Vassiliou et al study,[13] the construct validity of the GOALS was not only established on total score but also on each of the 5 GOALS items; hence, a score using only 4 of the 5 GOALS items has construct validity. Therefore, item 5 was

Figure 2 MISTELS Simulator. On the right is the superior part of the box with camera and light-emitting diodes.

excluded from the statistical analysis with the total GOALS score lowered to a maximum of 20.

The GOALS score has been validated in its English version. We used a version translated into French according to the validation process of a questionnaire (double and retro translation).

Simulators

The MISTELS program, developed by Fried et al,[15–17] is a validated tool for the training and evaluation of laparoscopic skills. It is made up of an inanimate box with a camera and monitor. The box has 2 openings for the placement of two 12-mm trocars and a 0° charge-coupled device (CCD) color camera (Fig. 2). The instruments are the same as those used in the operating room. The simulator and its accessories can be easily transported in a case at a total cost of €4,000. Its program includes 5 standardized tasks: (1) transfer task (6 plastic rings are transferred from the non-dominant hand to the dominant hand and then positioned around a small post and then the process is performed in reverse), (2) sectioning of a compress suspended along a premarked circular template (Fig. 3A), (3) placing of a clip (on a previously marked line on an appendage), and (4) and (5) suturing with intra- and extracorporeal knots. The simulator used for this study is the property of the Center for Surgical Teaching and Research (CERC).

The LAP Mentor is a virtual-reality simulator of the latest validated generation[18–20] with a tactile feedback system. It is a portable laparoscopy column. The operator can work with 2 instruments that he/she can select. The camera is either stationary or can be simultaneously held by an assistant. The virtual reality images are elaborated from magnetic resonance and in vivo laparoscopy images. It costs approximately €80,000. Three categories of exercises can be performed on this simulator: 9 basic exercises (depth manipulation, rapidity), 1 suture exercise with intracorporeal knots, and 1 complete surgical procedure such as a cholecystectomy (Fig. 3B). The simulator was lent to CERC by Ethicon Laboratories (Ethicon, Issy les Moulineaux, France) within the framework of a national program.

Training

There was a predefined program in both MISTELS and LAP Mentor groups; group 1 (MISTELS) candidates repeated at each session the 5 standardized tasks described previously, and group 2 (LAP Mentor) attempted at each session all 9 basic exercises, the intracorporeal knot suture exercise, and 1 cholecystectomy. Group 1 underwent 5 individual 60-minute sessions over a period of 1 month. In group 2, sessions were organized in pairs with each pair undergoing five 120-minute sessions over a period of 1 month. Therefore, the time spent on the simulator was equivalent in both groups and corresponded

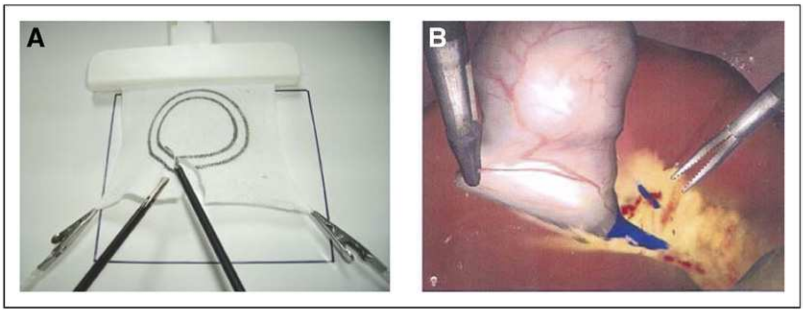

Figure 3 (A) Cutting exercise on MISTELS. (B) Virtual cholecystectomy on the LAP Mentor.

Table 1 Background characteristics of candidates: experience of candidates before evaluation and number of procedures performed during the study

	MISTELS	LAP-Mentor	Control	P MISTELS vs control	P LAP-M vs control	P MISTELS vs LAP-M
No. of candidates	6	6	7	—	—	—
Seniority (median)						
No. of rotations	5	3	5	.25	.15	.38
No. of surgery	4	3	4	.77	.38	.25
No. of laparoscopy	3	1	3	.94	.06	.06
Overall procedures (median)	12	13	11	.57	.32	.75
As operator	2	5	4	.03	.66	.04
As assistant operator	10	8	5	.13	.31	.47

MISTELS = Mcgill Inanimate System for Training and Evaluation of Laparoscopic Skills.

to the longest training times proposed in the literature.[21] All the sessions were supervised by the same teacher whose objective was to have the residents do all the exercises in each program and to intensify effort for exercises that the candidates failed. Equal advices were given in both groups, with regards to bimanual dexterity, depth perception, nontraumatic manipulation of tissues, and efficacy.

Statistical analysis

The GOALS scores obtained were compared among the 3 groups by means of a nonparametric test (Mann-Whitney U test). Links between quantitative variables were measured by the Spearman rank correlation coefficient (r). All the data were analyzed by SPSS 13.0 (SPSS Inc, Chicago, IL). For all the bilateral tests, the threshold of significance was fixed at 5%.

Results

Nineteen candidates were included in the study and evaluated. The 3 groups were comparable in seniority and in the number of rotations of laparoscopic surgeries performed (Table 1). As for the laparoscopic tasks performed by each resident during the study, there was no significant difference between the 3 groups in terms of overall laparoscopic tasks (operator or assistant operator) but there was a significant difference in procedures as operator between the MISTELS and the control groups in favor of the control group (P = .03) and between the MISTELS and the LAP Mentor groups in favor of the LAP Mentor group (P = .03). However, there was no significant difference between the LAP Mentor and the control groups.

The mean GOALS scores obtained from the first laparoscopy were comparable except between the MISTELS and the control groups. There was a high positive correlation between the number of surgical rotations and the initial GOALS score (r = .64, P = .003). There was no significant difference between the difficulty VAS of the first and second evaluation laparoscopies. However, there was a significant difference between the VAS for the first laparoscopies performed by the control group compared with those by the LAP Mentor group and between those by the LAP Mentor group compared with those by the MISTELS group. There was a significant improvement in GOALS scores after training in the MISTELS group (P = .04) with a mean score of 9.3 (range 7–11) for the first evaluation and 12.4 (range 11–14) for the second evaluation. This difference was also significant in the LAP Mentor group (P = .03) with a mean score of 9.2 (range 7–13) and then 13.2 (range 12–15). This difference was not significant in the control group (P = .35); the mean score obtained from the first evaluation of the control group was 12.2 (range 10.5–12.5) versus 11.7 (range 8.5–14.5) for the second evaluation (Table 2). The means of the differences in GOALS scores for each group before and after the training session are presented Table 2. There was a significant difference (P = .03) in favor of the MISTELS group versus the control group. Likewise, the progression in score was significantly higher in the LAP Mentor group (P = .007) versus the control group. There was no significant difference between the MISTELS and the LAP Mentor groups (P = .28) (Fig. 4). In the MISTELS and the LAP Mentor groups, the difference between the initial and final GOALS scores decreased with the number of surgical rotations (r = −.58, P = .046). As for the interrater reliability analysis, the intraclass correlation coefficient was 0, 31, but there was an equal gap between the 2 raters for each assessment and the hierarchy of the scores was the same.

Comments

Our study revealed a significant difference in STS progression between the groups who benefitted from simulator training and the control group. We did not note a significant difference in progression between the MISTELS group (a relatively inexpensive simulator) and the LAP Mentor group (a more expensive one). The efficacy of the surgical simulation was broadly studied for the acquisition of basic tasks for the beginners[22–24] on models that were more or less true to reality.[25] There are 4 types of laparoscopic simulation: (1) simplified inanimate models (MISTELS), which have the advantage of being inexpensive, transportable, and always available; (2)

Table 2 GOALS score and VAS of difficulty before (GOALS 1 and VAS 1) and after (GOALS 2 and VAS 2) the training

	MISTELS	LAP Mentor	Control	*P* value MISTELS vs control	*P* value LAP-M vs control	*P* value MISTELS vs LAP Mentor
GOALS 1	9.33	9.17	12.21	.006	.06	.68
VAS 1	3.63	1.17	3.08	.87	.046	.03
GOALS 2	12.41	13.17	11.85	—	—	—
VAS 2	2.71	2.34	2.64	.94	.57	.42
Progression (GOALS 2-GOALS 1)	3.08	4	−.36	.03	.007	.28
P value GOALS 2 vs GOALS 1	.04	.03	.35			

GOALS = Global Operative Assessment of Laparoscopic Skills; MISTELS = Mcgill Inanimate System for Training and Evaluation of Laparoscopic Skills; VAS = visual analog scale.

Progression between GOALS 1 and GOALS 2 is significantly higher in the MISTELS (*P* = .03) and the LAP Mentor group (*P* = .007) versus the control groups.

virtual simulators (LAP Mentor), which are more sophisticated, making it possible to perform both basic tasks and complete operations but at a much higher cost; (3) living animal models, which are expensive, are less available, and pose ethical problems; and (4) cadavers, which present the same limits as animal models.[26]

There is a wealth of data on the efficacy of laparoscopic simulators in terms of acquisition and the evaluation of dexterity. It is clear that practicing on a simulator increases performances on this simulator.[13,16,27] When an evaluation was made outside of the operating room on swine models, simulation also increased performances in these models.[27–29] Therefore, there is a great amount of data in the literature that has prompted Champion and Gallagher[30] to state that "poor scientific reflection in medical simulation has become too common." Sutherland et al[31] listed 30 controlled randomized studies with a total of 760 participants; after a review of the literature, they stated that one cannot rigorously conclude on the positive impact of simulation on STS. They advanced various hypotheses to explain the lack of proof provided in-

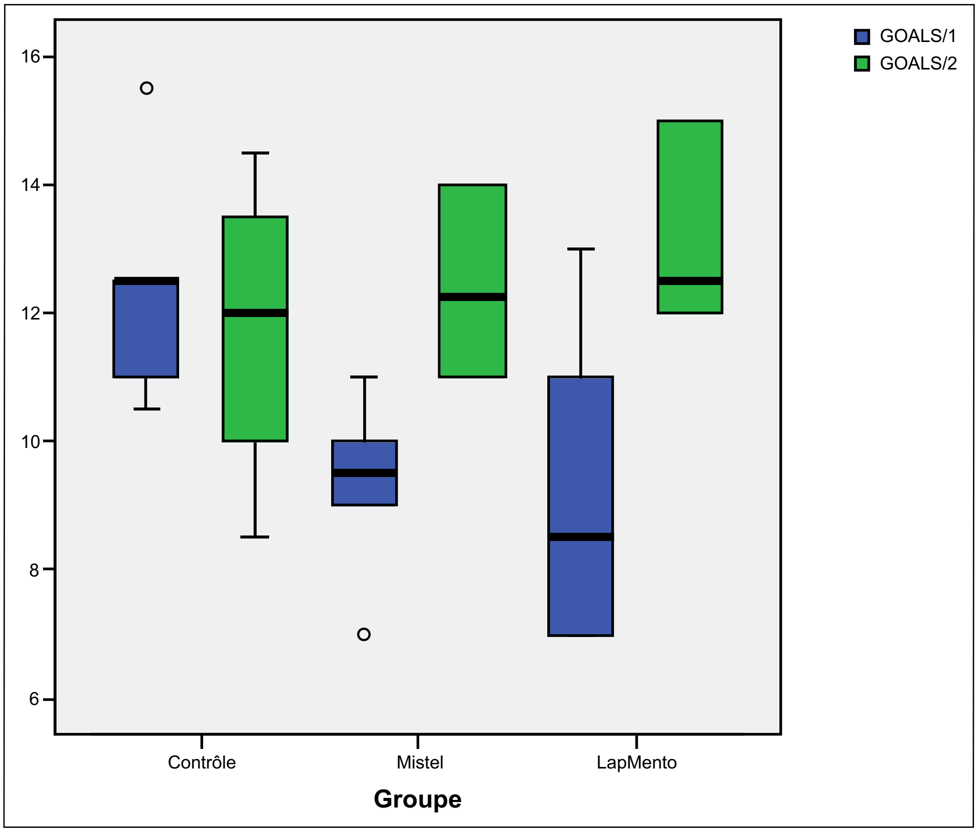

Figure 4 The distribution of GOALS scores in the 3 groups before and after the training.

cluding cohorts that are too small, multiple comparison tools that have often not been validated, numerous simulators that do not make it possible to study one in a satisfactory manner, and too short training time.

Finally, only 3 studies have reported the impact of simulator training during real laparoscopic procedures in man.[32–34] Grantcharov et al[32] studied the impact of Minimally Invasive Surgical Trainer- Virtual Reality (MIST-VR) simulator training in a multicenter study. They compared 2 groups: one underwent training (n = 8), and the other did not (n = 8). Evaluation criteria were the time required to perform a laparoscopic cholecystectomy, an error score, and a score for the economy of movements (analog scale). There was a significant difference between the 2 groups for all 3 criteria. However, these scores have not been validated in the literature. Moreover, the time between the 2 evaluations was only 2 weeks. Seymour et al[33] studied the impact of MIST-VR training versus controls on STS in a real situation. A significantly positive effect was noted. Unfortunately, the evaluation score was once again a nonvalidated error score. In addition, there was no evaluation in the operating room before the training, and the times between simulator training and the evaluation were not stated. Likewise, Scott et al[24] reported an improvement in STS but again with a score that was not validated.

In the present study, the analysis of the initial levels of residents in terms of the number of surgical rotations did not reveal a difference. Knowing all the operations performed by residents before the present study would have been relevant to accurately analyze the impact of experience in this work. Unfortunately, operations performed during residency are not prospectively identified in France. However, the 4 digestive surgery departments of Marseille offer a quite homogeneous training, thus leading to comparable experiences for all residents.

The initial GOALS score differed significantly between the MISTELS and the control groups. This difference can be explained by the small cohort in this study and by the fact that candidates were not randomized; 3 groups of residents were formed, each corresponding to a different rotation. Only randomization based on the initial GOALS score would have enabled us to avoid this difference.

It was difficult to obtain uniformity in the difficulty of cholecystectomy evaluations in this study. In their article on validation of the GOALS score, Vassiliou et al[13] noted a VAS that was similar in the beginner and expert groups. This was not the case in our study. This confirms our choice to not include item 5 of the GOALS score for statistical analysis because this item is influenced by the degree of difficulty of each case.

The GOALS scores before and after the pedagogic operation in the control group did not reveal a difference. The interrater reliability was low, yet the gap between the 2 observers' scores from one evaluation to another was equal, and, more crucially, the hierarchy of the scores was the same between them.

A significant difference was noted in the MISTELS and LAP Mentor groups, and when we measured the difference in scores before and after the pedagogic operation by comparing the MISTELS group or the LAP Mentor group with the control group, it was significant. Therefore, simulator training increases the resident level of STS in the operating room. In the Fitts and Posner[35] model of technical skill acquisition, the first cognitive stage consists in understanding each elementary stage of the task. At this stage, performances are mediocre and require the total attention of the trainee. The second assimilation phase enables the trainee to go from knowledge of elementary stages to adapted motor skills that make it possible to move on to the elementary stages with sufficient concentration. In the third autonomy stage, reached through training, the trainee automates the sequence of elementary stages of the task by devoting his/her attention to another object. Therefore, work on the simulator appears to be preparatory and complementary to mentorship but cannot replace it. Simulation enables the trainee to begin the first 2 phases of the acquisition process (cognition and assimilation), and it makes him/her aware of the need for the third stage (automation), which, given the current state of surgical simulators, can only be acquired with mentorship teaching, which is indispensable in surgical training.

The differences in GOALS scores before and after the pedagogic operation between the MISTELS and the LAP Mentor groups were not significant. The LAP Mentor did not prove its superiority for a more rapid acquisition of laparoscopic technical skills when compared with a first-generation MISTELS simulator that has proven efficacy.[17] The interest of a LAP Mentor simulator can be found in the specific tasks (ie, cholecystectomies, bypasses, and hernias) that are available in virtual reality. The cholecystectomy procedure in virtual reality that was chosen for this study did not prove its efficacy in the acquisition of basic surgical skills during laparoscopic cholecystectomy in the operating room. Other studies are required to evaluate this type of training, in particular by studying the impact that it could have on the Fitts and Posner[34] automation stage by exposing the trainee to the different levels of difficulty and the anatomic variations that make it possible to concentrate a number of cases in a shorter period. The low cost of the MISTELS simulator enables all schools of surgery to equip themselves with a validated tool for the acquisition of basic STS.

The Fundamentals of Laparoscopic Surgery Program used in the curriculum offered by the American College of Surgeons uses the MISTELS simulator by integrating time objectives in the teaching of basic laparoscopy procedures. We did not adopt this teaching method because we think that the automation process of basic tasks is not sufficiently advanced in a beginner to justify a standardized approach based on minimal performance time (knowing that performance time is dependent on the degree of automatism). It can only have little or no impact on the time to perform a task as long as the automation process has not been reached. In a preliminary study, we found this result in open surgery,[35] and the same observation has also been made for mini-invasive surgery.[36] We preferred training adapted to each candidate by rectifying the errors committed in the various tasks.

The fact that there is a negative correlation between seniority and progression of the GOALS score suggests that the interest of simulator training is all the greater for beginners. As early as 1995, Heppell et al[37] stressed the close relationships established from the beginning of the curriculum between residents and teachers during the teaching of basic surgical tasks, helping residents acquire a more rapid understanding of the complex environment of an operating room. This sort of teaching promotes an active and curious approach to the technical aspect of surgical practice.

In conclusion, the time devoted to the teaching of surgery is increasingly reduced, imposing the development of teaching practices outside of the operating room. We have confirmed that teaching on a laparoscopy simulator, associated with mentorship, provides better acquisition of basic STS in real situations than mentorship only, particularly at the beginning of training. This phase of mentorship teaching, which is not substitutable, can be maximized by teaching on a simulator. That should begin as soon as possible in the curriculum of a resident with early concentration on the automation phase of surgery as well as on other aspects of an operation, in particular surgical strategy.

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Appendix 1 GOALS Score

Appendix 1: GOALS Score (Global Operative Assessment of Laparoscopic Skills).

Date: ______________
Candidate: _____________________________

Global Rating Scale

1 Depth Perception

1. Constantly overshoots target, wide swings, slow to correct.
2.
3. Some overshooting or missing of target, but quick to correct.
4.
5. Accurately directs instruments in the correct plan to target.

Score:

2 Bimanual Dexterity

1. Uses only one hand, ignores nondominant hand, poor coordination between hands.
2.
3. Uses both hands but does not optimize interaction between hands.
4.
5. Expertly uses both hands in a complementary manner to provide optimal exposure.

Score:

3 Efficiency

1. Uncertain, inefficient efforts; many tentative movements; constantly changing focus or persisting without progress.
2.
3. Slow but planned movements are reasonably organized.
4.
5. Confident, efficient and safe conduct, maintains focus on task until it is better performed by way of an alternative approach.

Score:

4 Tissue Handling

1. Rough movements, tears tissue, injures adjacent structures, poor grasper control, grasper frequently slips.
2.
3. Handles tissues reasonably well, minor trauma to adjacent tissue (ie, occasional unnecessary bleeding, or slipping of the grasper).
4.
5. Handles tissues well, applies appropriate traction, negligible injury to adjacent structures.

Score:

5 Autonomy

1. Unable to complete entire task, even with verbal guidance.
2.
3. Able to complete task safely with moderate guidance.
4.
5. Able to complete task independently without prompting.

Score:

Total /25

Visual Analog Scale (VAS) of difficulty

(place a mark on the line)

Very easy, normal anatomy, Well-defined planes, no adhesions, scar or inflammatory tissue ●————————● **Extremely difficult**, complex anatomy, no planes, scar and/or inflammatory tissue