Development of a Comprehensive Ex-Vivo Technical Skills Curriculum for an Advanced Minimally Invasive Surgical Procedure

by

Vanessa Nicole Palter

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Institute of Medical Science
University of Toronto

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Abstract

It is well recognized that a certain component of surgical residency training has transitioned from the operating room to the surgical skills lab. Although a significant amount of important work has validated simulators as viable systems for teaching technical skills outside the operating room, the next step is integrating simulators into a comprehensive curriculum. Several frameworks for curricular design have been described in the literature; however, few curricula have been described or validated for minimally invasive surgical procedures. This study describes the design and validation of a comprehensive technical skills curriculum for laparoscopic colorectal surgery, an advanced laparoscopic procedure.

The initial step in this project utilized the Delphi consensus methodology to develop a procedure-specific evaluation tool for laparoscopic colorectal surgery. This evaluation tool demonstrated reliability and validity in the context of expert and novice performance in the operating room. The next phase of the project also used the Delphi method to develop international consensus on a proficiency-based virtual reality program designed to teach the technical skills necessary to perform laparoscopic colorectal surgery. This virtual reality training program was then integrated into a comprehensive curriculum consisting of psychomotor training on the virtual
reality simulator, as well as cognitive training and a cadaver lab. The final component of this project was a randomized single-blinded controlled trial that demonstrated that surgical residents who participated in the comprehensive curriculum exhibited superior technical skills in the operating room, and superior cognitive knowledge relating to laparoscopic colorectal surgery, compared to residents who received only conventional residency training.
Acknowledgments

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Chapter 1
Introduction

1 Introduction

1.1 Ex-Vivo training models

Surgical residency training programs have traditionally used the operating room to teach surgical skills to trainees through graded responsibility under direct supervision. However, this strategy is no longer feasible. New legislation has shortened resident work hours, resulting in fewer opportunities for instruction in the operating room\(^1\). In addition, patient safety concerns have made it undesirable for novice surgeons to learn a new procedure on a real patient. As such, it has become necessary to shift a significant amount of resident technical skills training from the operating room to the surgical skills laboratory. The advent of new technology, such as minimally invasive (laparoscopic) surgery, has similarly contributed to the need for systematic skills training in a safe, simulated environment. The technical skill set for laparoscopic surgery is different from that of open surgery due to altered depth perception, diminished tactile feedback, and the requirement of developing video-eye-hand coordination, all factors which contribute to the long learning curve for this type of surgery\(^2\). A variety of ex-vivo models have been developed to be used outside the operating room, to allow for the teaching of minimally invasive technical skills to surgical trainees.

1.1.1 Laparoscopic Box Trainers

Laparoscopic box trainers consist of a box, with slits on the superior surface for trocar insertion. Real laparoscopic instruments are inserted through the trocars, into the box, where the procedure in question is simulated\(^3\). A camera inside the box provides video-output to a monitor on which the trainee can watch their own movements\(^3\). These models can simulate a variety of laparoscopic techniques including laparoscopic suturing, knot tying, clip applying, and coordination drills\(^4\). One of the most well described box trainers is the McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS) physical laparoscopy trainer. The MISTELS system consists of 5 tasks: peg transfer, cutting, placing a ligating loop, and
suturing with an intra-corporeal and extra-corporeal knot. The MISTELS tasks have been adopted by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) into the Fundamentals of Laparoscopic Surgery (FLS) program, which is a comprehensive curriculum to teach basic laparoscopic skills. The details of the FLS program will be discussed later in the Introduction. Evidence of learning on laparoscopic box trainers has been well established. In a blinded randomized control trial, Traxer et al. demonstrated that practice on a video-trainer resulted in a 51% reduction in time (as measured on the simulator p=0.003), and improvement in technical ability (measured by a validated global assessment tool in a porcine model p=0.0008) as compared to a no-training control group. Similarly, various groups have established the educational value of the MISTELS system by demonstrating that the MISTELS score correlates with laparoscopic performance in an animal model and the operating room, and can also differentiate between individuals at different levels of training. More importantly, Stelzer et al. and Korndoffer et al. demonstrated that the skills learned on the MISTELS system translate into an improved technical performance in a live porcine model. The ability of the technical skills learnt on a video-trainer to transfer to the operating room has also been demonstrated in three randomized, blinded trials. The results from these studies are synthesized in a systematic review by Sutherland et al. that confirm the efficacy of technical skills training on laparoscopic box trainers.

1.1.2 Virtual Reality (VR) Simulators

The current literature similarly lends support to virtual reality training as a medium for technical skills training. Training by virtual reality simulation encompasses systems designed to teach laparoscopic, endoscopic and percutaneous interventions. There is a wide range in the fidelity of virtual reality simulators ranging from the Minimally Invasive Surgical Trainer – Virtual Reality (MIST-VR) system which is a low fidelity system designed to teach general laparoscopic proficiency, to systems that teach specific procedural skills such as vessel clipping, and to simulators that replicate entire operations. As a group, virtual reality simulators consist of laparoscopic instruments connected to a desktop computer. As the laparoscopic instruments are moved, the trainee is able to follow their path on the computer screen. Virtual reality simulators vary in their use of haptics (force feedback). Unlike bench-top models, VR systems allow for practice at varying levels of difficulty, and across a range of clinical situations, thus accommodating learners with a range of technical abilities. Also, VR systems are able to
provide feedback automatically at the completion of each task. This feedback consists of factors including the time to complete the task, how economical the trainee is in their movements, as well as the number of errors that are performed during the execution of a task\textsuperscript{17}.

A variety of VR simulators have demonstrated construct validity, meaning that they can distinguish between expert and novice performance. The MIST-VR has been shown to distinguish between expert, intermediate, and novice performance with respect to time, economy of movement and number of errors\textsuperscript{18-20}. This also holds true for more high fidelity VR simulators such as the LapSim VR simulator (Surgical Science, Gothenberg, Sweden) that can simulate procedural tasks such as cutting or clipping blood vessels\textsuperscript{21-24}. In addition, it has been shown that performance on high fidelity VR simulators correlates with technical performance in the operating room\textsuperscript{25, 26}.

Learning has been demonstrated to occur on a variety of VR simulators. Studies have shown that novices reach expert proficiency after approximately 10 trials on VR simulators, and that learning curves exhibit individual variations\textsuperscript{18, 20-24, 27-30}. This is important since it indicates that trainees at similar levels may take different amounts of time to reach expert proficiency\textsuperscript{17}. After proficiency has been achieved, it has been shown that some degree of retention of what was learned can persist for up to 7 months\textsuperscript{31}.

Like laparoscopic box trainers, the technical skills learnt on virtual reality simulators transfer to analogous clinical situations. 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 residency training\textsuperscript{32-36}. The exception to this is a study by Ahlberg et al. that compared the performance of medical students trained on the MIST-VR to a control group performing laparoscopic appendectomy on a porcine model\textsuperscript{37}. The results from this study showed no difference between the VR trained group and the control group. However, this could be explained by the fact that in this study, the medical students trained for a certain amount of time on the simulator rather than to expert levels of proficiency. This underlines the fact that that learning occurs at different rates for different individuals, and therefore training to expert levels of technical proficiency rather than for certain amounts of time is essential in ex-vivo technical skills training.
Ultimately the transferability of technical skills learned on a VR simulator to technical performance in the operating room, on a real patient, is one of the most important parameters to investigate when assessing the utility of VR simulators as a technical skills training tool. Although few well-designed randomized controlled trials have investigated this, as a group, these studies support the transferability of the technical expertise acquired on VR simulators. Seymour et al. randomized residents to 2 groups: a VR group where residents trained to expert levels of proficiency, and a control group. In the operating room VR trained residents performed a laparoscopic cholecystectomy significantly better with respect to time, a decreased injury rate, and were more likely to progress\(^{38}\). These results were replicated by Grantcharov et al. in a blinded randomized controlled study, with validated assessment measures\(^{39}\). Similarly, Larsen et al. demonstrated that training on a VR simulator resulted in improved technical performance in laparoscopic salpingectomy with respect to time and score on a validated technical skills assessment tool\(^{37, 40}\). Finally, this improvement in technical ability as a result of VR training has been shown to persist for up to 10 cases in the operating room\(^{41}\). This certainly underlines the potential importance of ex-vivo training in ensuring maximal standards of patient safety in the operating room.

### 1.1.3 A comparison of VR simulators and laparoscopic box trainers

Although there is strong evidence supporting both VR training and laparoscopic box training as adjuncts to conventional residency training, the benefit of one form of training over the other is less clear. Several studies demonstrated no difference between both forms of training\(^{42-47}\). Three authors, however, did demonstrate a difference in technical skill acquisition between laparoscopic box trainers and virtual reality simulators. In a randomized, blinded trial, VR trained residents exhibited superior technical performance during a laparoscopic cholecystectomy in the operating room as compared to box trained residents\(^{48}\). Similar results were demonstrated in a randomized study where VR trained medical students performed fewer errors than box-trained medical students on an ex-vivo laparoscopic suturing drill\(^{49}\). In contrast, a randomized controlled study assessing laparoscopic suturing in an ex vivo environment showed learning with box trainers and not with VR simulators\(^{50}\). However, this study was limited by the fact that it used time-based training for both intervention groups rather than proficiency-based training. These results were summarized in a 2008 systematic review and a Cochrane review.
which both concluded that there was not convincing evidence that demonstrated clearly either VR or box training as a superior method of ex-vivo training\textsuperscript{51, 52}.

Although both VR and box training allow trainees to surmount the early part of their learning curve in a safe, simulated environment, there are some advantages to VR training. These include the fact that virtual reality systems can simulate both basic as well as advanced procedures, that they are able to reproduce complications such as bleeding or difficult anatomy, and that their use does not require an expert for feedback or assessment\textsuperscript{53}. Indeed, unlike black-box trainers, virtual reality simulators are able to automatically generate assessment parameters such as time taken, or economy of movement, which allows for comparison between performances and between individuals\textsuperscript{53}.

1.2 Technical Skills Assessment

Parallel to the development of simulators for technical skill training in laparoscopy has been the development of assessment tools for measuring these acquired skills. Assessment allows for monitoring of skills acquisition of surgical trainees, and provides a base for constructive feedback along the learning curve for new procedures\textsuperscript{54}. Objective measures of performance are crucial to determine advancement to the next stage of training for surgical trainees, or re-entry after a career break for staff surgeons\textsuperscript{54}.

Simulators must demonstrate acceptable reliability and validity before they are integrated into high-stakes assessment. Reliability refers to the precision of a test. A test has a high level of reliability if repeating the test on two separate occasions results in an identical test score\textsuperscript{55}. Conventionally, in order for an assessment tool to be useful for assessment, it must have a reliability index of greater than 0.8\textsuperscript{55}. Validity refers to the concept of a test measuring what it is designed to measure. Face validity measures the degree to which the test appears to mimic the task that it is based upon\textsuperscript{55}. Construct validity is an assessment of whether the test can distinguish between differing levels of skill\textsuperscript{55}. Predictive validity in the context of surgical simulation, refers to the degree to which performance on the test predicts performance in the operating room\textsuperscript{55}.

Assessment tools can be classified into three categories: observational tools, virtual reality, and motion analysis. Observational tools rely on an expert observer who assesses technical ability
according to defined criteria on either a global rating scale or a procedure-specific checklist. Virtual reality simulators provide immediate and automatic assessment by recording metrics such as time taken, and error score. Dexterity analysis equates technical ability to the number and speed of a surgeon’s hand movements.

1.2.1 Observational Tools

The observational tool that is most extensively validated in the literature is the OSATS global rating scale developed by Reznick’s group in 1997\textsuperscript{56}. This global rating scale assesses technical performance in a holistic manner (Table 1). The reliability, construct, concurrent, and predictive validity of OSATS has been shown for both a bench-station exam as well as in the operating room for a variety of technical procedures\textsuperscript{54, 57-67}. In addition, OSATS has been modified for laparoscopic surgery (Table 2). The inter-rater reliability of the modified OSATS is moderate with a Cohen’s kappa of 0.71 and a Cronbach’s alpha of 0.76 reported for video-based assessment of operating room performance\textsuperscript{39, 54}. The modified OSATS has also demonstrated construct validity in that the scale differentiates between expert and novice performance of a laparoscopic cholecystectomy in the operating room\textsuperscript{39, 54}. Another global rating scale, the Global Assessment of Laparoscopic Skill (GOALS) designed specifically for laparoscopic surgery was developed by Vassiliou’s group in 2005\textsuperscript{68}. Initial work with GOALS showed that the scale had high internal consistency (Cronbach’s Alpha =0.91) and high inter-rater reliability (intraclass correlation coefficient 0.82 for staff surgeons and 0.89 for trained observers)\textsuperscript{68}. In addition, GOALS has demonstrated construct validity in the context of direct observation in the operating room as well as in the context of the video-analysis of operating room recordings for two basic laparoscopic procedures (laparoscopic cholecystectomy, and appendectomy)\textsuperscript{68, 69}. Although global rating scales are effective at assessing technical skills, these scales are generic, and as such, it is difficult to use these scales to give meaningful feedback to trainees learning specific surgical procedures. As a response, procedure-specific evaluation tools, which represent a hybrid between global rating scales and checklists, have been developed. Although these tools represent an important means of assessing technical proficiency relating to a specific operative procedure, they are currently limited to a small number of laparoscopic procedures including laparoscopic cholecystectomy, gastric bypass, and laparoscopic colorectal surgery\textsuperscript{70-72}. 
<table>
<thead>
<tr>
<th>General Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respect For Tissue</td>
<td>Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments</td>
<td>Careful handling of tissue but occasionally caused inadvertent damage</td>
<td>Consistently handled tissues appropriately with minimal damage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time &amp; Motion</td>
<td>Many unnecessary moves</td>
<td>Efficient time/motion but some unnecessary moves</td>
<td>Economy of movement and maximum efficiency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Instrument Handling</td>
<td>Repeatedly makes tentative or awkward moves with instruments</td>
<td>Competent use of instruments although occasionally appeared stiff or awkward</td>
<td>Fluid moves with instruments and no awkwardness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge of Instruments</td>
<td>Frequently asked for the wrong instrument or used an inappropriate instrument</td>
<td>Knew the names of most instruments and used appropriate instrument or the task</td>
<td>Obviously familiar with the instruments required and their names</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of Assistants</td>
<td>Consistently placed assistants poorly or failed to use assistants</td>
<td>Good use of assistants most of the time</td>
<td>Strategically used assistant to the best advantage at all times</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flow of Operation &amp; Forward Planning</td>
<td>Frequently stopped operating or needed to discuss next move</td>
<td>Demonstrated ability for forward planning with steady progression of operative procedure</td>
<td>Obviously planned course of operation with effortless flow from one move to the next</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge of Specific Procedure</td>
<td>Deficient knowledge. Needed specific instruction at most operative steps</td>
<td>Knew all important aspects of the operation</td>
<td>Demonstrated familiarity with all aspects of the operation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 1: OSATS Global Rating Scale**

<table>
<thead>
<tr>
<th>General Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Economy of Movement (Time &amp; Motion)</td>
<td>Many unnecessary moves</td>
<td>Efficient time/motion but some unnecessary moves</td>
<td>Economy of movement and maximum efficiency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confidence of Movement (Instrument Handling)</td>
<td>Repeatedly makes tentative or awkward moves with instruments</td>
<td>Competent use of instruments although occasionally appeared stiff or awkward</td>
<td>Fluid moves with instruments and no awkwardness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respect For Tissue</td>
<td>Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments</td>
<td>Careful handling of tissue but occasionally caused inadvertent damage</td>
<td>Consistently handled tissues appropriately with minimal damage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Precision of Operative Technique (Flow of Operation)</td>
<td>Imprecise, wrong technique in approaching the operative interventions</td>
<td>Careful technique with occasional errors</td>
<td>Fluent, secure and correct technique in all stages of the operative procedure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 2: Modified OSATS Global Rating Scale**
1.2.2 Virtual reality

Virtual reality simulators have the ability to provide automatic, instantaneous, non-biased measures of performance\textsuperscript{73}. This assessment can serve to monitor progress while learning a technical skill, can aid in the provision of structured feedback, and ultimately ensures that the training objectives have been met\textsuperscript{17}. Virtual reality simulators, like any tool that is used for the assessment of technical skills, must demonstrate acceptable reliability and validity before they are integrated into high-stakes assessment.

Laparoscopic VR simulators have shown acceptable face and construct validity, with effective discrimination between novices, intermediates and experts\textsuperscript{19-24, 29, 30, 74-76}. The demonstration of construct, concurrent, and face validity across a range of virtual reality simulators has wide implications for training programs. Performance on these simulators could be utilized to track progress as a trainee learns a task, or to define expert levels of proficiency in order to determine when a trainee is ready to progress to learning in a real operating room and practice on real patients\textsuperscript{17}. However, it is important to note, that as a group, these studies serve to illustrate that not all assessment parameters on a VR simulator are of equal validity. The parameters that have the most evidence to support their use are time, economy of movement, and to a certain extent scores for that particular task. These three assessment parameters are consistent across various types of simulators. Although these parameters are useful for assessment, they are not necessarily meaningful for trainees, and may not provide them with insight into the weaknesses of their performance\textsuperscript{17}.

1.2.3 Motion Analysis

Laparoscopic surgery is well suited to motion analysis in that a surgeon’s hand movements are confined to the movements of the laparoscopic instruments\textsuperscript{55}. As such, various tools to measure hand movements have been developed. An example of a device to measure hand motion is the Imperial College Surgical Assessment Device (ICSAD) which has sensors that are attached to the back of the surgeons hands\textsuperscript{55}. Studies using the ICSAD have shown that experienced surgeons making less hand movements than novices during both basic and more advanced laparoscopic procedures in the operating room\textsuperscript{55, 77, 78}. The Advanced Dundee Endoscopic Psychomotor Tester (ADEPT) is another motion analysis system. The ADEPT, however, can only be used in an ex-vivo environment. It consists of a static dome that encloses a defined
workspace with two laparoscopic graspers\textsuperscript{79}. The system measures time taken, angular path length, and instrument error score. Construct and concurrent validity have been shown for this system\textsuperscript{80,81}.

### 1.2.4 Comparing Assessment Systems

Various modalities exist to assess technical skills ranging from low-tech methods such as global rating scales to more technologically advanced systems such as VR simulators or motion tracking devices. Each of these methods of assessment has specific advantages and disadvantages. Global rating scales and procedure-specific checklists require an expert to observe technical performance. Having an expert observer, however, can introduce a potential source of bias into the outcome of the assessment. As such, in studies using observational assessment tools to measure outcomes, a great deal of effort is made to ensure that the observer is blinded either to the randomization, or to the identity of the individual performing the technical task. Although observational tools require the presence of an expert, they are very versatile and can be used to assess technical performance in both a simulated environment as well as in the operating room. Also, they are associated with very little cost, since they simply consist of completing a form. Procedure-specific checklists also have the potential to provide meaningful feedback to the trainee regarding the specifics of improving a particular technical skill. This is in contrast to both virtual reality simulators and motion analysis. Although VR simulators automatically provide non-biased assessment of a trainee, the information that they provide (time, error score, and economy of movement) is not necessarily meaningful for the resident and does not help them specifically improve their technical performance. On the other hand, this feedback is automatically generated and does not require the presence of an expert. Finally, while motion analysis avoids bias, it requires an expert to set up the system, and does not provide feedback that is meaningful to a trainee. Currently motion analysis systems are only utilized in the context of research studies.

### 1.3 How to optimize simulator training

Evidence exists supporting the use of simulators for surgical training. However, not all training on simulators is equal. In order to develop an evidence-based curriculum for technical skills training in a simulated setting, it is essential to determine the best, and most efficient methods of
training. Key features of simulation training include the optimal provision of feedback, deliberate practice, training to proficiency and the opportunity to practice at varying levels of difficulty.

1.3.1 Feedback

In a summary of the design of an effective surgical skills curriculum, Stefanidis makes note of the importance of feedback in a structured curriculum to teach technical skills.\textsuperscript{82} It is thought that feedback provides motivation, reinforces correct actions, and provides information about errors as the basis for correction.\textsuperscript{83} Feedback can be either intrinsically or extrinsically generated. Intrinsic feedback is generated within the performer of the task and consists of the visual, auditory or haptic perceptions during task performance.\textsuperscript{82} Extrinsic feedback is provided by an external source, usually an expert observer, and aims to enhance intrinsic feedback.\textsuperscript{82}

Extrinsic feedback is the usual type of feedback in surgical education, where an expert physician provides a meaningful critique designed to improve the technical performance of a trainee. Studies have shown that extrinsic feedback accelerates technical skill acquisition.\textsuperscript{43, 84-86} This is perhaps most extremely illustrated in a study that demonstrated an absence of learning after 5 practice attempts on a colonoscopy VR simulator in the absence of feedback.\textsuperscript{84} The type of extrinsic feedback also seems to affect technical performance. Summary expert feedback, or feedback that occurs at task completion, is more efficacious than concurrent feedback, which occurs as the learner is performing the task.\textsuperscript{83} Although both forms of feedback result in equal technical learning initially, trainees who received summary feedback outperformed residents who received concurrent feedback at a 1 month retention test.\textsuperscript{83} It is theorized that this may be related to the fact that concurrent feedback either distracts from the intrinsic feedback naturally present, or that learners may use concurrent feedback as a crutch.\textsuperscript{83} These theories are supported by a study showing that limited feedback is more efficacious than continuous feedback.\textsuperscript{87} The authors hypothesized that this was because the continuous feedback limited the learners to develop insight into their actions and consequently limited their ability to develop their own learning strategy. Finally, it has been shown that expert feedback is more useful for trainees than information relating to motion efficiency.\textsuperscript{85} It is therefore important when developing a surgical skills curriculum to incorporate the provision of feedback into technical skills training. For feedback to be of maximal use to the trainee, it should be provided by an expert, at the conclusion of a motor task, and in a limited fashion.
1.3.2 Practice Schedule

It is intuitive that practice results in an improvement in technical performance. However, surgical trainees are limited in the amount of the time that they have available for practice outside the operating room. What type of practice is most conducive to learning a technical skill efficiently? Ericsson advocates deliberate practice as being essential in the development of technical expertise. Deliberate practice refers to the idea that practice should be mindful and related to the representative context of the target performance. This in turn relates to feedback and the requirement of both intrinsic and extrinsic feedback systems to guide and inform practice. The distribution of practice sessions can also affect the efficiency and quality of learning. Moulton et al. demonstrated in a randomized controlled trial that distributed as opposed to massed practice results in improved acquisition and transfer of a technical skill learnt on a simulated model. These findings have also been replicated in other work. It is thought that distributed practice allows the learned skills to consolidate in the learner’s long term memory between practice sessions. Currently, it is hypothesized that practice sessions ranging from 45 minutes to 1 hour are optimal for learning, although this is based primarily on expert opinion, rather than on well-designed studies.

1.3.3 Proficiency-Based training

The goal of simulation training is to develop what Gallagher terms the “pre-trained novice.” A pre-trained novice is a trainee who has trained using simulation to a point where many of the psychomotor skills and spatial judgments are automated. As a result, in the operating room, the trainee can focus on higher-level skills such as learning the steps of the operation, or the management of complications. Gallagher states that the goal of any surgical training program should be to ensure that junior surgical residents practice in a simulated environment until basic psychomotor tasks are automated. How long does it take for automaticity to occur? Gallagher argues that it is different for every individual trainee. As a result, he advocates training on a simulator until residents reach a level of benchmark performance that is established from having experts performing the task that trainees will be using to train. The efficacy of proficiency-based rather than time-based training is supported by the literature. The fundamentals of curriculum design, however, are complicated by our unclear understanding of surgical expertise. The definition of expert could conceivably alter depending on the task. Moreover, it has not been well established in the literature how many experts are required to develop these
expert levels of proficiency, or how often trainees should perform the task at the expert level in order to have attained proficiency.

1.3.4 Variability of Practice

In a surgical skills curriculum, practice of motor tasks should ideally occur at varying levels of difficulty. Ali et al. demonstrated that practice at a higher level of difficulty on a VR simulator resulted in increased learning than practice simply at an easier level\textsuperscript{95}. Moreover, Aggarwal et al. demonstrated that participation in a VR training program that allowed progression between various levels of difficulty resulted in increased learning\textsuperscript{96}. It has also been shown that difficult training conditions can result in an improved performance on the simulator, although these do not necessarily translate to the operating room\textsuperscript{97}. VR simulators are ideally suited to provide training opportunities at varying levels of difficulty. Within each task on a VR simulator, metrics such as tissue friability, or the size of objects can be modified thus making a task more or less difficult. In addition, within one VR simulator, many different tasks can be practiced ranging from basic tasks such as camera navigation, to performing operations in their entirety, for example, laparoscopic cholecystectomy, or colonoscopy. Different levels of training and progression through a sequentially more difficult curriculum could stimulate trainees’ interest and increase their motivation, two factors which are deemed essential for learning and the long-term effectiveness of surgical skills curricula within residency training programs\textsuperscript{82}.

1.4 Development of a comprehensive curriculum for technical skills

Defining an evidence-based training program on a simulator is essential in the development of a comprehensive curriculum for technical skills. However, this is not sufficient. A cognitive learning component is also thought to be first critical step for surgical skills acquisition\textsuperscript{98}.

1.4.1 The Role of Cognitive Teaching in a Surgical Skills Curriculum

Support for including cognitive training into technical skills training programs derives from our current understanding of the acquisition of motor skills and surgical expertise. Fitts and Posner’s three stage motor theory of learning is accepted in both the psychological literature as well as in the medical education literature\textsuperscript{99}. Reznick and MacRae summarize how this theory fits into the acquisition of technical expertise\textsuperscript{100}. In the first stage of learning, the cognitive stage, the trainee
seeks to understand the steps of the task. Performance is erratic and occurs in sequential, distinct steps. After practice, the trainee reaches the integrative stage where the task is performed more fluidly, with fewer interruptions. The final stage is the autonomous stage, where the trainee no longer has to think about how to perform the skill, rather, they execute it automatically, almost without thinking.

Like Fitts and Posner, Schmit’s theory of motor learning emphasizes the importance of practice and feedback, but these authors theorize that learning occurs in a more circular schema rather than one that progresses linearly\textsuperscript{101}. The schema theory of learning relates the execution of a motor movement to previous experiences, and had been summarized in a recent review\textsuperscript{102}. Before the initiation of a technical skill, a trainee plans their movement by determining the relevant conditions relating to their present environment. The second phase of the movement involves the execution of the muscular movements required to perform the task. The third phase is the feedback received during execution of the task. The final phase is the knowledge of the outcome of the skill. Intrinsic feedback acquired during each of the phases is stored after the task is performed. Ultimately this knowledge feeds back into the schema, and the relationship between the constructs strengthens.

Both of these motor theories emphasize the importance of understanding the steps of a task in order to execute it correctly. Cognitive skills such as error detection, forward planning, and decision making are critical in order to execute a surgical procedure correctly, and should be taught using didactic methodologies prior to commencing the psychomotor component of technical skills teaching\textsuperscript{103}.

The importance of cognitive teaching has also been demonstrated in several recent studies. A study by Tang et al. showed that the majority of errors performed by trainees during simulated training occurred not due to technical mistakes, but rather from a knowledge gap, including a lack of understanding of the correct sequence of steps in the particular task\textsuperscript{104}. The advantages of cognitive training have also been demonstrated in a non-randomized study where residents allocated to a didactic training group (which included relevant anatomy, steps of a procedure, potential errors and complications), outperformed a similar group of non-cognitively trained residents on a virtual reality simulator\textsuperscript{105}. This study emphasizes that cognitive training not only improves an understanding of a particular operation or task, but also improves its execution. It
has also been shown that the addition of cognitive training to a technical skills curriculum, even if it reduces the amount of time available to practice a technical skill, does not affect the amount of technical skill learning that occurs\textsuperscript{106}. As a group these studies emphasize the importance of including a certain amount of cognitive teaching relating to the execution of a procedure in a surgical technical skills curriculum. This idea is articulated by Sefanidis and Heniford in their description of a formula for a successful surgical skills curriculum. The authors state that didactic teaching should accompany skills training on simulators in order to improve trainees’ knowledge and understanding of the task that they are learning\textsuperscript{82}. Moreover, they theorize that the combination of didactics and psychomotor training will improve retention of the learned skill more than either modality alone\textsuperscript{82}. The idea of including both technical skills teaching as well as cognitive teaching in a comprehensive curriculum for technical skills acquisition is reflected in the structure of the FLS program\textsuperscript{23}. In addition, the American College of Surgeons/Association of Program Directors in Surgery national skills curriculum modules also consist of a technical training module as well as an emphasis on cognitive learning\textsuperscript{107, 108}.

1.4.2 Frameworks for Curriculum Development

At this point, key features of ex-vivo technical skills training have been defined; which include the optimal provision of feedback, deliberate practice, training to expert levels of proficiency, opportunities to practice at varying levels of difficulty, and the inclusion of both cognitive teaching and psychomotor training. The next step in curriculum development is to incorporate these concepts into a comprehensive ex-vivo curriculum. Several frameworks for curricular development have been proposed in the literature\textsuperscript{15, 82, 109}. Sarker and Patel hypothesized that a trainee should progress through a curriculum in the following manner: watching a simulated task, performing a simulated task, feedback, watching a real task, and finally, performing a real task. Ultimately all of the components of the curriculum are interconnected and relate back to one another (Figure 1). Stefanidis and Heniford built on this concept and described a curriculum that commenced with a baseline assessment, followed by deliberate practice with feedback in a simulated environment, training to proficiency, and a post-training assessment (Figure 2). Aggarwal et al.’s concept is similar. The curriculum described by this groups contains knowledge-based learning, training in a laboratory environment, ensuring that the learned skills transfer to a real environment, and ultimately granting privileges for independent practice (Figure 3). Aggarwal’s group also emphasized that it is essential to deconstruct the task that one
wishes to teach. This is essential in order to define a validated tool for assessment. While the specifics of the aforementioned curricula are somewhat different, the overall principles espoused by the authors are similar. These curricula all emphasize cognitive learning, training to proficiency, as well an assessment component.

Figure 1. Sarker and Patel’s Framework for Curriculum Development
Figure 2. Stefanidis and Heniford's Framework for Curriculum Development
1.5 Curricula for Laparoscopic Technical Skills

Although frameworks to establish proficiency-based technical skill curricula have been outlined, and both laparoscopic box-trainers and VR simulators have been extensively evaluated as viable models to teach technical skills, few evidence-based curricula for laparoscopic procedures have been described or evaluated.
1.5.1 Curricula on Box-Trainers

The most well described curriculum for basic laparoscopic skills is the FLS curriculum. In 2005, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the American College of Surgeons (ACS) joined together to manage the FLS program\textsuperscript{110}. Currently, FLS certification is required for American surgical residents to write their surgical board exams. The FLS curriculum consists of both an cognitive and a technical skills component\textsuperscript{110}. The cognitive component is web-based and consists of didactic modules organized into content areas which cover material related to pre-operative, intra-operative, and post-operative considerations for laparoscopic procedures. The technical component is based on the MISTELS program. In the technical training component, trainees perform a series of basic laparoscopic tasks in a laparoscopic box trainer. These tasks include pattern cutting, peg transfer, endoloop, intracorporeal stitch and square knot, and extra-corporeal stitch and square knot. At the end of the curriculum, trainees are assessed by a multiple-choice test and a technical skills assessment. The technical skills training portion of the FLS program has demonstrated feasibility, construct validity, and predictive validity\textsuperscript{5,111,112}. Learning curves on the technical skills training portion of the curriculum have been defined, and the transfer of these learned skills to the operating room has been demonstrated\textsuperscript{5,113}. Proficiency-based curricula for FLS have also been described\textsuperscript{114}. A randomized controlled single blinded trial demonstrated that practice using the proficiency-based curriculum resulted in improved technical performance in the operating room as measured using a validated assessment tool\textsuperscript{113}. In addition, it has been shown that practice using the proficiency based curriculum improves the technical skills of junior residents to those of senior residents after only 7.5 hours of simulator training\textsuperscript{115}. Technical skills learnt on the FLS system are also resistant to decay and have been shown to persist on a porcine model for up to 5 months\textsuperscript{31}.

The reliability and validity of the cognitive assessment portion of FLS has been assessed. In a Beta test involving eight centres in North America, the internal consistency of the test was 0.81 (Cronbach’s Alpha) and there was a significant difference in score on the cognitive component of the test between junior and senior residents (p<0.01), and among senior residents and staff surgeons (p<0.01)\textsuperscript{112}. A similar program for endoscopic surgery, the Fundamentals of Endoscopic Surgery (FES) is currently under development\textsuperscript{115}. 

The strong evidence supporting the FLS curriculum as well as the fact that it was recently made mandatory for surgical residents in the United States to complete the FLS curriculum in order to write their board exams, have contributed to the successful broad implementation of this curriculum for basic laparoscopy. The FLS curriculum also closely follows the framework described by Aggarwal et al. FLS consists of both cognitive and psychomotor teaching: these components are assessed independently and are used in granting privileges for independent practice. In addition, as described above, the psychomotor training component of the curriculum has been extensively validated and the technical skills learnt have been shown to transfer to the real environment. However, FLS training and certification requires a significant amount of resources relating to expert time commitment, and the cost of the FLS materials.

### 1.5.2 Curricula on Virtual Reality Simulators

An alternative virtual reality curriculum for basic laparoscopy training, which is similar in concept to the FLS curriculum, was developed by Panait et al. in 2008\(^{116}\). This curriculum consists of a proficiency-based training component and an examination component. Benchmark levels for 17 virtual reality tasks were established by the performance of one minimally invasive surgery fellowship trained surgeon. After passing the 17 tasks, trainees perform an exam, which consists of 7 tasks. Construct validity, and learning curves have been demonstrated for this curriculum\(^{116}\). Currently, residents at Yale University must pass the curriculum prior to performing laparoscopy in the operating room. Based on the feasibility of this curriculum, the authors developed a second VR curriculum, the Yale Advanced Laparoscopic Skills Curriculum which consists of the same tasks as the basic curriculum but at a higher level of difficulty\(^{117}\).

Similar proficiency-based curricula for basic laparoscopic skills that describe progression through tasks at increasing levels of difficulty on a virtual reality simulator have also been described by Aggarwal et al. and Sinha et al.\(^{94, 96, 118}\). Although these virtual reality curricula show preliminary evidence of construct validity, and conform to current educational standards regarding proficiency-based training, more work needs to be done in order to assess the transferability of the acquired skills to the operating room. Finally, these studies are also limited by the fact that they do not incorporate a cognitive training component into the technical skills training element.
Currently, only one study evaluates a curriculum for a laparoscopic surgical procedure. Aggarwal et al. describe a proficiency-based virtual reality curriculum for laparoscopic cholecystectomy. Construct validity, expert levels of proficiency and learning curve data were assessed for 9 basic, 4 procedural and 1 full-procedural tasks on the LapMentor VR simulator (Simbionix Corporation, Cleveland, Ohio, USA). Eight basic tasks, 3 procedural tasks and the full procedural task showed acceptable construct validity. In developing this curriculum, construct validity was established for curricular tasks and expert levels of proficiency were determined based on the median scores of between 9 and 11 experts. The authors suggest that training should take place in distributed practice sessions separated by 1 hour each with a maximum of 2 practice sessions per day. More work needs to be done in order to determine whether skills learned via this curriculum will transfer to the operating room.

Unlike the FLS program, the current curricula for VR training in laparoscopic procedures are in their relative infancy. While Panait’s group requires residents to pass the curriculum prior to participating in the operating room, this may be premature. This is especially true in light of the fact that the proficiency criteria for this curriculum are based on the performance of only one expert surgeon. In addition, for all the VR curricula described above, more work needs to be done to incorporate cognitive learning into the curriculum as a whole and to ensure the transferability of the learned skills to a clinical environment. More data relating to the effectiveness of these VR curricula is essential since training on VR simulators may offer more versatility than box trainers. VR simulators can be programmed to model tasks at varying levels of difficulty, and one simulator can potentially contain multiple curricula thus accommodating trainees at different levels in their training and in different programs of study. Although FLS is the current gold standard for basic MIS training, there is a need to move beyond basic laparoscopy and to develop comprehensive curricula for training individuals in advanced minimally invasive surgery.

1.6 Laparoscopic colorectal surgery

Laparoscopic colorectal surgery is considered to be an advanced minimally invasive procedure. Performing this operation effectively requires the intra-corporeal ligation of large blood vessels, the creation of a viable anastomosis, and if the operation is for cancer, it requires harvesting an appropriate number of lymph nodes. The short-term benefits of the minimally invasive
approach for laparoscopic colorectal surgery have been demonstrated in several randomized controlled trials. It has been shown that compared to open surgery, laparoscopic colorectal surgery has advantages in terms of a shorter hospital stay, a decrease in post-operative pain, and less intra-operative blood loss\textsuperscript{121-123}. Most importantly, large scale randomized controlled trials have demonstrated that the oncologic outcomes of open and laparoscopic cases are equivalent. The five year survival outcomes from the COST (Clinical Outcomes of Surgical Therapy Study Group) trial, which randomized a total of 872 patients to receive either open or minimally invasive surgery, provided level I evidence that disease free survival, overall 5 year survival, overall recurrence rates, and sites of first recurrence were equivalent between both groups of patients\textsuperscript{124}. The three year and five year outcomes from the CLASICC (Conventional versus Laparoscopic Assisted Surgery in Colorectal Cancer) trial, which randomized 794 patients with either colonic or rectal tumors to receive either laparoscopic or open surgery, were similar, with no difference in overall survival, disease free survival, or local recurrence between the two groups of patients\textsuperscript{125,126}. Finally, the COLOR (COlon cancer Laparoscopic or Open Resection) trial, which randomized 1248 patients to receive either laparoscopic or open colorectal surgery, reported similar 3 year outcome measures\textsuperscript{127}.

With the evidence demonstrating both the short-term benefits of the laparoscopic approach to colorectal surgery, as well as the fact that the oncologic outcomes are equivalent to the open approach, more patients are requesting this procedure, and more surgeons are learning laparoscopic techniques. However, laparoscopic colorectal surgery is associated with a significant, variable learning curve. A variety of studies have demonstrated that the learning curve for laparoscopic colorectal surgery ranges from 30 cases to up to 80 cases, with the exception of Simons et al. who documented a learning curve of 11 to 15 cases\textsuperscript{120,128-136}. The variability in these studies may be due to several factors. First, the cases examined in these studies are heterogeneous with some groups examining all colorectal procedures together, while others focused on one particular operation, for example, laparoscopic sigmoid colectomy. Second, these studies examine cases that were performed from 1991 to 2007. Since both minimally invasive technology and laparoscopic techniques have undergone significant improvements over the past decades, these factors may have affected the evolution of the learning curve. Third, these studies have examined a variety of trends including operative time, conversion rates, as well as intra-operative and post-operative complication rates. Finally, while
several of the studies grouped together surgeons at several institutions, others looked at the learning curves of individual surgeons. Although as a group, these studies are heterogeneous with a range of documented learning curves, the majority of the work seems to indicate that for trained surgeons the learning curve for laparoscopic colorectal surgery is likely upward of 30 cases. As such, it can be hypothesized that for trainees learning this procedure, the learning curve may be even more significant. The complexity of the minimally invasive approach for laparoscopic colorectal surgery, as well as the documented significant and variable learning curve suggest that trainees learning this procedure do so in a standardized manner, ideally in a simulated environment.

1.7 Rationale, Hypothesis and Objectives

Although it has been established that the technical skills acquired by training on both box-trainers and VR simulators transfers to the operating room, outside the realm of research studies, there has been little progress with respect to a broad introduction of simulation-based laparoscopy training within surgical residency programs. It is speculated that this may be due to the fact that very few evidence-based ex-vivo curricula have been described in the literature for laparoscopic procedures. The purpose of this thesis is to develop a comprehensive curriculum for an advanced laparoscopic procedure, such as laparoscopic colorectal surgery. Due to the complexity of the laparoscopic approach for colorectal surgery, as well as the necessity for an adequate oncologic resection, it is essential that a curriculum be established for trainees, or practicing surgeons wishing to learn this new technology, in order for them to surmount the early part of the learning curve for this procedure in a simulated setting. This curriculum will consist of both a technical skills training component on a VR simulator as well as a cognitive training component. It will also adhere to current educational standards of proficiency-based training and deliberate distributed practice.

The first step in the development of this curriculum is to develop a procedure-specific evaluation tool for laparoscopic colorectal surgery, that ultimately will be used to assess the effectiveness of the curriculum. The second phase of this project will be to determine the essential elements of the virtual reality technical skills training component and to define benchmark expert levels of proficiency for training. The final objective of the study will be to define the cognitive training elements of the curriculum, and to validate the curriculum. The validation phase of the study will
be a single-blinded randomized controlled trial comparing the cognitive skills and the technical proficiency in the operating room between two groups of residents, one trained using the curriculum, and one that received conventional residency training.

We hypothesize that developing a technical skills curriculum for an advanced laparoscopic procedure in a methodologically rigorous fashion will set a new standard for technical skills curriculum design. This has the potential to affect surgical training programs on an international level, by standardizing not only the methods for curriculum development, but also the competencies required prior to performing an advanced laparoscopic procedure in the operating room. In addition, we expect that training to expert levels of proficiency in a simulated setting will allow trainees to exhibit a superior technical performance in the operating room as compared to residents who did not have simulation training. Finally, we expect that curricular training will result in trainees learning the cognitive elements of laparoscopic colorectal surgery. Results from this study have the potential to establish a standard for training in advanced laparoscopy across residency programs, and have the potential to improve patient safety in the operating room.
Chapter 2

2 Development of an objective evaluation tool to assess technical skill in laparoscopic colorectal surgery: a Delphi methodology

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2.1 Abstract

Background: Laparoscopic colorectal surgery (LCS) is an advanced procedure for which no objective tools exist to assess technical skill. The aim of this study was to determine expert consensus regarding items required on a rating scale for LCS, using a Delphi technique.

Methods: Experts rated the sub-steps of LCS from 1-5. Responses were returned to the panel until consensus (Cronbach's $\alpha \geq 0.80$) was reached. Sub-steps that 80% of experts rated as $\geq 4$ were included in the final instrument.

Results: Initially $\alpha$ was 0.81 for sigmoid colectomy, 0.77 for right (medial to lateral) colectomy, and 0.74 for the lateral to medial approach. In the second round $\alpha$ was 0.83 for medial to lateral right colectomy, and 0.82 for lateral to medial.

Conclusions: The Delphi method allowed the determination of consensus regarding the essential steps to be included in a tool designed to measure technical competence in LCS.

2.2 Introduction

With the advent of minimally invasive surgery, and the continued rapid development of new surgical technology, there is mounting pressure on practicing surgeons and certifying bodies to ensure that new surgical procedures are being performed competently and safely. In response, there has been some effort to create specific evaluation tools to allow for objective and reliable assessment of operative performance. This assessment can serve as a source of constructive feedback and can potentially be used for training and certification of practicing surgeons.
Examples of such tools include the OSATS\textsuperscript{56} and OPRS\textsuperscript{137} for open surgery, as well as several tools developed to assess technical skill in performing laparoscopic cholecystectomy\textsuperscript{54,68}. Objective assessment of technical performance is essential for several reasons. It allows for monitoring of the rate of technical skill acquisition of surgical trainees, and provides a basis for constructive feedback along the learning curve for new procedures\textsuperscript{54}. Furthermore, objective measures of performance are crucial for assessing competency prior to granting privileges for new procedures for trainees and staff surgeons\textsuperscript{54}. Finally, assessment of technical ability serves as a means by which to increase the accountability of the surgical profession to the public\textsuperscript{138}.

Laparoscopic colorectal surgery (LCS) is routinely performed both at academic institutions and in the community. LCS is considered an advanced minimally invasive procedure due to the fact that the procedure includes a number of technically challenging steps: ligation of large blood vessels, creation of a viable anastomosis, and retrieval of an adequate number of lymph nodes, all while limiting manipulation of the specimen and working in multiple quadrants of the abdomen\textsuperscript{120}. The long, variable learning curve for LCS, as well as evidence that patient outcomes may suffer early in the learning curve\textsuperscript{128}, necessitates that individuals learning LCS do so in a safe manner, with a means to objectively evaluate their performance before entering independent practice. To date no tools have been designed and validated to specifically assess performance during LCS. Furthermore, to be widely applicable, any tool that is developed must be reflective of practice across many institutions.

The aim of this study was to determine expert consensus regarding items required on a rating scale for laparoscopic right and sigmoid colectomy, using a Delphi technique. The outcome of the Delphi panel will be an instrument that can be used to evaluate a surgeon’s technical performance in laparoscopic right and sigmoid colectomy.

2.3 Methods
2.3.1 Study Design:

This study used a Delphi methodology to achieve consensus through expert opinion on the essential steps for a laparoscopic sigmoid colectomy and laparoscopic right colectomy.
Approval for this study was obtained from the Institutional Review Board at St Michael’s Hospital and The University of Toronto. The Delphi method was first developed by the RAND Corporation in 1948\textsuperscript{139-141}. It is an anonymous process where ideas are expressed to the participants in the form of a questionnaire\textsuperscript{142}. Responses are collated and analyzed and the process continues until “group” consensus is achieved\textsuperscript{142, 143}. The advantages of the Delphi method are well described. It eliminates the requirement for experts to physically meet, which improves feasibility, and lowers associated costs\textsuperscript{142}. It also allows for experts from diverse geographical locations to be recruited to the group\textsuperscript{142}. Finally, the anonymous nature of the Delphi process ensures that a single dominant group member does not inordinately influence the group’s outcome\textsuperscript{142}.

2.3.2 Selection of Experts:

Experts were identified in the following manner: they were leaders in their clinical field as evidenced by their role as opinion leaders within organizations such as The American Society of Colon and Rectal Surgeons (ASCRS), the Society of Gastrointestinal and Endoscopic Surgeons (SAGES), and other national surgical societies. In addition, of those individuals identified, we considered experts to be those who had a strong publication record in the field of minimally invasive colorectal surgery. The expert panel was specifically selected to represent a wide geographical area including Canada, the United States, Europe, and Australia (Table 3). In the literature, there is no consensus on the number of experts required for a Delphi survey\textsuperscript{139, 140}. We invited 27 individuals from 18 different institutions in 5 different countries to participate, with an email explaining the purpose and methodology of our study. Of the 27 experts initially contacted, 18 agreed to participate. The membership of the expert panel was not revealed to the participants.
<table>
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<th></th>
<th>Number of surgeons initially contacted</th>
<th>Number of surgeons who agreed to participate</th>
<th>Fellowship training</th>
<th>Peer-reviewed Publications (MIS or Colorectal) per person</th>
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<tr>
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<td>Mean: 35 Median: 22</td>
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<tr>
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<td>2</td>
<td>Colorectal: 100% (2/2) MIS: 0% (0/2)</td>
<td>Mean: 23 Median: 23</td>
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<td>3</td>
<td>2</td>
<td>Colorectal: 0% (0/2) MIS: 50% (1/2)</td>
<td>Mean: 23 Median: 23</td>
</tr>
</tbody>
</table>

Table 3: Composition of the Delphi expert panel

2.3.3 Delphi Round 1

Each expert who agreed to participate was sent an email containing a link where they could access the first round of an on-line survey. In this first iteration of the survey, we identified a list of the sub-steps required to complete a laparoscopic sigmoid resection and laparoscopic right colectomy (lateral to medial approach as well as medial to lateral approach). These sub-steps were compiled from three sources: 1) University of Toronto faculty expert opinion 2) surgical textbooks 3) published peer-reviewed literature. In the first iteration of the survey each surgical sub-step identified from any of these three sources was included in the survey for completeness (Table 4). Each expert was asked to rate the sub-steps on a Likert scale from 1 (strongly disagree) to 5 (strongly agree) with respect to the level that they believed that the step should be included in a final evaluation tool. In addition, participants were offered the opportunity to comment on each sub-step, or to clarify their ratings. All expert participants were sent 2 email reminders (1 month apart) reminding them to complete the first iteration of the survey.
Access and Port Insertion:
Creating a 12mm supra-umbilical port using an open technique
Insertion of Veres needle in the left subcostal area or through a supra-umbilical incision
Placing three or four additional ports under direct vision

Diagnostic Laparoscopy:
Inspecting the intra-abdominal contents with the laparoscopic camera

Exposure:
Placing the patient in steep Trendelenburg
Placing the patient with their right side up
Retracting the small bowel in the upper abdomen
Retracting the sigmoid colon from the pelvis in a cephalad and anterior direction
Identifying the left ureter
Identifying the origin of the inferior mesenteric artery (IMA)

Initial Dissection:
Creating an incision in the retrorectal fascia, behind the IMA
Identifying the presacral nerves
Dropping the presacral nerves posteriorly
Developing a plane posterior to the IMA
Continuing the dissection in a plane anterior to the retroperitoneal fascia
Isolating the IMA at its takeoff from the aorta
Dividing the IMA
Identifying the inferior mesenteric vein (IMV) at the level of the pancreas
Dividing the IMV if necessary
Bluntly sweeping the retroperitoneal fascia away from the posterior aspect of the left colon mesentery in a medial to lateral direction
Proceeding with the dissection in a medial to lateral direction until the lateral abdominal wall is reached
Taking down the lateral attachments of the sigmoid and descending colon to the abdominal wall
Dissecting superiorly until the rectum is adequately mobilized
Continuing the dissection inferiorly until the rectum is adequately mobilized

Mobilizing The Splenic Flexure:
Placing the patient in reverse Trendelenburg
Dividing the splenocolic ligament, renocolic ligament and omental attachments of the splenic flexure
Dissecting the greater omentum off the distal transverse colon in a left to right direction
Entering the lesser sac
Checking the length of the mobilized specimen to ensure that it will be of adequate length without tension

Bowel Resection:
Choosing the distal resection site with an appropriate margin (at least 10 cm) from the tumor
Scoring the mesorectum on either side of the rectum
Dividing the mesorectum at a right angle to the bowel
Dividing the rectum at a right angle
Creating a mini-laparotomy in the left lower quadrant or pfannenstiel incision
Utilizing a wound protector when the end of the proximal colon is delivered through the incision
Dividing the proximal end of the specimen
Placement of a purse-string suture
Inserting the EEA anvil into the end of the bowel and tying the purse-string suture
Placing the bowel back into the abdominal cavity
Closing the mini-laparotomy incision

Anastomosis:
Inserting and advancing the handle of the EEA through the anus towards the end of the rectum
Ensuring that the staple line is transverse across the end of the EEA device
Advancing the trocar posterior to the staple line
Checking the bowel orientation
Bringing together the two ends of the EEA
Firing the stapler
Checking the anastomosis by filling the pelvis with fluid and insufflating air through the anus while the bowel proximal to the anus is held closed
Closing of fascial defects greater than 5mm

Please comment (add sub-steps, comment on steps identified etc.):

**Table 4**: First iteration of Delphi survey: list of sub-steps identified for laparoscopic sigmoid colectomy
2.3.4 Delphi Round 2

We waited 74 days between giving participants access to the first and second iteration of the survey in order to balance an optimal response rate with ensuring that participants still remained interested in the process. In the second round of the survey, some of the sub-steps were altered based on feedback from the expert panel. The panelists considered these sub-steps, as in the first round, but were informed what the group mean and standard deviation were for each sub-step. The experts were asked to re-rate each sub-step given this information. For laparoscopic sigmoid colectomy, consensus was achieved after the first round of the Delphi, therefore the second iteration of the survey only contained the sub-steps for laparoscopic right colectomy. After the second iteration of the survey, consensus was reached for laparoscopic right colectomy.

2.3.5 Determining Consensus

For this study, the concept of consensus was pre-defined as a condition of homogeneity or consistency within the opinions of the expert panelists. There are no established criteria for determining consensus using a Delphi methodology. Based on the work of Graham et al., Cronbach’s $\alpha$ was chosen as the statistical index to quantify the reliability of a group of entities, in this case panelists\textsuperscript{142}. Based on this group’s rationale, it is assumed that each surgical sub-step is represented by a constant but unknown level of importance on a final rating scale, and that the opinions of the panelists as represented by their scores for each sub-step on a Likert scale are considered multiple measures of this characteristic. Therefore, the internal consistency of the expert panel for each sub-step is reflective of the internal consistency for each item. As Cronbach’s $\alpha$ approaches 1.0, it can be argued that there is consistency in the responses of the panelists, thus suggesting consensus. In the literature, there is no precise cut-off value for consensus for an assessment tool. Frequently it is stated that an $\alpha$ value of greater than 0.7 is an acceptable internal consistency value for research purposes, however, an $\alpha$ of greater than 0.9 is preferable when the scale will be eventually utilized for individual clinical diagnosis. In this case, determining consensus for an evaluation tool, an $\alpha$ of 0.8 was chosen as an acceptable value for consensus\textsuperscript{144}. 
2.3.6 Creation of Final Evaluation Tool

After consensus for laparoscopic right and sigmoid colectomy was achieved using the predetermined criteria above, the final evaluation tools were created. Surgical sub-steps that over 80% of participants rated as 4 (agree) or 5 (strongly agree) were included in the final instrument. Moreover, surgical sub-steps for the medial to lateral approach and lateral to medial approach for laparoscopic right colectomy were combined together to create one evaluation tool for laparoscopic right colectomy. Anchoring descriptors were created for points 1, 3, and 5 on the final Likert rating scale for each evaluation tool.

2.3.7 Primary Data Analysis

Means and standard deviations were calculated for all surgical sub-steps. Cronbach’s $\alpha$ was calculated for expert internal consistency for laparoscopic right and sigmoid colectomy. All statistical analysis was performed using SPSS (statistical package for social sciences version 16.0, Chicago, IL, USA).

2.4 Results

Twenty seven experts were initially contacted to be part of the expert panel. Eighteen of these experts agreed to participate and of those 18, 11 (61%) completed the first round of the Delphi Survey. Of the 11 that completed the first round of the survey, 10 (91%) completed the final round. In the first round of the Delphi consensus, Cronbach’s $\alpha$ for the surgical sub-steps of laparoscopic sigmoid colectomy was 0.81. For laparoscopic right colectomy (lateral to medial approach) Cronbach’s $\alpha$ was 0.74, and for the medial to lateral approach it was 0.77. In the second round, the list of sub-steps was modified based on suggestions from the panelists in round one. In the second round, Cronbach’s $\alpha$ increased to 0.82 for the lateral to medial approach, and 0.83 for the medial to lateral approach. After consensus was reached, the sub-steps that were ranked as a 4 (agree) or a 5 (strongly agree) by over 80% of respondents were included in the final evaluation tool (Table 5 and Table 6).
**ACCESS AND PORT INSERTION**

<table>
<thead>
<tr>
<th>Specific Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creating access and placing 3 or 4 additional ports under direct vision</td>
<td>Created clumsily &amp; with difficulty</td>
<td>Created adequately</td>
<td>Created quickly &amp; skillfully</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**EXPOSURE**

<table>
<thead>
<tr>
<th>Specific Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placing the patient in steep Trendelenburg</td>
<td>Not done</td>
<td>Done after delay and insufficiently</td>
<td>Done promptly allowing adequate exposure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retracting the small bowel in the upper abdomen</td>
<td>Insufficient retraction of the small bowel</td>
<td>Bowl retracted adequately with some difficulty</td>
<td>Expert retraction of the small bowel allowing good exposure of the pelvis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retracting the sigmoid colon from the pelvis in a cephalad and anterior direction</td>
<td>Difficulty achieving adequate retraction</td>
<td>Bowl retracted adequately with some difficulty</td>
<td>Expert retraction of the bowel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identifying the left ureter</td>
<td>Inadequate identification of ureter</td>
<td>Identified with some difficulty</td>
<td>Ureter clearly identified</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identifying the origin of the inferior mesenteric artery (IMA)</td>
<td>Inadequate identification of IMA</td>
<td>Identified</td>
<td>Origin of IMA clearly identified with excellent exposure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**INITIAL DISSECTION**

<table>
<thead>
<tr>
<th>Specific Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creating an incision in the rectorectal fascia, behind the IMA</td>
<td>Incision made in incorrect plane or extensive guidance required for incision. Tissue trauma and bleeding</td>
<td>Incision made tentatively, although in correct plane, some tissue trauma and bleeding</td>
<td>Incision made smoothly in correct plane</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identifying the presacral nerves</td>
<td>Inadequate identification</td>
<td>Identified</td>
<td>Clear identification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Developing a plane posterior to the IMA</td>
<td>Development of incorrect plane, tissue trauma and bleeding</td>
<td>Plane developed adequately with some difficulty</td>
<td>Plane developed smoothly with minimal bleeding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuing the dissection in a plane anterior to the retroperitoneal fascia</td>
<td>Development of incorrect plane, tissue trauma and bleeding</td>
<td>Plane developed adequately with some difficulty</td>
<td>Plane developed smoothly with minimal bleeding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Taking down the lateral attachments of the sigmoid and descending colon to the abdominal wall</td>
<td>Poor dissection technique. Bleeding</td>
<td>Lateral attachments taken down with minimal bleeding</td>
<td>Lateral attachments taken down in an expert manner with excellent hemostasis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuing the dissection inferiorly until the rectum is adequately mobilized</td>
<td>Poor technique, tissue trauma and bleeding.</td>
<td>Satisfactory mobilization with some difficulty</td>
<td>Excellent complete mobilization of rectum</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**MOBILIZING THE SPLENIC FLEXURE**

<table>
<thead>
<tr>
<th>Specific Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dividing the splenocolic ligament, renocolic ligament and omental attachments of the splenic flexure</td>
<td>Poor technique, tissue trauma and bleeding</td>
<td>Adequate mobilization of splenic flexure with some bleeding</td>
<td>Flexure dissected expertly with excellent mobilization</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Checking the length of the mobilized specimen to ensure it will be of adequate length without tension

Length of specimen not checked

Specimen length checked briefly

Methodical checking of specimen length

**BOWEL RESECTION**

<table>
<thead>
<tr>
<th>Specific Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dividing the mesorectum at a right angle to the bowel</td>
<td>Divided with incorrect angle</td>
<td>Divided with an approximate right angle</td>
<td>Mesorectum divided at a right angle</td>
<td>Divided with incorrect angle</td>
<td>Divided with an approximate right angle</td>
</tr>
<tr>
<td>Creating a mini-laparotomy in the left lower quadrant or pfannenstiel incision</td>
<td>Laparotomy created clumsily with inexpert technique</td>
<td>Laparotomy created satisfactorily</td>
<td>Laparotomy created quickly in correct position</td>
<td>Laparotomy created clumsily with inexpert technique</td>
<td>Laparotomy created satisfactorily</td>
</tr>
<tr>
<td>Utilizing a wound protector when the end of the proximal colon is delivered through the incision</td>
<td>Wound protector not utilized</td>
<td>Wound protector utilized</td>
<td>Wound protector utilized</td>
<td>Wound protector not utilized</td>
<td>Wound protector utilized</td>
</tr>
</tbody>
</table>

**ANASTOMOSIS**

<table>
<thead>
<tr>
<th>Specific Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checking the orientation of the bowel</td>
<td>Orientation not checked</td>
<td>Orientation checked briefly</td>
<td>Orientation checked in an expert fashion</td>
<td>Orientation not checked</td>
<td>Orientation checked briefly</td>
</tr>
</tbody>
</table>

**Table 5:** Evaluation tool to assess technical skill in laparoscopic sigmoid colectomy
### ACCESS AND PORT INSERTION

<table>
<thead>
<tr>
<th>Specific Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creating access and placing 3 or 4 additional ports under direct vision</td>
<td>Created clumsily &amp; with difficulty</td>
<td>Created adequately</td>
<td>Created quickly and skillfully</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### DIAGNOSTIC LAPAROSCOPY

<table>
<thead>
<tr>
<th>Specific Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspecting the intra-abdominal contents with the laparoscopic camera</td>
<td>Cursory inspection, or not done</td>
<td>Moderately detailed inspection, areas not visualized</td>
<td>Careful and thorough inspection</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### INITIAL EXPOSURE

#### Specific Skill: Medial to Lateral Approach

<table>
<thead>
<tr>
<th>Specific Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identifying the ileocolic vascular pedicle by applying traction to the cecum</td>
<td>Insufficient or traction in a incorrect direction. Poor identification of pedicle</td>
<td>Satisfactory traction and identification</td>
<td>Traction in correct direction and clear identification of the vascular pedicle</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Specific Skill: Lateral to Medial Approach

<table>
<thead>
<tr>
<th>Specific Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposing and identifying the “valley” at the base of the cecum and the terminal ileal mesentery – this marks the junction of the mesentery with the retroperitoneum</td>
<td>Incorrect plane identified</td>
<td>Identified</td>
<td>Clear identification with excellent exposure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### DIVISION OF ILEOCOLIC VASCULAR PEDICLE

<table>
<thead>
<tr>
<th>Specific Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scoring the peritoneum under the ileocolic vessels</td>
<td>Scoring of peritoneum in incorrect location, excessive tissue traction, bleeding</td>
<td>Peritoneum scored satisfactorily, with some tissue damage and bleeding</td>
<td>Peritoneum scored correctly and accurately</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skeletonizing the ileocolic vessels</td>
<td>Vessels poorly isolated, excessive tissue damage and bleeding</td>
<td>Vessels isolated appropriately with some tissue damage</td>
<td>Vessels skeletonized in an expert manner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dividing the ileocolic vessels</td>
<td>Divided with trauma or bleeding, Not adequate length from the bowel</td>
<td>Divided adequately</td>
<td>Divided expertly with no trauma</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### INITIAL DISSECTION

#### Specific Skill: Medial to Lateral Approach

<table>
<thead>
<tr>
<th>Specific Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developing a plane between the mesocolon and the retroperitoneum in a medial to lateral direction</td>
<td>Difficulty developing correct plane, bleeding</td>
<td>Plane developed with some difficulty, adequate hemostasis</td>
<td>Plane developed correctly with excellent hemostasis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identifying the duodenum</td>
<td>Duodenum not identified</td>
<td>Satisfactory identification</td>
<td>Clear identification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuing the medial to lateral dissection until above the duodenum and the head of the pancreas and under the transverse mesocolon</td>
<td>Dissection in incorrect plane and with inadequate exposure, tissue</td>
<td>Dissection to correct location with minimal trauma</td>
<td>Dissection continued expertly, in correct plane and to correct</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identifying the right branch of the middle colic artery</td>
<td>Poor identification, inadequate dissection</td>
<td>Satisfactory identification</td>
<td>Clear identification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>---------------------------------------------</td>
<td>---------------------------</td>
<td>---------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dividing the right branch of the middle colic artery</td>
<td>Divided with poor hemostasis</td>
<td>Divided adequately</td>
<td>Divided safely with good hemostasis</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Specific Skill: Lateral to Medial Approach**

<table>
<thead>
<tr>
<th>Scoring the peritoneum around the cecum and the terminal ileum (TI) along this valley and entering the retroperitoneal plane</th>
<th>Difficulty entering retroperitoneal plane</th>
<th>Entered correct retroperitoneal plane</th>
<th>Entered into correct plane smoothly and accurately</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opening the right lateral peritoneal reflection (lateral to the cecum and the ascending colon) and dissecting towards the midline</td>
<td>Difficulty remaining in correct plane</td>
<td>Correct plane developed with some difficulty</td>
<td>Correct plane developed</td>
</tr>
<tr>
<td>Exposing the duodenum</td>
<td>Poor exposure</td>
<td>Adequate exposure</td>
<td>Good exposure</td>
</tr>
<tr>
<td>Mobilizing the ascending colon to the midline</td>
<td>Difficulty with mobilization or excessive bleeding</td>
<td>Mobilization with moderate hemostasis</td>
<td>Mobilization with excellent hemostasis</td>
</tr>
</tbody>
</table>

**MOBILIZATION OF THE HEPATIC FLEXURE**

<table>
<thead>
<tr>
<th>Specific Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positioning the patient in reverse Trendelenburg with their right side up</td>
<td>Patient not positioned correctly</td>
<td>Patient positioned correctly after some delay</td>
<td>Patient repositioned at correct point in the operation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dividing the omental attachments at the transverse colon</td>
<td>Attachments divided with poor technique, correct plane not identified, bleeding</td>
<td>Attachments divided with some bleeding</td>
<td>Attachments divided with good hemostasis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entering the lesser sac and dividing the omentum proximally</td>
<td>Trouble entering lesser sac. Omentum divided with associated trauma</td>
<td>Lesser sac entered in the correct plane with some difficulty, minimal bleeding</td>
<td>Lesser sac entered and omentum divided in an expert manner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medial-caudal retraction of the flexure</td>
<td>Flexure not retracted in correct direction</td>
<td>Flexure retracted adequately after some repositioning</td>
<td>Flexure retracted appropriately and in correct direction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dividing the flexure with an appropriate energy source</td>
<td>Flexure divided with excessive tissue trauma, bleeding</td>
<td>Flexure divided adequately</td>
<td>Flexure divided in an expert manner with no tissue trauma or bleeding</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**EXTERIORIZATION BOWEL RESECTION AND ANASTOMOSIS**

<table>
<thead>
<tr>
<th>Specific Skill</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dividing the proximal and distal bowel intra- or extra-corporeally</td>
<td>Bowel divided with tissue trauma and gross contamination</td>
<td>Bowel divided with minimal spillage</td>
<td>Bowel divided cleanly and expertly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using a wound protector if the bowel is exteriorized</td>
<td>Wound protector not used</td>
<td>Wound protector used</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anastomosis performed according to the surgeon’s preference</td>
<td>Anastomosis made clumsily with spillage of bowel contents, bleeding, or under tension</td>
<td>Anastomosis made adequately with some assistance</td>
<td>Anastomosis made with no spillage, good hemostasis and no tension</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 6**: Evaluation tool to assess technical skill in laparoscopic right colectomy
2.5 Discussion

The purpose of this study was to design a tool for assessment of technical competence in laparoscopic colorectal surgery. The final procedure-specific checklist was developed through an online survey using the Delphi methodology. It represents the consensus of experts in minimally invasive colorectal surgery across Canada, the United States, Europe, and Australia. This systematic approach, as well as the solicitation of global expert opinion, strengthens the content validity of this evaluation tool. The fact that the internal consistency improved between the first and the second round indicates Delphi is an effective means of developing consensus among key opinion leaders in a field. This is the first step in the development of a rigorous methodology to define technical competence in laparoscopic colorectal surgery. The modified Delphi methodology utilized not only was efficacious at developing consensus, but was also associated with only a minimal cost. Indeed, the expert panel was recruited and communicated with over email, and the survey was on-line, thus negating the need for postage and paper. Moreover, it can be argued that face-to-face interaction is not optimal in consensus development as dominant group members can inadvertently monopolize the discussion. Although Delphi has been utilized in many arenas in health care including the development of diagnostic criteria, research questions, and clinical skills, it has not yet been utilized in the creation of technical skills assessment forms\textsuperscript{141, 142, 145}. The development of tools to evaluate technical competence, especially for complex surgical procedures is essential in order to optimize resident training and ensure operative excellence. This study demonstrates that a Delphi methodology is an effective method by which to determine expert consensus in the initial phases of the development of such a tool.

Although initially only 11 of the 18 experts who agreed to participate in the Delphi survey completed the first round of the survey, this response rate of 61% is consistent with other published rates of survey response rates in the health professional literature\textsuperscript{146}. The loss of only 1 panelist in the second iteration is lower than the rate of attrition published in the literature\textsuperscript{147}. This could be attributed to the fact that the survey substantially decreased in length on the second round. Moreover, we utilized factors such as personalized email reminders, which have been shown to increase response rates\textsuperscript{146}. Even the loss of one participant, however, could have influenced the outcome of our study. Indeed, Cronbach’s $\alpha$ is sensitive to the number of panelists, with a decreasing number of panelists likely to decrease the value of Cronbach’s $\alpha$\textsuperscript{142}. 
The fact that Cronbach’s $\alpha$ increased in the second round from 0.74 to 0.82 and 0.77 to 0.83 indicates that the increase in consensus in the remaining panelists more than adequately offset the loss of one of the experts.

It is interesting that after only one round of the Delphi survey, consensus was achieved for the relevant sub-steps of laparoscopic sigmoid colectomy. This could be explained by the fact that laparoscopic sigmoid colectomy, while being a complex minimally invasive procedure, is generally approached by various surgeons in a similar manner. Determining the essential sub-steps for laparoscopic right colectomy, however, required an additional iteration of the survey before adequate consensus was reached. Moreover, this portion of the survey generated more commentary from the panelists and in some cases, elicited very strong opinions. This may relate to the fact that there exists no consensus as to the optimal surgical approach for a laparoscopic right colectomy. In the literature, medial to lateral as well as lateral to medial, approaches have been described\textsuperscript{148-151}. It should be emphasized, however, that the goal of this study was not to develop consensus regarding the optimal approach for right colectomy, but rather to develop an evaluation tool that would be applicable to all surgical approaches. As such, in the creation of the final evaluation tool for right colectomy, we elected to combine the identified sub-steps for both the medial to lateral as well as the lateral to medial approach and create one tool for laparoscopic right colectomy.

Although the Delphi method is considered one of the ideal means by which to elicit expert knowledge and determine a consensus while minimizing the detrimental effects of group interactions, this method is not without its limitations. First, the Delphi process has been criticized due to the fact that the breadth of the question under consideration is in part controlled by the investigator\textsuperscript{142}. In an attempt to minimize this issue, we deliberately constructed our initial round of the Delphi survey to contain as many surgical sub-steps as possible based on the initial data collection from key informant interview and a broad literature search. A possible drawback of this, however, was that the initial survey was quite long which may have explained why several experts who had agreed to participate did not complete the initial round. The Delphi method has also been criticized as having no evidence of reliability. This means that if the same survey was presented to a different panel of experts, or the same experts at a later point in time, there is no guarantee that a similar consensus might be obtained\textsuperscript{141, 147}. There are reports in the literature, however, that Delphi studies replicated several years later have found similar
In an attempt to mitigate this, we elicited the opinions of a broad range of experts; however, we were limited by the fact that not all of the experts initially contacted agreed to participate. Although the number of experts solicited was relatively small, nonetheless, the panelists represented a wide geographic area with a shared expertise.

One of the limitations of this study was that certain expert panelists did not rate all sub-steps in the survey, thus generating missing data points. Missing data was dealt with in the following manner: An average score was calculated for a particular sub-step, and the missing data point was then replaced with the average score. Cronbach’s $\alpha$ was then calculated using that data point replaced with an average score. Then Cronbach’s $\alpha$ was calculated with the missing data point replaced with a 3 (neutral). This was based on the assumption that since the panelist omitted the question, they did not feel strongly one way or the other whether that sub-step was contained in the final evaluation tool. Ultimately there was no difference in the final Alpha regardless of how the missing data points were manipulated, and thus for consistency, the Cronbach’s $\alpha$ reported are calculated with missing data replaced by group averages. Another limitation of this study includes the fact that there currently exists no standard in the literature for which to determine consensus in a Delphi survey. Indeed, a wide range of methodologies have been utilized including standard deviation, or a certain percentage of respondents agreeing with an item. Based on the work of Graham et al. we chose to use Cronbach’s $\alpha$ to allow quantification of group consensus, as a measure of reliability among the panelists. We did not compare Cronbach’s $\alpha$ to other measures of consensus as we felt that pre-determining a specific consensus cutoff prior to receiving any survey results was important to reduce investigator bias.

In conclusion, the Delphi method allowed for the determination of expert consensus regarding the essential surgical sub-steps to be included in an evaluation tool designed to measure technical competence in laparoscopic colorectal surgery. This is the first step in a project to describe a methodology for defining technical proficiency in laparoscopic colorectal surgery. With the development of the evaluation tool, the next phase in this project is to ensure the reliability and validity of this tool. The long term objective of this project is to create a validated evaluation tool that will be used in residency training programs, as well as for credentialing practicing surgeons. This will be the first study to validate an evaluation tool specific for laparoscopic colorectal surgery. Creating an evaluation tool that deconstructs the key elements of a complex procedure, such as laparoscopic colorectal surgery, will allow the trainee to identify and
comprehend the critical steps of the procedure in the correct order. Indeed, it has been shown that deconstructing complex operations into their component steps allows learners to more easily grasp the fundamentals of executing whole procedures\textsuperscript{152}. We hypothesize that this will facilitate the training of surgical residents, and potentially shorten learning curves in the operating room. Finally, we expect that the results of the study will improve the overall quality of patient care by standardizing the competencies required for surgeons to engage in independent practice.
Chapter 3

3 A Prospective Study Demonstrating the Reliability and Validity of Two Procedure-Specific Evaluation Tools to Assess Operative Competency in Laparoscopic Colorectal Surgery

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A Prospective Study Demonstrating the Reliability and Validity of Two Procedure-Specific Evaluation Tools to Assess Operative Competency in Laparoscopic Colorectal Surgery]

3.1 Abstract

Background: Laparoscopic colorectal surgery is considered an advanced minimally invasive procedure with a long, variable learning curve. Developing an evaluation tool is essential in order to ensure that individuals reach a certain level of competence prior to performing this procedure independently. To achieve standardization and wide implementation, an assessment tool must be reflective of practice across many institutions.

Study Design: The purpose of this study was to validate two procedure-specific evaluation tools for laparoscopic colorectal surgery that were developed using innovative consensus methodology. Two procedure-specific rating scales for laparoscopic right and sigmoid colectomy were created using the Delphi method. Nine novice and nine expert laparoscopic sigmoid colectomy videos were prospectively collected; and nine novice and ten expert laparoscopic right colectomy videos were recorded. Two experts rated the videos using the procedure-specific technical skills evaluation tool for either laparoscopic right colectomy or laparoscopic sigmoid colectomy.
Results: There were statistically significant differences between the expert and novice scores on the laparoscopic right colectomy evaluation tool: the median score of novices was 63.8% and the expert score was 73.1% (p=0.02). Similarly, there was a significant difference between the median novice score on the sigmoid tool (58.6%) compared to the median expert score (70.7%) (p=0.003) Cronbach’s Alpha was 0.82 for the right colectomy evaluation tool and 0.79 for the sigmoid rating scale.

Conclusions: The procedure-specific evaluation tools for laparoscopic right and sigmoid colectomy demonstrate strong reliability and construct validity, and have the potential to be used for technical skills assessment and feedback.

3.2 Introduction

In the past several decades, the clinical competence of practicing surgeons has become a matter of growing public concern. Reports of serious complications in the literature have highlighted the importance of physicians being adequately trained before attempting operations on patients\textsuperscript{153-155}. As new surgical technologies, notably minimally invasive surgery, have become widely adopted in the surgical community, there is increased pressure on training programs and certifying bodies to ensure safe and competent implementation in clinical practice.

Laparoscopic colorectal surgery is considered an advanced minimally invasive procedure. Performing this operation successfully involves the ligation of large blood vessels, working in multiple quadrants of the abdomen, and if the operation is for cancer, harvesting an appropriate number of lymph nodes\textsuperscript{120}. A significant, variable learning curve, ranging from 11 to 80 cases, has been demonstrated to exist for practicing surgeons learning laparoscopic colorectal surgery\textsuperscript{120, 128-131, 156-158}. It can be hypothesized that for surgical residents, this learning curve may be longer. It is thus essential that a means of assessing technical performance in this
advanced procedure is developed. This tool will be used to monitor training progress, provide constant feedback along the learning curve, and serve as an instrument for certification.

Historically, technical competence was assessed using non-validated methods such as the subjective opinions of experienced colleagues, or case logs detailing the number of operative procedures performed. As a response to the subjective nature of these methods of assessment, over the past decade, several evidence-based technical skills evaluation tools have been developed. In the late 1990s, Reznick’s group in Toronto developed and validated the Objective Structured Assessment of Technical Skill (OSATS), which, in its original iteration consisted of a global rating scale component and a task-specific checklist. Subsequent work demonstrated the reliability and validity of the global rating scale component of the OSATS across a range of situations from bench station exams to live operating room procedures. With the advent of minimally invasive surgery, the OSATS global rating scale has been adapted for laparoscopy, and other global rating scales have been developed and validated to assess technical skills. Although the evidence demonstrating the reliability and validity of these global rating scales for both open and laparoscopic procedures is extensive, global rating scales can be criticized due to the fact that they do not provide feedback that is meaningful to the trainee. Specifically, they assess general components of technical expertise and do not provide information relating to the specific operative steps or techniques in which trainees require practice. As a response, procedure-specific evaluation tools have been developed, which represent a hybrid between global rating scales and checklists. Although these tools represent an important means of assessing technical proficiency relating to a specific operative procedure, they are currently limited to a small number of laparoscopic procedures, with only one tool to our knowledge developed for laparoscopic colorectal surgery. Moreover, for the most part, the procedure-specific evaluation tools currently in use have been developed in an
in institution specific manner, relying on local rather than global expertise. To achieve standardization and wide-implementation, an assessment tool must be reflective of practice across many institutions. As such, using innovative consensus methodology, our group designed two procedure-specific evaluation tools for laparoscopic right colectomy and laparoscopic sigmoid colectomy\textsuperscript{167}. The surgical steps within these tools were developed based on the consensus of experts in North America, Europe and Australia, and thus the final tools are representative of international rather than local practice\textsuperscript{167}. The objective of this current study was to assess the reliability and validity of these tools in the context of a live operating room performance with subsequent blinded video review. We hypothesize that based on the systematic manner in which these procedure-specific evaluation tools were created, an acceptable level of inter-rater reliability will be demonstrated by both tools, and that both rating scales will effectively distinguish between expert and novice performance in the operating room.

3.3 Methods

3.3.1 Study Design:
This study was a prospective study designed to assess the inter-rater reliability and validity of two procedure-specific technical skills rating scales for laparoscopic colorectal surgery used in the context of blinded video-review. The study protocol was approved by the local Institutional Review Board and all participants were included after obtaining informed consent.

3.3.2 Participants:
Study participants were general surgical staff and fellows (n=10) and residents (n=13) at a large University training program. Participants were recruited through e-mail and were stratified into a novice group and an expert group. Inclusion criteria for the novice group included being at the PGY-3 level or above and having performed less than 10 laparoscopic colorectal procedures.
Inclusion criteria for the expert group included being either a staff or a minimally invasive surgery (MIS) fellow who had performed greater than 100 laparoscopic right or sigmoid colectomies.

3.3.3 Operative Tasks:

Individuals in the expert and the novice group performed either a laparoscopic right colectomy or a laparoscopic sigmoid colectomy in the operating room. Novices were assisted by experienced colorectal surgeons in the usual fashion, which included verbal instruction and takeover if necessary. There were no formal criteria for takeovers. Takeovers were at the discretion of the staff surgeon and could be based on factors including the failure of a novice to progress or to simply to speed up the case. If a takeover occurred, the observer noted the time on the video so that this could be excluded from analysis during the subsequent rating of the videos. When experts were performing the procedure, novices were given the opportunity to do small parts of the case if time or circumstances permitted. The operative procedure was video-recorded through the laparoscopic camera from port insertion until the end of the case. As such, no identifying data of the patient or the operating team was recorded. In addition, the video recording did not record any sound. A member of the study team was present during each of the cases to facilitate the recording and to document any potential takeovers by the supervisor. A case was coded as a novice case if the novice performed greater than 70% of the procedure (subjective opinion of the observer), and the same criteria was applied to the coding of the expert cases.

3.3.4 Assessment tools:

Two assessment tools were utilized in this study: a procedure-specific technical skills evaluation tool for laparoscopic right colectomy and laparoscopic sigmoid colectomy. These tools were developed using the Delphi consensus methodology whereby international experts rated a
comprehensive list of surgical sub-steps for both laparoscopic right and sigmoid colectomy with respect to the degree to which they felt they were relevant to include in a rating scale for these procedures. This was done in an iterative fashion until consensus (Cronbach’s Alpha >0.8) was achieved. The final tools ultimately subdivided the relevant procedures into specific surgical sub-steps. An individual’s performance on each of the sub-steps is rated on a Likert scale of 1-5 with anchoring descriptors on points 1, 3, and 5 (Table 5 and Table 6).

3.3.5 Video Analysis:

The videotapes were presented to 2 independent experts for rating. These expert raters were individuals not associated with the study who were receiving fellowship training in either colorectal surgery or minimally invasive surgery. The raters were blinded as to whether the surgeon in the video was an expert or a novice. Both raters participated in a brief orientation session where they went through both rating scales with a member of the study team, were instructed to use the entire range of the Likert scale, and were given the opportunity to ask questions. The experts rated the videos using the procedure-specific technical skills evaluation tool for either laparoscopic right colectomy or laparoscopic sigmoid colectomy. The raters were also given access to the take-over information and were instructed to fast-forward the parts of the videos that were to be excluded from the analysis of that particular video. If a step in the rating scale was not performed or visualized on the video, the raters were instructed to rate it as “not applicable”.

3.3.6 Sample Size:

A power calculation was performed to assess how many novices and experts were required per group. The power calculation was based on work with the Global Operative Assessment of Laparoscopic Skills (GOALS). In this study, the minimum relevant difference between groups
was 6.4. Using a standard deviation of 4.5, a power of 0.8 and alpha of 0.05, the minimum required videos in the novice and expert group was $8^{68}$.

### 3.3.7 Statistical Analysis:

Statistical analysis was carried out using SPSS software version 18.0 (Chicago, Il, USA). Descriptive statistics were calculated for all variables. Final scores for each video were converted into percentage scores and analyzed as such. Data is reported as medians (interquartile) range. The reliability of both procedure specific evaluation tools was assessed using Cronbach’s Alpha. The data was not normally distributed and as such the difference between expert and novice scores on the two assessment tools was analyzed using the Mann-Whitney U test. A $p$ of $<0.05$ was considered to be statistically significant.

### 3.3.8 Results

A total of 23 laparoscopic right colectomy videos and 20 sigmoid videos were collected. 4 of the laparoscopic right videos and 2 of the sigmoid videos were unable to be analyzed due to a failure of the recording system.

A total of 9 novice and 10 expert laparoscopic right hemicolecotmy videos were analyzed. All cases were performed by unique novices and experts. A total of 9 novice and 9 expert laparoscopic sigmoid colectomy videos were analyzed, All cases were performed by unique novices and experts. Median PGY level for all the novices was 3 (range 3-5). Patient ASA ranged from 1-4 (median 3). 10 of the right colectomies were done with the medial to lateral approach and 9 were done using the lateral to medial approach. All laparoscopic sigmoid procedures were done using the medial to lateral approach.
In the novice sigmoid colectomy videos, takeovers occurred in 7/9 videos, with the most common step for takeover being dividing the rectum (6/7 videos), dissecting the mesorectum (4/7 videos) and dissecting the splenic flexure (3/7 videos). 3/9 expert videos had a takeover event. The most common step was port insertion (2/3) and medial dissection (2/3). In each case the takeover event in the expert videos was to allow a novice to do a small part of the case.

Takeovers occurred in 4/10 novice laparoscopic right colectomy videos. The most common reason for takeover was ileocolic dissection, (2/4), hepatic dissection (2/4), and anastomosis (2/4). For the experts, takeovers occurred in 2/10 videos to allow a resident to do a small portion of the case. In one video it was to allow the resident to do small parts of the ileocolic and transverse colon dissection, and in the other video it was to allow the resident to do some of the hepatic dissection.

3.3.9  Reliability

3.3.9.1  Laparoscopic Sigmoid Colectomy

The rating scale for laparoscopic sigmoid colectomy consists of 18 specific tasks. Although most tasks were present and able to be analyzed in all the videos, several of the tasks relating to “mobilizing the splenic flexure”, “bowel resection” and “anastomosis” were performed on less than 14 of the 18 videos depending on the task in question (Table 7).

In 7 instances, 1 rater was able to rate more videos than the other rater for a particular task (in 5 of these cases the discrepancy between rated videos was 1) (Table 7)

The overall inter-rater agreement of the two raters’ total scores for the laparoscopic sigmoid colectomies was satisfactory with Cronbach’s alpha of 0.79. Raters were in less agreement if novices were performing the procedure (Cronbach’s Alpha 0.58) than experts (Alpha=0.64).
<table>
<thead>
<tr>
<th>Specific Task on Rating Scale</th>
<th>Rater 1</th>
<th></th>
<th>Rater 2</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total number of videos in which specific task was rated</td>
<td>If task not done was it an expert or novice video</td>
<td>Total number of videos in which specific task was rated</td>
<td>If task not done was it an expert or novice video</td>
</tr>
<tr>
<td><strong>Access and Port Insertion</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creating access and placing 3 or 4 additional ports under direct vision</td>
<td>17/18</td>
<td>Novice=1</td>
<td>17/18</td>
<td>Novice=1</td>
</tr>
<tr>
<td><strong>Exposure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placing the patient in steep Trendelenburg</td>
<td>18/18</td>
<td></td>
<td>0/18</td>
<td></td>
</tr>
<tr>
<td>Retracting the small bowel in the upper abdomen</td>
<td>18/18</td>
<td></td>
<td>18/18</td>
<td></td>
</tr>
<tr>
<td>Retracting the sigmoid colon from the pelvis in a cephalad and anterior direction</td>
<td>18/18</td>
<td></td>
<td>18/18</td>
<td></td>
</tr>
<tr>
<td>Identifying the origin of the inferior mesenteric artery (IMA)</td>
<td>17/18</td>
<td>Novice=1</td>
<td>18/18</td>
<td></td>
</tr>
<tr>
<td><strong>Initial Dissection</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creating an incision in the rectorectal fascia, behind the IMA</td>
<td>17/18</td>
<td>Novice=1</td>
<td>17/18</td>
<td>Novice=1</td>
</tr>
<tr>
<td>Identifying the presacral nerves</td>
<td>17/18</td>
<td>Novice=1</td>
<td>17/18</td>
<td>Novice=1</td>
</tr>
<tr>
<td>Developing a plane posterior to the IMA</td>
<td>17/18</td>
<td>Novice=1</td>
<td>18/18</td>
<td></td>
</tr>
<tr>
<td>Continuing the dissection in a plane anterior to the retroperitoneal fascia</td>
<td>17/18</td>
<td>Novice=1</td>
<td>18/18</td>
<td></td>
</tr>
<tr>
<td>Taking down the lateral attachments of the sigmoid and descending colon to the abdominal wall</td>
<td>18/18</td>
<td></td>
<td>18/18</td>
<td></td>
</tr>
<tr>
<td>Continuing the dissection inferiorly until the rectum is adequately mobilized</td>
<td>18/18</td>
<td></td>
<td>17/18</td>
<td>Novice=1</td>
</tr>
<tr>
<td><strong>Mobilizing the Splenic Flexure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dividing the splenocolic ligament, renocolic ligament and omental attachments of the splenic flexure</td>
<td>7/18</td>
<td>Novice=7</td>
<td>7/18</td>
<td>Novice=7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expert=4</td>
<td></td>
<td>Expert=4</td>
</tr>
<tr>
<td>Checking the length of the mobilized specimen to ensure it will be of adequate length without tension</td>
<td>13/18</td>
<td>Novice=4</td>
<td>9/18</td>
<td>Novice=5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expert=1</td>
<td></td>
<td>Expert=4</td>
</tr>
<tr>
<td><strong>Bowel Resection</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Dividing the mesorectum at a right angle to the bowel | 14/18 | Novice=3 | 12/18 | Novice=4
| Expert=1 | Expert=2 |

Creating a mini-laparotomy in the left lower quadrant or pfannenstiel incision | 0/18 | Novice=9 | 0/18 | Novice=9
| Expert=9 | Expert=9 |

Utilizing a wound protector when the end of the proximal colon is delivered through the incision | 0/18 | Novice=9 | 0/18 | Novice=9
| Expert=9 | Expert=9 |

| Anastomosis |
| Checking the orientation of the bowel | 10/18 | Novice=5 | 11/18 | Novice=5
| Expert=3 | Expert=2 |

Table 7: Details of the raters’ evaluation of the laparoscopic sigmoid videos

3.3.9.2 Laparoscopic Right Colectomy

The rating tool for laparoscopic right colectomy consists of 19 tasks for the medial to lateral approach, and 18 tasks for the lateral to medial approach. Although most tasks were able to be analyzed on all the videos, several of the tasks relating to “dissection of the ileocolic vascular pedicle” and “distal bowel resection and anastomosis” were performed on less than 12 videos. In several instances, 1 rater was able to rate more videos than the other rater for a particular task (in 12 of these cases the discrepancy between number of rated videos was 1) (Table 8).

The overall inter-rater agreement between the two raters’ overall scores for the laparoscopic right colectomies was satisfactory with a Cronbach’s alpha of 0.82. Cronbach’s Alpha was 0.82 for the medial to lateral approach and 0.84 for the lateral to medial approach. There was less agreement among raters if experts were performing the procedure (Cronbach’s Alpha 0.64) versus novices (Cronbach’s Alpha 0.79).
<table>
<thead>
<tr>
<th>Specific Task on Rating Scale</th>
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<td></td>
<td>Total number of videos in which specific task was rated</td>
<td>If task not done was it an expert or novice video</td>
</tr>
<tr>
<td>1. Access and Port Insertion</td>
<td>19/19</td>
<td></td>
</tr>
<tr>
<td>Creating access and placing 3 or 4 additional ports under direct vision</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Diagnostic Laparoscopy</td>
<td>19/19</td>
<td></td>
</tr>
<tr>
<td>Inspecting the intra-abdominal contents with the laparoscopic camera</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Initial Exposure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Medial to Lateral Approach</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identifying the ileocolic vascular pedicle by applying traction to the cecum</td>
<td>9/10</td>
<td>Novice=1</td>
</tr>
<tr>
<td>b) Lateral to Medial Approach</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposing and identifying the “valley” at the base of the cecum and the terminal ileal mesentery – this marks the junction of the mesentery with the retroperitoneum</td>
<td>9/9</td>
<td></td>
</tr>
<tr>
<td>4. Division of Ileocolic Vascular Pedicle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scoring the peritoneum under the ileocolic vessels</td>
<td>12/19</td>
<td>Novice=3</td>
</tr>
<tr>
<td>Skeletonizing the ileocolic vessels</td>
<td>12/19</td>
<td>Novice=3</td>
</tr>
<tr>
<td>Dividing the ileocolic vessels</td>
<td>12/19</td>
<td>Novice=3</td>
</tr>
<tr>
<td>5. Initial Dissection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Medial to Lateral Approach</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Developing a plane between the mesocolon and the retroperitoneum in a medial to lateral direction</td>
<td>9/10</td>
<td>Novice=1</td>
</tr>
<tr>
<td>Identifying the duodenum</td>
<td>9/10</td>
<td>Novice=1</td>
</tr>
</tbody>
</table>
Continuing the medial to lateral dissection until above the duodenum and the head of the pancreas and under the transverse mesocolon | 9/10 | Novice=1 | 8/10 | Novice=1 | Expert=1

Identifying the right branch of the middle colic artery | 9/10 | Novice=1 | 8/10 | Novice=1 | Expert=1

Dividing the right branch of the middle colic artery | 9/10 | Novice=1 | 8/10 | Novice=1 | Expert=1

**b) Lateral to Medial Approach**

Scoring the peritoneum around the cecum and the terminal ileum (TI) along this valley and entering the retroperitoneal plane | 9/9 | 8/9 | Novice=1

Opening the right lateral peritoneal reflection (lateral to the cecum and the ascending colon) and dissecting towards the midline | 9/9 | 8/9 | Novice=1

Exposing the duodenum | 9/9 | 8/9 | Novice=1

Mobilizing the ascending colon to the midline | 9/9 | 8/9 | Novice=1

**6. Mobilization of the Hepatic Flexure**

Positioning the patient in reverse Trendelenburg with their right side up | 19/19 | 1/19

Dividing the omental attachments at the transverse colon | 19/19 | 19/19

Entering the lesser sac and dividing the omentum proximally | 19/19 | 19/19

Medial-caudal retraction of the flexure | 19/19 | 19/19

**7. Exteriorization, Bowel Resection and Anastomosis**

Dividing the proximal and distal bowel intra- or extracorporeally | 6/19 | Novice=5 | 5/19 | Novice=6 | Expert=8

Using a wound protector if the bowel is exteriorized | 0/19 | 0/19

Anastomosis performed according to the surgeon’s preference | 6/19 | Novice=5 | 4/19 | Novice=7 | Expert=8

Table 8: Details of the raters’ evaluation of the laparoscopic sigmoid videos
3.3.10 Construct Validity

Rater 1’s median novice score on the evaluation tool for laparoscopic right colectomy was 63.8 (60.8-74.3) and the median expert score on the tool was 73.1 (66.8-78.5) (p=0.019). Rater 2’s scores similarly demonstrated statistical significance between novice and expert performance (67.1(60-75.5) vs 74.6(67.8-75.7) p=0.008) Rater 1’s median novice score on the evaluation tool for laparoscopic sigmoid colectomy was 58.5 (57.7-64.5), and the median expert score was 70.7 (68.3-76.2) (p=0.003). Rater 2’s scores also demonstrated statistical significance between expert and novice performance (novice 64.8(56.4-70.0), expert 74.6(67.4-75.2) p=0.015).

3.4 Discussion

The present study assessed the inter-rater reliability and construct validity of two procedure-specific evaluation tools for laparoscopic colorectal surgery created using the Delphi consensus methodology in the context of a blinded video recording of a live operating room procedure. Although various global rating scales have been validated as tools to assess laparoscopic performance, they have significant limitations as training tools as they do not provide useful feedback to the learner. Conversely, task-specific checklists provide trainees with a detailed method of how to perform the operation thus enabling formative feedback and deliberate practice. Task-specific checklists, however, have been shown to be less reliable and construct valid than global rating scales. Procedure-specific rating scales may address this problem by occupying a middle ground between global rating scales and checklists, thus facilitating their potential role as both an assessment and a feedback tool.

In a discussion of the quality of an assessment tool, it is important to address both its reliability and validity. Inter-rater reliability refers to the degree to which a difference in score on the tool is reflected by the difference in quality of the performance rather than a difference between the
raters. In this study, the evaluation tool for laparoscopic sigmoid colectomy had a Cronbach’s alpha of 0.79 and the tool for laparoscopic right colectomy had a Cronbach’s alpha of 0.82. These values for inter-rater reliability indicate that the tool for laparoscopic sigmoid colectomy approaches the cutoff of 0.8 deemed acceptable for assessment\textsuperscript{169}, while the tool for laparoscopic right colectomy surpasses this value regardless of whether a medial to lateral or a lateral to medial approach is taken. It is interesting to note that the tool for laparoscopic right, which had a higher level of consensus during the Delphi process that was used in its creation, also demonstrates an increased level of inter-rater reliability compared to the tool for laparoscopic sigmoid colectomy. It is therefore worth considering that in future studies that use the Delphi method to create technical skills evaluation tools, a higher cutoff for consensus than previously endorsed should be considered in order to achieve higher reliability in the final evaluation tool end product.

It is worth noting the degree of inconsistency among the raters relating to whether a specific surgical step was able to be evaluated on the videos. Although in most cases, the raters only disagreed about 1 video, it was somewhat surprising that even this level of inconsistency existed. This could have perhaps been avoided with a more intensive training session for the raters. Although raters were oriented in detail to the structure of the evaluation tool, a supervised session where the raters reviewed a video in the presence of a study team member could have perhaps reduced this level of inconsistency. This is supported by the fact that in the GOALS study, which assessed the reliability of a procedure-specific evaluation tool for laparoscopic cholecystectomy, using a trained rater rather than a non-trained rater increased the intraclass correlation coefficient between the raters from 0.81 to 0.89\textsuperscript{68}. 
Construct validity refers to the idea that an evaluation tool should effectively distinguish between novice and expert performance of a given surgical procedure. In this study, statistically significant differences in scores were demonstrated between expert and novice performance on both evaluation tools, and with both raters. Ideally, one would expect to see a narrow range of performance within both the expert and novice group. Although the range in the expert and novice scores was quite narrow for laparoscopic sigmoid colectomy, it was slightly wider for both the expert and novice group for laparoscopic right colectomy. This could be explained by several factors. First, laparoscopic right colectomy is a less difficult procedure technically than laparoscopic sigmoid colectomy, and it is conceivable that trainees with less technical proficiency were able to perform laparoscopic right colectomies, whereas a narrower range of junior trainees were in fact able to complete a laparoscopic sigmoid colectomy. Similarly, staff surgeons earlier in their learning curve may be performing more laparoscopic right colectomies than sigmoid colectomies, or have an earlier threshold for conversion during the latter procedure. This may also explain why the raters were more reliable in assessing novice performance compared to expert performance for laparoscopic right colon whereas the converse was true with laparoscopic sigmoid colectomies. It should, however, be noted that in this study the number of experts and novices was relatively small, and that this discrepancy in ranges may in fact be due to a relatively modest sample size.

In the analysis of the results of this study, the final scores on both the sigmoid and right colectomy evaluation tools were converted to percentages. This was done since the maximal raw score on the right colectomy tool varied whether a medial to lateral or lateral to medial approach was taken. In addition, for the sigmoid tool, not all parts of the procedure were visualized on all videos. For example, in certain cases, port insertion, or specimen extraction could not be visualized. In this case, for feasibility reasons it was elected to convert the data to percentages to
avoid discarding a video if it was impossible to complete the rating tool in its entirety. This technique has also been performed in similar studies. The highest potential total score on the tool for laparoscopic sigmoid colectomy was 80 and the lowest was 50. The highest potential score on the tool for laparoscopic right colectomy was 90 and the lowest was 50. As such, transforming the data to a total of 100, while it had the potential to introduce greater spread in the data than what was originally reflected in the final totals, was necessary in order to analyze the data in a meaningful way.

A significant limitation of this study was that several items identified through the prior Delphi consensus phase of this study were unable to be analyzed on the laparoscopic videos since they are steps that are impossible to visualize through the laparoscopic camera. These include “creating a mini laparotomy” or “using a wound protector”. As such, the construct validity and reliability measurements of these tools do not include these particular steps. Although including these steps may be useful for teaching and providing residents with feedback related to their performance, they should not be included for assessment purposes. Completing the assessment tools live in the operating room could have circumvented this potential weakness; however, we believe that a strength of this particular study is the fact that we reduced potential bias by having blinded experts analyze the final video recordings.

In order for an evaluation tool to be incorporated into existing residency programs or continuing education courses, the tool must not only demonstrate appropriate reliability and validity metrics, but it must also be reflective of international practice. To date, most evaluation tools have been designed using expertise local to one institution. The tools described in this study represent an exception to this. This is especially important when considering a procedure such as laparoscopic right colectomy for which there is no consensus in the literature as to the best way to perform the
dissection$^{150,151}$. At this point, evidence from this study supports the use of these tools in the context of blinded-video review for live operating room procedures. Although these tools are potentially useful to provide trainees information with respect to their technical performance in the operating room, more work needs to be done for them to be used in high-stakes assessment. Specifically it would be interesting to investigate the psychometric properties of the tool in live, rather than in video based assessment, in a simulated environment such as the cadaver lab, the ability of the tool to discriminate between trainees at similar levels of performance, or the ability of the tools to assess technical progress over time.

In conclusion, in the context described in this study, the procedure-specific evaluation tools for laparoscopic right colectomy and sigmoid colectomy have demonstrated acceptable inter-rater reliability and construct validity. These assessment tools have the potential to provide the trainee with an objective evaluation of their technical as well as relevant feedback related to their operative performance. In future work with these rating scales, stringent rater training including practice using the rating scales should be considered in order to improve inter-rater reliability. The next step is to continue to investigate the psychometric properties of these tools with the ultimate goal of incorporating them in a systematic manner into a residency training curriculum for laparoscopic colorectal surgery.
Chapter 4

4 Designing a Proficiency-Based Content Validated Virtual Reality Curriculum for Laparoscopic Colorectal Surgery: A Delphi Approach

[Accepted for Publication July 21/2011 as Palter V.N., Grantcharov T.P. Designing a Proficiency-Based Content Validated Virtual Reality Curriculum for Laparoscopic Colorectal Surgery: A Delphi Approach in Surgery]

4.1 Abstract

Background: Although task training on virtual reality simulators has been shown to transfer to the operating room, to date no VR curricula have been described for advanced laparoscopic procedures. The purpose of this study was to develop a proficiency-based VR technical skills curriculum for laparoscopic colorectal surgery.

Methods: The Delphi method was used to determine expert consensus on which VR tasks (on the LapSim simulator) are relevant to teaching laparoscopic colorectal surgery. 20 international experts rated all the LapSim tasks on a Likert scale (1-5) with respect to the degree to which they thought that a particular task should be included in a final technical skills curriculum. Results of the survey were sent back to participants until consensus (Cronbach’s Alpha >0.8) was reached. A cross-sectional design was utilized to define the benchmark scores for the identified tasks. Ten expert surgeons completed all identified tasks on the “easy”, “medium” and “hard” settings of the simulator.

Results: In the first round of the survey, Cronbach’s $\alpha$ was 0.715 and after the second round, consensus was reached at 0.865. Consensus was reached for 7 basic tasks and for 1 advanced suturing task. Median expert time and economy of movement scores were defined as benchmarks for all curricular tasks.
Conclusions: This study used Delphi consensus methodology to create a curriculum for an advanced laparoscopic procedure that is reflective of current clinical practice on an international level and conforms to current educational standards of proficiency-based training.

4.2 Introduction:

Surgical residency training programs have traditionally used the operating room to teach surgical skills to trainees through graded responsibility under direct supervision. However, due to shortened resident work hours, ethical concerns regarding trainees learning procedures for the first time on patients, and the advent of new technology such as laparoscopy, this strategy is no longer feasible. As such, it has become necessary to shift a portion of residency training from the operating room to the surgical skills laboratory. Several recent systematic reviews have demonstrated that technical skills training in an ex-vivo environment, whether on a bench-top model, or a virtual reality simulator, translates into an improvement in operating room performance\(^{14, 51, 52, 170}\). Moreover, the technical improvements seen on a VR simulator have shown to persist for at least 10 cases in the operating room\(^{41}\). Virtual reality simulators have several advantages over bench-top simulators; these include their ability to simulate complications such as bleeding, their ability to automatically generate assessment parameters allowing for comparison between individuals and performances, as well as the fact that they are able to simulate tasks at varying levels of difficulty allowing for a natural gradation of training\(^3\).

With the strong body of evidence supporting the role of virtual reality simulation in technical skills training, it is somewhat surprising that outside of the realm of research studies, few virtual reality training curricula have been developed for minimally invasive procedures. Several groups have described curricula for basic laparoscopy including curricula for basic minimally invasive tasks, or for less complex procedures such as laparoscopic cholecystectomy\(^{96, 116, 119}\). Although these curricula represent an important step in defining virtual reality curricula for minimally invasive procedures, and largely conform to current educational theories regarding proficiency-based learning and distributed practice, as a group, they are largely developed using local expertise. Specifically, experts at one institution determine which tasks or components are included in the final curriculum. In order to ensure the applicability of the developed curricula, it is essential that the final educational product is reflective of practice across diverse institutions.
In addition, to our knowledge, no virtual reality technical skills curricula have been described for advanced minimally invasive procedures.

Laparoscopic colorectal surgery is considered an advanced minimally invasive procedure. Performing this procedure successfully involves ligating large blood vessels, working in multiple quadrants of the abdomen, and creating a viable anastomosis\textsuperscript{120}. A long variable learning curve\textsuperscript{128} has been described for laparoscopic colorectal surgery, which underscores the necessity of developing a technical skills curriculum for learning this procedure, ideally in a simulated environment. The purpose of this study is twofold. The first aim was to develop a virtual reality technical skills curriculum for laparoscopic colorectal surgery using consensus methodology; followed by defining expert benchmarks of proficiency for this curriculum.

4.3 Methods:

4.3.1 Study design

This study used Delphi methodology to obtain consensus on the essential components of a virtual reality curriculum for laparoscopic colorectal surgery. In addition, a cross-sectional design was utilized in order to determine expert levels of proficiency for the defined curriculum. The study was approved by the local Institutional Review Board.

4.3.2 Participants for Delphi Consensus:

Participants for the Delphi consensus portion of the study were required to be leaders in their clinical field as evidenced by their role as opinion leaders within organizations such as The American Society of Colon and Rectal Surgeons (ASCRS), the Society of Gastrointestinal and Endoscopic Surgeons (SAGES), or other national surgical societies. Furthermore, they were required to be familiar with the virtual reality system used for the curriculum. Finally, the experts were required to be practicing surgeons who were involved in training laparoscopic colon and rectal surgery both at the resident and continuing professional development level. Twenty experts were recruited by e-mail to respond to an on-line survey. The experts were intentionally selected to represent a wide geographic area. In North America, eleven experts were contacted, and in Europe, nine experts were contacted with the assistance of the Dutch Society for Endoscopic Surgery. Membership of the expert panel was not revealed to the survey participants.
4.3.3 On-Line Survey:

The virtual reality system that was utilized for the technical skills training portion of the curriculum was the LapSim laparoscopy trainer (Surgical Science, Gothenburg, Sweden). Construct validity, learning curves, and transfer of skills learnt on the LapSim have been demonstrated\textsuperscript{21, 24, 40, 41, 53, 171, 172}. The system consists of 11 basic tasks, 10 advanced tasks, and 6 procedural tasks specific to general surgery. Not all tasks on the LapSim, however, are relevant to laparoscopic colorectal surgery. The role of the Delphi panel was to determine, through expert consensus, those tasks that are relevant to teaching the technical skills required to perform laparoscopic colorectal surgery. These tasks were compiled into an on-line survey using the survey software Survey Monkey (Palo Alto, California). The participants in the expert panel were required to rate each identified task on a Likert scale from 1 to 5 detailing the degree to which they agreed or disagreed that a particular component should be included in a final technical skills curriculum. Results of the survey were sent back to participants with group averages and standard deviations until expert consensus was reached. Expert consensus was pre-defined as Cronbach’s Alpha >0.8, which has been shown to be an acceptable method of consensus determination\textsuperscript{142}.

4.3.4 Final Structure of the Technical Skills Curriculum:

After Cronbach’s Alpha greater than 0.8 was achieved for the on-line survey, an outline of the final technical skills portion of the curriculum was created. Specific curricular tasks that over 80% of the experts rated as either 4 (agree) or 5 (strongly agree) on the final scale were included in the final technical skills curriculum. The technical portion of the final curriculum will require execution of the identified tasks on the “easy”, “medium” and “hard” levels of the simulator. The settings for each level were taken from a recent European study in which consensus was reached on defining levels for the LapSim Basic Skills 3.0 package\textsuperscript{93}. Levels for the tasks that were not discussed in the European consensus document (Handling Intestines, and Stitch and Square Knot) were defined using an identical concept with local expertise.

4.3.5 Participants for Expert Benchmark Levels:

Nine experts in minimally invasive surgery were identified. An expert was defined as an individual who has completed more than 100 advanced minimally invasive procedures.
4.3.6 Tasks:
Each expert was familiarized to the simulator by a member of the study team (V.P or M. G.). Experts watched the instructional video for each task, but did not warm up or practice on the simulator. During the familiarization period, the expert had opportunities to ask questions. Each expert completed each component of the curriculum on the “easy”, “medium” and “hard” levels in a pre-defined sequence. No assistance was provided during completion of the curriculum.

4.3.7 Generation of Expert Benchmark Scores:
Experts were scored based on the automatic assessment parameters generated by the simulator. The parameters of interest were time, as well as those parameters related to economy of motion, specifically instrument angular path and path length. Expert benchmark scores for “time”, “path length” and “angular path” were determined for each curricular component on the 3 levels (easy, medium, and hard) by calculating the median score of the 10 experts.

4.3.8 Statistical Analysis
For the second round of the consensus survey, means and standard deviations were calculated for all LapSim tasks, and were reported back to the expert panelists. Cronbach’s Alpha was used to determine consensus on the final curriculum tasks among the expert panelists. Median expert scores were calculated in order to determine expert levels of proficiency for the identified curricular tasks. All statistical analysis was performed on SPSS (Statistical Package for Social Sciences version 18.0, Chicago, IL, USA).

4.4 Results:
Of the 20 experts contacted to participate in the Delphi panel, 19 responded to the first round of the consensus survey. The responses of 2 respondents were excluded from analysis. The first since they completed less than 1/3 of the survey, and the second since they gave each curricular task the same score, indicating a lack of attention to the survey process. After the first round of the survey, Cronbach’s Alpha was 0.715 indicating a lack of consensus. Twelve experts completed the second round of the survey. After the second round consensus was achieved with Cronbach’s Alpha of 0.865. After consensus was reached, the LapSim tasks that 80% of the panel rated as a 4 or 5 on the Likert scale were included in the final curriculum (Table 9). Easy, medium, and hard levels were defined for each curricular task (levels available upon request).
Nine experts completed the virtual reality curriculum in its entirety. Median expert scores were set as benchmarks for each task on each of the 3 levels of difficulty (Table 10).

<table>
<thead>
<tr>
<th>LapSim Task</th>
<th>Percentage of Experts Endorsing the Task in the Final Curriculum</th>
<th>Task Included in the Final Virtual Reality Curriculum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Camera Navigation</td>
<td>66%</td>
<td>No</td>
</tr>
<tr>
<td>Instrument Navigation</td>
<td>58%</td>
<td>No</td>
</tr>
<tr>
<td>Coordination</td>
<td>83%</td>
<td>Yes</td>
</tr>
<tr>
<td>Grasping</td>
<td>83%</td>
<td>Yes</td>
</tr>
<tr>
<td>Cutting</td>
<td>100%</td>
<td>Yes</td>
</tr>
<tr>
<td>Clip Applying</td>
<td>92%</td>
<td>Yes</td>
</tr>
<tr>
<td>Lifting and Grasping</td>
<td>92%</td>
<td>Yes</td>
</tr>
<tr>
<td>Suturing</td>
<td>58%</td>
<td>No</td>
</tr>
<tr>
<td>Precision and Speed</td>
<td>25%</td>
<td>No</td>
</tr>
<tr>
<td>Handling Intestines</td>
<td>100%</td>
<td>Yes</td>
</tr>
<tr>
<td>Fine Dissection</td>
<td>92%</td>
<td>Yes</td>
</tr>
<tr>
<td>Cholecystectomy Part 1</td>
<td>17%</td>
<td>No</td>
</tr>
<tr>
<td>Cholecystectomy Part 2</td>
<td>8%</td>
<td>No</td>
</tr>
<tr>
<td>Needle Passing</td>
<td>50%</td>
<td>No</td>
</tr>
<tr>
<td>Interrupted Stitching</td>
<td>76%</td>
<td>No</td>
</tr>
<tr>
<td>Running Stitching</td>
<td>83%</td>
<td>No</td>
</tr>
<tr>
<td>Square Knot</td>
<td>76%</td>
<td>No</td>
</tr>
<tr>
<td>Surgeon’s Knot</td>
<td>67%</td>
<td>No</td>
</tr>
<tr>
<td>Stitch and Square Knot</td>
<td>83%</td>
<td>Yes</td>
</tr>
<tr>
<td>Stitch and Surgeon’s Knot</td>
<td>83%</td>
<td>No</td>
</tr>
<tr>
<td>Interrupted Suturing</td>
<td>92%</td>
<td>No</td>
</tr>
<tr>
<td>Running Suturing</td>
<td>92%</td>
<td>No</td>
</tr>
<tr>
<td>Side-to-side anastomosis</td>
<td>76%</td>
<td>No</td>
</tr>
<tr>
<td>Appendectomy Loop Technique</td>
<td>33%</td>
<td>No</td>
</tr>
<tr>
<td>Appendectomy Single Staple Task</td>
<td>67%</td>
<td>No</td>
</tr>
<tr>
<td>Appendectomy Dual Staple Task</td>
<td>33%</td>
<td>No</td>
</tr>
<tr>
<td>Appendectomy Optional Staple Task</td>
<td>50%</td>
<td>No</td>
</tr>
<tr>
<td>Peg Transfer</td>
<td>33%</td>
<td>No</td>
</tr>
<tr>
<td>Pattern Cutting</td>
<td>42%</td>
<td>No</td>
</tr>
<tr>
<td>Endoloop</td>
<td>58%</td>
<td>No</td>
</tr>
</tbody>
</table>
This study used Delphi consensus methodology to create a curriculum for an advanced laparoscopic procedure that is reflective of current clinical practice on an international level and conforms to current educational standards of proficiency-based training. The main purpose is to

### Table 10: Expert levels of proficiency for the curricular tasks

Data reported as: Median (interquartile range)

<table>
<thead>
<tr>
<th>Task</th>
<th>Level</th>
<th>Time (s)</th>
<th>Right instrument path length (m)</th>
<th>Right instrument angular path (°)</th>
<th>Left instrument path length (m)</th>
<th>Left instrument angular path (°)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Coordination</strong></td>
<td>1</td>
<td>59 (46-76)</td>
<td>1.79(1.49-2.45)</td>
<td>492 (391-728)</td>
<td>0.66(0.07-0.87)</td>
<td>178 (74-283)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>55 (41-65)</td>
<td>1.52(1.44-1.73)</td>
<td>419 (368-455)</td>
<td>0.51(0.36-0.78)</td>
<td>134 (109-226)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>67(56-86)</td>
<td>1.89(1.61-2.15)</td>
<td>478 (418-540)</td>
<td>0.73(0.64-1.45)</td>
<td>274 (219-478)</td>
</tr>
<tr>
<td><strong>Grasping</strong></td>
<td>1</td>
<td>Right instrument time: 40(35-49)</td>
<td>1.65(1.47-2.12)</td>
<td>337(276-528)</td>
<td>1.55(1.34-2.15)</td>
<td>380(296-395)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Right instrument time: 51(41-86)</td>
<td>1.98(1.82-2.63)</td>
<td>354(325-432)</td>
<td>2.25(1.64-2.96)</td>
<td>408(348-583)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Right instrument time: 61(54-86)</td>
<td>2.46(2.20-2.79)</td>
<td>421(402-479)</td>
<td>2.45(2.02-3.11)</td>
<td>443(361-556)</td>
</tr>
<tr>
<td><strong>Cutting</strong></td>
<td>1</td>
<td>92(75-108)</td>
<td>1.17(0.93-1.46)</td>
<td>239(202-352)</td>
<td>0.93(0.86-1.35)</td>
<td>234(194-313)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>70(34-84)</td>
<td>0.87(0.69-1.14)</td>
<td>180(141-225)</td>
<td>0.57(0.49-0.70)</td>
<td>157(122-175)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>88(67-154)</td>
<td>1.03(0.75-1.43)</td>
<td>190(143-305)</td>
<td>0.85(0.62-1.30)</td>
<td>212(127-285)</td>
</tr>
<tr>
<td><strong>Clip Applying</strong></td>
<td>1</td>
<td>104(80-134)</td>
<td>1.27(1.13-1.70)</td>
<td>174(164-242)</td>
<td>1.41(1.11-1.70)</td>
<td>223(177-286)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>111(60-165)</td>
<td>1.46(0.84-3.25)</td>
<td>268(106-470)</td>
<td>1.41(0.68-2.25)</td>
<td>217(94-345)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>109(84-143)</td>
<td>1.27(1.16-2.30)</td>
<td>196(125-461)</td>
<td>1.44(0.83-1.65)</td>
<td>249(116-282)</td>
</tr>
<tr>
<td><strong>Lifting and Grasping</strong></td>
<td>1</td>
<td>103(90-115)</td>
<td>1.98(1.60-2.28)</td>
<td>420(346-490)</td>
<td>2.12(1.65-2.23)</td>
<td>445(352-497)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>98(83-112)</td>
<td>1.95(1.69-2.28)</td>
<td>402(343-479)</td>
<td>1.93(1.80-2.38)</td>
<td>431(377-460)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>122(102-149)</td>
<td>1.91(1.72-2.33)</td>
<td>429(376-517)</td>
<td>2.06(1.79-2.46)</td>
<td>428(396-511)</td>
</tr>
<tr>
<td><strong>Handling Intestines</strong></td>
<td>1</td>
<td>88(66-100)</td>
<td>2.01(1.64-2.24)</td>
<td>527(440-601)</td>
<td>2.64(1.78-3.89)</td>
<td>712 (482-989)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>101(74-133)</td>
<td>2.81(2.05-4.65)</td>
<td>741(551-1161)</td>
<td>3.34(2.57-133)</td>
<td>921(641-1123)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>137(111-179)</td>
<td>5.32(3.60-5.88)</td>
<td>1361(926-1548)</td>
<td>6.19(4.38-7.42)</td>
<td>1549(1199-1702)</td>
</tr>
<tr>
<td><strong>Fine Dissection</strong></td>
<td>1</td>
<td>72(67-78)</td>
<td>0.56(0.53-0.63)</td>
<td>117(111-124)</td>
<td>0.37(0.31-0.45)</td>
<td>82(70-104)</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>91(73-125)</td>
<td>0.69(0.49-0.93)</td>
<td>116(98-176)</td>
<td>0.33(0.26-0.40)</td>
<td>74(50-96)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>85(67-117)</td>
<td>0.63(0.52-0.77)</td>
<td>112(104-115)</td>
<td>0.28(0.26-0.39)</td>
<td>63(57-87)</td>
</tr>
<tr>
<td><strong>Stitch and Square Knot</strong></td>
<td>n/a</td>
<td>329(287-370)</td>
<td>5.41(3.53-6.73)</td>
<td>1323(910-1650)</td>
<td>5.79(4.05-7.20)</td>
<td>1277(959-1649)</td>
</tr>
</tbody>
</table>
design a procedural skills curriculum which will result in improved technical proficiency when performing laparoscopic colorectal surgery in the operating room. Very few virtual reality curricula have been developed for minimally invasive procedures\textsuperscript{96,116,119}. Moreover, these curricula have been developed based on local expertise. The design of the virtual reality curriculum for laparoscopic colorectal surgery in this study represents a departure from these traditional methods of curricula development. The Delphi methodology ensures that the final curriculum represents consensus among international experts regarding which component psychomotor tasks are essential to reducing the learning curve associated with this procedure. This is particularly important in light of the fact that many of the LapSim tasks show construct validity\textsuperscript{21-23,29,93}, but are not necessarily relevant to learn laparoscopic colorectal surgery.

The advantages of the Delphi method have been well described in the literature\textsuperscript{142}. These advantages include the anonymous nature of the process, ensuring that a dominant participant does not inadvertently sway the opinion of the group. In addition, the Delphi process is relatively inexpensive, since it is performed either using the internet or a conventional mailed survey. Finally, it allows experts in a geographically disparate area to weigh in equally on a topic. Although the Delphi methodology has been successfully utilized in the development of diagnostic criteria, clinical scales, research questions and technical skills evaluation tools\textsuperscript{141,142,145,173}, to our knowledge, this is the first time that it has been used in the development of a technical skills curriculum. The identified tasks represent the consensus of experts in North America and Europe. Currently, there is no consensus in the literature regarding the number of experts required for a robust expert panel in the Delphi consensus process\textsuperscript{139,140}. We elected to contact 20 experts with an expected response of 15 since we were hoping to balance a wide variety of expert opinion with selecting individuals that were thought to be invested in the process. During the survey process, the number of expert respondents decreased by 29\%, from 17 in the first round, to 12 in the second round. This is relatively consistent with what has been described in the literature\textsuperscript{142,143,174}. Since the expert panelists were chosen among a fairly homogeneous group with respect to qualifications, this likely would not significantly alter the final result of the panel. It should be noted, however, that since the Delphi process is anonymous, there is no way of determining if the lost panelists were from a particular geographic region, thus potentially skewing the consensus to a particular region. Although losing a certain number of panelists is almost inevitable with the Delphi process, using Cronbach’s Alpha to
determine consensus somewhat mitigates this phenomenon. This is due to the fact that Cronbach’s Alpha is sensitive to the number of panelists with a decrease in panelists related to a corresponding decrease in Alpha. The fact that in this study Cronbach’s Alpha increased on the second round of the survey indicates that the increase in consensus more than offset the loss of panel members.

Based on the results from the Delphi process, 7 basic tasks and 5 suturing tasks were rated by over 80% of the experts as either a 4 or 5 on the Likert scale, indicating that 80% of the panel either agreed or strongly agreed that these tasks should be included in a technical skills curriculum for laparoscopic colorectal surgery. After review of the tasks that were selected, we elected to choose the stitch and square knot task as a representative suturing task. This was done since it was felt that including 5 suturing tasks was redundant and would potentially be a source of frustration for the trainees. Indeed, it has been shown that although suturing in a virtual reality environment has transfer validity, trainees at a more junior level can have difficulty learning suturing on a VR system and report low levels of face validity for this particular task. In addition, due to the complexity of the suturing task and the limitations related to how to increase the level of difficulty for this task on the simulator, it was decided to have only one level for this particular task in the final curriculum.

Creating expert benchmark levels of proficiency is essential in the development of a proficiency-based curriculum. Several studies have demonstrated that learning curves on virtual reality simulators vary between individuals at the same level of training. It is therefore essential that this developed virtual reality technical skills training curriculum be designed for trainees to practice on the virtual reality simulator until they reach expert benchmarks of motor proficiency. All experts completed this phase of the study. The variability of the experts’ scores is reflected in the inter-quartile ranges for each benchmark level of proficiency (Table 10). These large inter-quartile ranges can be explained by the fact that although the experts had all completed greater than 100 minimally invasive procedures independently, they had variable levels of experience on the virtual reality simulator, and this likely resulted in several outlying scores. Median scores, rather than mean scores, were therefore used in order to minimize this outlier effect on the various benchmarks. In addition, it was somewhat surprising that the experts’ median scores did not consistently lower as they progressed through the three levels of difficulty for each task (Table 10). In fact, a common pattern was for the expert score to increase from level 1 to 2 and
then to decrease again at level 3. This may be related to the fact that the change in difficulty from level 1 to 2 might not have been high enough to completely mitigate any familiarization and learning effects on the simulator, whereas the increase in difficulty from level 1 to 3 was significant enough to produce a decrease in performance across most tasks and performance measures.

The LapSim virtual reality simulator automatically computes performance metrics such as time, economy of motion, and error parameters. Time and economy of motion scores are consistent between tasks and include a measure of instrument path length and instrument angular path. Error scores differ between tasks and can include measurements such as tissue damage, amount of bleeding, or factors such as dropped clips or percentage of visualized bowel depending on the task. As previously stated, various studies have demonstrated the construct validity of the LapSim tasks. Interestingly, for the most part, construct validity is limited to time and economy of motion scores rather than error scores. Aggarwal et al. attribute this to the inherent difficulties in defining a surgical error. The authors state that while there is no standard definition for a medical error, it is relatively simple for a computer to measure quantitative parameters such as instrument time or movement. As such, in this study, time and economy of motion parameters rather than error scores were chosen to represent the expert benchmark levels of proficiency. In addition, since construct validity has been determined for the majority of the LapSim tasks, repeating a construct validity assessment was deemed unlikely to add additional value to this described study.

Although the use of LapSim as the VR simulator for this curriculum can be criticized since unlike some other virtual reality simulators, it does not contain procedural based tasks specifically related to laparoscopic colorectal surgery, it should be emphasized that the role of this technical skills training curriculum is to teach the psychomotor component skills to perform an advanced laparoscopic procedure. Currently, there are no studies comparing the efficacy of virtual reality task based training with procedural based-training on technical proficiency in the operating room. Rather, the bulk of evidence seems to suggest that basic task training on VR simulators translates to improved performance on both the simulator as well as to non-analogous tasks in the operating room. Moreover, it is important to emphasize that this virtual reality technical skills curriculum is designed to teach the psychomotor tasks necessary to performing laparoscopic colorectal surgery, not the cognitive elements related to performing the procedure
such as understanding the flow of the operation or troubleshooting. It is also important to note that the strength of the curriculum is contingent upon the rigor of the Delphi process and the experts who contributed their opinion. Specifically, the experts are required to be knowledgeable regarding the various LapSim tasks and their potential relevance to laparoscopic colorectal surgery. Unfamiliarity regarding the subtleties of the specific virtual reality tasks could potentially lead the experts to potentially under-rate or over-rate exercises thus introducing a level of bias into the virtual reality curriculum. We attempted to minimize this potential source of bias by first being judicious in the expert panel selection and ensuring that panelists were specifically familiar with the LapSim system, not simply virtual reality simulation in a general sense. In addition, we chose the cut-off for task inclusion as greater than 80% of the participants rating the task as either a 4 (“agree”) or a 5 (“strongly agree”) on a Likert scale. This was done in order to ensure that potential outlying opinions were not factored into the final consensus of the group.

This described virtual reality technical skills curriculum is to our knowledge the first curriculum designed for an advanced minimally invasive procedure such as colorectal surgery. Moreover, while the design of the curriculum conforms to current educational theories regarding proficiency-based training, it represents a departure from the traditionally locally designed curricula in the literature. The tasks contained within this curriculum were decided upon based on international expert consensus determined using Delphi consensus methodology. This represents the initial step of developing a comprehensive technical skills curriculum for laparoscopic colorectal surgery. After acquiring the necessary psychomotor tasks on the virtual reality component of the curriculum, trainees will participate in cognitive training as well as a training session in the cadaver lab designed to integrate their acquired motor and cognitive skills. We expect that residents trained using this method of systematic technical skills training will exhibit superior technical ability in the operating room compared to residents trained using conventional methods. This has the potential to affect not only technical skills acquisition, but also to improve patient care in the operating room.
Chapter 5

5 Validation of an Evidence-Based Technical Skills Curriculum for Laparoscopic Colorectal Surgery: A Randomized Controlled Trial

[Accepted for publication September 7th 2011 as Palter V.N., Grantcharov T.P. Validation of an Evidence-Based Technical Skills Curriculum for Laparoscopic Colorectal Surgery: A Randomized Controlled Trial in Annals of Surgery]

5.1 Abstract

Background: Although a significant amount of work has been done to validate simulators as viable systems for teaching technical skills outside the operating room, the next necessary step is to integrate simulator training into a comprehensive curriculum. The purpose of this study is to develop and validate a comprehensive ex-vivo technical skills curriculum for laparoscopic colorectal surgery.

Methods: This prospective, single-blinded randomized controlled trial allocated 23 surgical residents to either conventional residency training or participation in an ex-vivo comprehensive curriculum for laparoscopic colorectal surgery. All participants completed a pre-test for technical proficiency on a VR simulator. Residents allocated to the curriculum group trained to expert levels of proficiency on a VR simulator, and participated in a cognitive training component. After the intervention, all study participants completed a laparoscopic right colectomy in the operating room on a patient. The OR cases were video recorded and assessed using 2 validated assessment tools. Technical proficiency of both groups was also assessed on the VR simulator, and cognitive knowledge relating to the procedure was evaluated with a multiple-choice test.

Results: Curricular trained residents demonstrated superior performance in the operating room with respect to scores on a global rating scale (16.0(14.5-18.0) versus 8.0(6.0-14.5) p=0.030) and number of operative steps performed (16.0(12.5-17.5) versus 8.0(6.0-14.5) p=0.021) compared to conventionally trained residents. Although curricular trained residents also had a higher score
on the procedure-specific rating scale (71.1(54.4-81.6) compared to 51.1(36.7-74.4) p=0.122), this was not statistically significant. Curricular trained residents also had a significantly higher score on the multiple-choice test compared to conventionally trained residents (10(9-11) versus 7.5(5.3-7.5) p=0.047). Curricular residents out preformed conventionally trained residents in 7 out of 8 tasks on the VR simulator.

Conclusions: Participation in a comprehensive-ex-vivo training curriculum for laparoscopic colorectal surgery results in improved cognitive knowledge technical proficiency and improved technical performance in the operating room compared to conventional residency training.

5.2 Introduction

It is well recognized that a certain component of modern surgical residency training has transitioned from the operating room to the surgical skills lab. As such, ex-vivo models including bench top simulators and virtual reality simulators have been developed to teach laparoscopic skills in a safe, simulated environment. The effectiveness of these models has been demonstrated in several randomized controlled trials and systematic reviews. Although a significant amount of important work has been done to validate simulators as viable systems for teaching technical skills outside the operating room, the next necessary step is to integrate simulation training into a comprehensive curriculum.

While technical skills training is a necessary component of a comprehensive curriculum for a surgical procedure, it is not sufficient. Cognitive knowledge is also thought to be equally essential in the effective performance of an operation. It has been shown that cognitive errors, such as a lack of understanding of the correct sequence of steps in an operation, trigger the majority of mistakes in a procedural task rather than technical errors. This is supported by psychomotor learning theory, which states that the cognitive stage, where a novice develops a mental picture of the motor task, is the first step in a trainee mastering a motor skill. In order to do this correctly, the trainee must understand the steps of the operation in the correct order and how to troubleshoot unexpected developments.

Although both laparoscopic box trainers and VR simulators have been evaluated extensively as viable models to teach laparoscopic skills, few comprehensive curricula for training in minimally invasive surgery have been described or evaluated. The Fundamentals of Laparoscopic Surgery
program is the most well described comprehensive curriculum for basic laparoscopy, and is the curriculum with the most evidence concerning its validity\textsuperscript{115} 5, 111. The FLS program, however, is limited by the fact that it is designed to teach only basic component laparoscopic skills. Other curricula on VR simulators have been described for basic laparoscopy, but they do not contain a cognitive teaching component, and at this point there is no evidence that the learnt skills transfer to the operating room\textsuperscript{94, 96, 116, 118}. Although Aggarwal et al. have moved beyond component laparoscopic skills, and describe a proficiency-based curriculum for a complete basic laparoscopic procedure, currently evidence for the transferability of the learned skills to the operating room is lacking\textsuperscript{119}. It is necessary to expand on the existing training curricula for laparoscopic surgery, not only to introduce a more formal cognitive element into surgical skills training programs, but also to move beyond basic laparoscopy, and to develop curricula for training individuals in advanced minimally invasive surgery. To our knowledge, at this point, no comprehensive technical skills curricula have been developed or validated for an advanced laparoscopic procedure.

Laparoscopic colorectal surgery is considered an advanced minimally invasive procedure with a significant learning curve that can range up to 80 cases\textsuperscript{120, 128-136}. The long variable learning curve for this procedure suggests that trainees learning laparoscopic colorectal surgery should do so in a standardized manner, ideally in a simulated environment. To this end, using innovative consensus methodology, our group developed a proficiency-based technical skills curriculum on a virtual reality simulator for laparoscopic colorectal surgery. This was described in Chapter 4.

The purpose of this current study was to incorporate the psychomotor technical skills training component on the virtual reality simulator into a comprehensive curriculum for laparoscopic colorectal surgery and ultimately to validate the curriculum. Specifically our first objective was to assess whether compared to conventional residency training, participation in a structured comprehensive curriculum consisting of VR training and cognitive learning, resulted in improved technical proficiency in the operating room. Second this study aims to address whether participation in the curriculum results in improved cognitive knowledge relating to the technical aspects of performing laparoscopic colorectal surgery. We hypothesized that residents trained using this curriculum would have an improved understanding of the technical aspect of performing laparoscopic colorectal surgery, and would also demonstrate increased technical
proficiency in the operating room compared to residents receiving only conventional residency training.

5.3 Methods

5.3.1 Study Design

This study was a randomized, single blinded two-armed trial conducted at a tertiary academic centre (Figure 4, 5). Institutional ethics approval was received, and written informed consent was obtained from all participants.

Figure 4. Design of the randomized controlled study to assess curricular effectiveness
5.3.2 Participants

Participants were University of Toronto residents in their second, third, or fourth post-graduate year (PGY) of training in general surgery who volunteered to participate. Participants were recruited by e-mail. In order to be included in the study, participants had to have performed less than 10 laparoscopic colorectal procedures as the primary surgeon. Residents were enrolled in the control and intervention group in a randomized fashion using a sealed envelope technique. Participants had an equal probability of being assigned to either group. Due to the nature of the intervention they were not blinded to their group assignment.

5.3.3 Initial Assessment

After randomization, residents in both the control and the intervention group completed the easy level of the technical skills curriculum on the virtual reality simulator (LapSim, Surgical Science, Gothenburg, Sweden). Prior to commencing the task, all participants received a standardized
orientation to the simulator and a video-demonstration on the simulator of how to perform all the
tasks correctly. All residents also completed a short questionnaire designed to assess their
demographics and their laparoscopic experience to-date.

5.3.4 Intervention

Residents who were randomized to the intervention group completed the technical skills
curriculum for laparoscopic colorectal surgery in its entirety. The curriculum consists of three
components. A technical skills training program on a virtual reality simulator (LapSim), a
cognitive training component, and cadaver lab training.

5.3.5 Virtual Reality Training

The virtual reality technical skills training curriculum was previously described in Chapter 4.
Briefly, a proficiency-based curriculum for laparoscopic colorectal surgery was created using
Delphi consensus methodology. Eight LapSim tasks (7 basic tasks, and 1 suturing task) were
identified by an international expert panel as being relevant to learning laparoscopic colorectal
surgery. Easy, medium, and hard levels were created for each task using previously described
parameters\textsuperscript{178}. Expert benchmark levels of proficiency for each task were created. Study
participants practiced on the simulator until they were able to reach expert levels of proficiency
for each task or until they had practiced a task 10 times. Participants were able to practice the
tasks in any order of their choosing. Each practice session was no longer than 1 hour in length.
This practice schedule was informed by our current understanding of distributed practice for
maximal learning effectiveness\textsuperscript{89}. A member of the study team (V.P.) was present during each
practice session to facilitate using the simulator. After completing each task, participants were
able to see how they performed relative to the expert-benchmarks and what elements of their
motor movements they needed to improve on to increase their score. This feedback was
automatically provided by the simulator.

5.3.5.1 Cognitive Training

The cognitive training component of the curriculum consisted of self-directed reading and video
based learning. All residents in the intervention group were provided with reading material
related to how to perform a laparoscopic right and sigmoid colectomy. Specifically, the
“Segmental Colon Resection” chapter from the online ACS textbook\textsuperscript{179}, the “Laparoscopic Right
Colon Resection” and “Laparoscopic Sigmoid Colon Resection” from the ACS/APDS curriculum as well as the recommended readings from the ACS/APDS module. The video training component consisted of a group seminar session. Participants watched sequential video clips of laparoscopic right and sigmoid colectomies. After each video-clip was shown, the expert facilitating this session prompted the participants to think of what surgical step came next; or how to troubleshoot problems such as difficult anatomy, or complications such as bleeding. The purpose of the cognitive session was to allow participants to understand the flow of the operation and conceptualize how to plan and execute a laparoscopic right and sigmoid colectomy.

5.3.5.2 Cadaver Training

Finally, the cadaver lab portion of the curriculum consisted of a three hour interactive teaching session where residents participated in a cadaver lab where they had the opportunity to perform either a laparoscopic right or sigmoid colectomy. The participants worked on pairs on the cadavers with a staff expert facilitating. More senior residents were paired with more junior residents. The more senior resident assisted the more junior resident to perform the laparoscopic right colectomy and the more junior resident assisted the more senior resident to perform the laparoscopic sigmoid colectomy. The purpose of the cadaver lab portion of the intervention was to allow the study participants to integrate the technical skills they learnt during the VR training component with the cognitive skills they learnt during the video-teaching portion of the curriculum.

5.3.6 Final Assessment

The final assessment occurred within a 5 month period of the intervention. The final assessment consisted of an intra-operative assessment, a cognitive assessment and an assessment of performance on the virtual reality simulator. In addition, during the assessment period, all study participants re-completed the demographics questionnaire that they initially completed at the start of the study.

5.3.6.1 Intra-operative Performance

To assess the impact of curricular training on technical and cognitive skill acquisition, the assessment phase of the study occurred in the operating room during a surgical procedure on a patient. Participants in both the control and the intervention group performed a laparoscopic
right hemi-colectomy on a patient with a staff member assisting in the usual fashion, which included verbal instruction and takeover if necessary. The faculty member was blinded as to the randomization of the residents. The operative procedure was video-recorded through the laparoscopic camera from port insertion until the end of the case. As such, no identifying data of the patient or the operating team was recorded. In addition, the video recording did not record any sound. A member of the study team was present during each of the cases to facilitate the recording and to document any potential takeovers by the faculty member. The videos were given to an individual who was experienced in video-assessment, not affiliated with the study team, who rated the videos using two previously validated tools: a procedure-specific evaluation tool and the modified OSATS global rating scale to assess general laparoscopic skill (Table 2, Table 6)\textsuperscript{39,167}. The rater was also provided with the take-over information from the operating room. The rater was instructed to assess only the parts of the case that were performed by the study participant. If a step on the procedure-specific evaluation tool was not performed, then the rater was instructed to rate it as not applicable.

5.3.6.2 Cognitive Knowledge Assessment

Each study participant completed a brief multiple-choice test, which was designed to assess their understanding of how to perform a laparoscopic right and sigmoid colectomy (Appendix 1).

5.3.6.3 Performance on the Virtual Reality Simulator

Participants in both the intervention and the control group completed the “easy” level of the curriculum on the virtual reality simulator. All residents were re-oriented to the simulator and were shown the videos on the simulator containing instructions on how to complete each task correctly.

5.3.7 Outcome Assessment

The primary outcome assessment was the difference in operative performance between residents in the control and the intervention groups as measured by scores on the modified OSATS. Operative performance was chosen as the primary outcome measure since it most accurately represents whether participation in the comprehensive curriculum was able to produce an improvement in performance in a real clinical situation. The secondary outcome measures in this study are the differences in scores on the procedure-specific rating scale, the differences in the
number of surgical sup-steps able to be performed in the operating room by each participant, as well as the difference in multiple-choice test scores, and scores on the virtual reality simulator (time and economy of motion) between groups.

5.3.8 Sample Size

In previous work with OSATS, the average difference between expert and novice groups was 6 points. Using an alpha of 0.05, a power of 0.80, and a population standard deviation of 4.5, the sample size required for each group is at least 9 individuals. Due to the potential for drop out we aimed to recruit at least 22 residents (11 per group) in order to ensure an adequate sample size.

5.3.9 Statistical Analysis

Descriptive statistics were calculated for all variables. Data is reported as median (interquartile range). Q-Q plots were performed for all data sets to assess for normality. All data except multiple choice test scores was not normally distributed and as such differences between groups were assessed using the Mann-Whitney U test. A difference between groups in multiple choice test scores was assessed using the Student’s T test for independent groups. All statistical analysis was performed using SPSS version 18 (SPSS Inc., Chicago, USA). A p<0.05 was considered statistically significant.

5.4 Results

5.4.1 Initial Assessment

At the outset of the study, laparoscopic experience was similar between groups (Table 11). In addition, there was no statistically significant differences with respect to time, or economy of movement parameters between the intervention and control group on the various elements of the pre-test on the virtual reality simulator with the exception of the grasping task, and the path length for the fine dissection task (Table 12).
<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Intervention</th>
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</thead>
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<td></td>
<td></td>
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<tr>
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</tr>
<tr>
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<td></td>
<td></td>
</tr>
<tr>
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<td>1(2)</td>
<td>1(2)</td>
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<td>0</td>
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<td>0-5</td>
<td>0-6</td>
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<tr>
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<td></td>
</tr>
<tr>
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<td>0(1)</td>
<td>1(1)</td>
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<td>0</td>
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<tr>
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<td>26(25)</td>
<td>25(23)</td>
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<tr>
<td>Mean (St dev)</td>
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<td>30(37)</td>
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<tr>
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**Table 11:** Demographics for the randomized controlled portion of the study
Table 12: Pre-test scores on the virtual reality simulator for residents in the control and intervention group. Data is presented as median (interquartile range). Highlighted cells represent tasks where there was a statistically significant difference between the performances of the intervention and the control group.

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<th>Coordination</th>
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<tr>
<td>Median Time (s)</td>
<td>68(60-120)</td>
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<td>Median Path Length (m)</td>
<td>2.66(2.09-4.23)</td>
<td>2.67(2.34-3.06)</td>
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<td>108(89-116)</td>
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<td>732(557-910)</td>
<td>599(486-600)</td>
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<td>103(81-129)</td>
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<td>Median Path Length (m)</td>
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<td>Median Angular Path (°)</td>
<td>455(360-520)</td>
<td>379(306-558)</td>
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<td>799(764-940)</td>
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</thead>
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<tr>
<td>Median Time (s)</td>
<td>109(87-135)</td>
<td>102(72-117)</td>
<td>0.17</td>
</tr>
<tr>
<td>Median Path Length (m)</td>
<td>5.25(4.38-5.95)</td>
<td>4.35(3.96-5.93)</td>
<td>0.98</td>
</tr>
<tr>
<td>Median Angular Path (°)</td>
<td>1336(1130-1470)</td>
<td>1197(876-1685)</td>
<td>0.93</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fine Dissection</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Time (s)</td>
<td>113(91-155)</td>
<td>85(72-107)</td>
<td>0.09</td>
</tr>
<tr>
<td>Median Path Length (m)</td>
<td>1.66(1.16-2.09)</td>
<td>1.62(0.03-1.73)</td>
<td>0.03</td>
</tr>
<tr>
<td>Median Angular Path (°)</td>
<td>394(269-444)</td>
<td>207(169-375)</td>
<td>0.05</td>
</tr>
</tbody>
</table>

5.4.2 Intervention

5.4.2.1 Time to reach proficiency in the virtual reality portion of the curriculum

Most tasks on the virtual reality curriculum (13 out of 19) required 2 or less trials to pass (Table 13). All residents were able to pass 13 of the 19 tasks in the virtual reality curriculum (Table 13). The average total time to complete the curriculum was 4 hours and 14 minutes (st dev. 4 minutes).
Table 13: Time to Complete the Virtual Reality Curriculum. Highlighted cells represent the tasks where not all residents were able to pass.

<table>
<thead>
<tr>
<th>Task</th>
<th>Average Time Per Person Mean(st.dev.)</th>
<th>Number of Trials Until Proficiency</th>
<th># unable to pass</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median (Range)</td>
<td>Mode</td>
<td></td>
</tr>
<tr>
<td>Coordination-1</td>
<td>113(24)</td>
<td>2(1-3)</td>
<td>1</td>
</tr>
<tr>
<td>Coordination-2</td>
<td>104(12)</td>
<td>2(1-4)</td>
<td>1</td>
</tr>
<tr>
<td>Coordination-3</td>
<td>10(16)</td>
<td>2(1-4)</td>
<td>3</td>
</tr>
<tr>
<td>Grasping-1</td>
<td>64(6)</td>
<td>2(1-3)</td>
<td>0</td>
</tr>
<tr>
<td>Grasping-2</td>
<td>225(22)</td>
<td>3(1-11)</td>
<td>0</td>
</tr>
<tr>
<td>Grasping-3</td>
<td>201(16)</td>
<td>3(1-6)</td>
<td>4</td>
</tr>
<tr>
<td>Cutting-1</td>
<td>305(24)</td>
<td>3(1-7)</td>
<td>0</td>
</tr>
<tr>
<td>Cutting-2</td>
<td>615(52)</td>
<td>10(1-10)</td>
<td>7</td>
</tr>
<tr>
<td>Cutting-3</td>
<td>7543(23)</td>
<td>9(1-13)</td>
<td>2</td>
</tr>
<tr>
<td>Clipping-1</td>
<td>167(56)</td>
<td>2(1-3)</td>
<td>2</td>
</tr>
<tr>
<td>Clipping-2</td>
<td>213(35)</td>
<td>2(1-6)</td>
<td>1</td>
</tr>
<tr>
<td>Clipping-3</td>
<td>229(40)</td>
<td>2(1-3)</td>
<td>2</td>
</tr>
<tr>
<td>Lifting &amp; Grasping-1</td>
<td>210(20)</td>
<td>4(1-7)</td>
<td>1</td>
</tr>
<tr>
<td>Lifting &amp; Grasping-2</td>
<td>311(24)</td>
<td>2(1-11)</td>
<td>2</td>
</tr>
<tr>
<td>Lifting &amp; Grasping-3</td>
<td>331(25)</td>
<td>2(1-10)</td>
<td>2</td>
</tr>
<tr>
<td>Fine Dissection-1</td>
<td>183(23)</td>
<td>3(1-10)</td>
<td>0</td>
</tr>
<tr>
<td>Fine Dissection-2</td>
<td>147(31)</td>
<td>4(1-11)</td>
<td>1</td>
</tr>
<tr>
<td>Fine Dissection-3</td>
<td>193(40)</td>
<td>4(1-10)</td>
<td>0</td>
</tr>
<tr>
<td>Handling Intestines-1</td>
<td>156(36)</td>
<td>2(1-6)</td>
<td>2</td>
</tr>
<tr>
<td>Handling Intestines-2</td>
<td>134(30)</td>
<td>1(1-3)</td>
<td>1</td>
</tr>
<tr>
<td>Handling Intestines-3</td>
<td>769(41)</td>
<td>1(1-3)</td>
<td>0</td>
</tr>
<tr>
<td>Stitch and Square Knot</td>
<td>22388(158)</td>
<td>6(1-10)</td>
<td>2</td>
</tr>
</tbody>
</table>

5.4.3 Final Assessment

5.4.3.1 Performance in the Operating Room

Residents in the intervention group showed a higher level of technical proficiency than residents trained using conventional residency training (intervention OSATS score 16.0(14.5-18.0), Procedure-Specific score 71.1(54.4-81.6); control OSATS 8.0(6.0-14.5) Procedure-Specific 51.1(36.7-74.4) p=0.030, p=0.122 respectively) (Figures 6, 7). Residents in the intervention group were also able to perform more operative steps of the procedure than residents in the control group (16.0(12.5-17.5) versus 8.0(6.0-14.5) p=0.021) (Figure 8).
Figure 6. Difference in operating room performance between the control and intervention group as measured by the Modified OSATS global rating scale. Horizontal bars, boxes, whiskers and circles represent the median, interquartile range, range, and outliers respectively.
Figure 7. Difference in operating room performance between the control and intervention group as measured by the Procedure-Specific Evaluation Tool for laparoscopic right colectomy. Horizontal bars, boxes, and whiskers represent the median, interquartile range, and range respectively.
5.4.3.2 Performance on the Multiple Choice Test

The overall score on the test was higher for residents in the intervention group than in the control group (intervention 10(9-11), control 7.5(5.3-7.5) p=0.047) (Figure 9).
5.4.3.3 Performance on the Virtual Reality Simulator

Residents in the intervention group were significantly faster on 6 out of the 7 post-test tasks, and had significantly better economy of movement scores on 5 out of the 7 tasks (Table 14).
Table 14: Differences between the intervention and control group during the virtual reality portion of the post-test. Data is presented as median (interquartile range). Highlighted cells represent statistically significant differences between intervention group and control group performance.

5.5 Discussion

This randomized controlled trial describes a comprehensive training curriculum for an advanced laparoscopic procedure. The curriculum adheres to current standards of proficiency-based training, distributed practice, and consists of both a psychomotor training component as well as a cognitive learning component. To our knowledge this is the first randomized controlled trial that demonstrates that participating in a comprehensive ex-vivo training curriculum for an advanced minimally invasive procedure translates to improved technical performance in the operating room. This has important implications both for residency training programs, and for patient safety in the operating room.

Residents who participated in this curriculum had a significantly higher global rating score in the operating room than conventionally trained residents. In addition, they were able to perform
significantly more of the procedure. The importance of this is underlined by the relative inexperience of the participants in this study. At the outset of the study, the median number of laparoscopic right colectomies done by the group was 0 with a range from 0-6. At the final assessment in the operating room, residents in the intervention group were able to perform a median of 16 out of a possible 19 steps compared to a median of 8 by the control group. This is especially significant since the ability to perform more of the operation occurred in tandem with a global improvement in advanced laparoscopic ability as evidenced by the difference in global rating scores between the two groups.

Although there was a trend towards the intervention group having a higher score on the procedure-specific rating scale, it is not completely unexpected that the difference between the two groups did not achieve significance. Although evidence exists for the reliability and construct validity of this tool, this is in the context of comparing resident and staff performance, not differences in performance among residents with similar operating room experience. Indeed, it is not expected that residents who participate in the curriculum would have a performance in the operating room that is comparable to a performance by an expert surgeon. Rather our data demonstrates that participation in the curriculum results in residents surmounting a significant portion of their learning curve in a safe, simulated environment.

To date, the few curricula in the literature describing curricula for laparoscopic skills focus on assessing technical proficiency as a measure of the success of the curriculum. Although acquiring specific technical skills is obviously an essential skill to learn from the curriculum, learning cognitive knowledge relating to how to perform the procedure correctly is also essential. To this end, we included not only specific didactic teaching relating to how to perform laparoscopic surgery correctly in the curriculum, but also cadaver training which gave residents in the intervention group a chance to consolidate their technical knowledge with their cognitive learning. The effectiveness of the cognitive training is evidenced by the fact that residents who participated in the curriculum had a higher score on the cognitive knowledge post-test compared to the conventionally trained residents.

It is not surprising that the curriculum-trained residents outperformed the conventionally trained residents on the majority of the virtual reality simulator post-test tasks. However, it is interesting to note that there were no significant differences between the groups with respect to the
coordination tasks, and the economy of movement parameters for the handling intestines task. This could be related to the fact that these tasks were arguably the easiest tasks on the post-test. Perhaps the operating room experience gained by both groups of residents during the study was enough to result in equivalent performance on this task.

A potential limitation of this study is the fact that the two study groups were heterogeneous. In order to recruit an adequate number of residents we had to recruit PGY2s, 3s and 4s. In order to mitigate this, an inclusion criterion for the study was that the participants were required to be novices in laparoscopic colorectal surgery (performed less than 10 laparoscopic colorectal procedures). Although randomization was expected to distribute these differences between the two groups, nonetheless, during the study period, simply being a senior resident rather than a junior resident could have resulted in a very different operating room experience that may have affected the study results.

In addition, the drop out rate of the study should be mentioned. Initially 25 residents were recruited to the study. At the post intervention assessment, we were able to record 9 residents in each group in the operating room, and had 7 residents in the control group and 9 in the intervention group do the VR testing, and 8 resident in the control group and 11 in the intervention group complete the multiple choice test. Based on the dropout rates of similar educational studies investigating effects in the operating room, a dropout rate of at least 10% was expected\textsuperscript{180-183}. As such, we intentionally over-recruited at the outset of the study, and our dropout rate fits within the range described in the literature. It is important to note, however, that the individuals in the study who were unable to participate in the post-intervention final assessment did not decline participation. Rather it was for logistical reasons (which included travel issues getting to the simulator, resident participation in electives out of the city, or resident participation in rotations in hospitals that did not perform laparoscopic right colectomies) that made it difficult to obtain post-assessment measurements from all individuals who agreed to participate in the study. Also, we believed that it was important to balance getting the post intervention data from a maximum number of participants with conducting this portion of the study within a reasonable amount of time. A five month period within which to collect the post-intervention assessment data was chosen since it has been shown in the literature that technical skills learnt on simulators can persist variably, from 5 to 7 months\textsuperscript{31,184}.
The curriculum described in this study is unique compared to the few comprehensive curricula described in the literature. This curriculum contains not only a proficiency-based VR training component, but also a cognitive based video instruction session and a cadaver lab where the residents have the opportunity to consolidate their psychomotor skills and their cognitive skills in a low risk simulated environment. While the comprehensive nature of this curriculum undoubtedly contributed to the fact that curriculum trained residents showed superior technical performance in the operating room and superior knowledge relating to the performance of a laparoscopic right colectomy, this required significant resources. Specifically, implementing this curriculum in residency training programs in its current state requires a virtual reality simulator, a staff member to facilitate the video-based teaching session, and cadavers. While there is a significant cost associated with ex-vivo training, other work has shown that for a complex laparoscopic task (laparoscopic suturing), over after a five year period, VR training becomes more cost effective than conventional residency training. Since the goal of curriculum development is to validate and develop well designed ex-vivo curricula that will ultimately be implemented in a longitudinal fashion in residency training programs, it is reasonable to hypothesize that over the long term, the savings accrued by implementing this curriculum could be substantial.

This study demonstrates the validity of a proficiency-based comprehensive curriculum for laparoscopic colorectal surgery. Training using a comprehensive curriculum consisting of VR training, structured cognitive teaching, and cadaver-based simulation resulted in improved knowledge relating to laparoscopic colorectal surgery and improved technical ability in the operating room compared to conventionally trained residents. Implementing this curriculum in surgical residency programs would transition a certain portion of the learning curve for advanced laparoscopy outside the operating room, which could have significant potential effects on patient safety.
Chapter 6

6 Discussion and Future Directions

Our work to date has focused on developing an evidence-based comprehensive ex-vivo training curriculum for laparoscopic colorectal surgery. The initial step in the development of this curriculum was to create a procedure-specific evaluation tool for laparoscopic colorectal surgery. This tool was developed using Delphi consensus methodology, and demonstrated satisfactory inter-rater reliability and validity in the context of assessing videos of operating room performance. The second phase of this project was to determine the components of the ex-vivo curriculum. We used the Delphi consensus methodology to develop a proficiency-based training curriculum on a virtual reality simulator, which was designed to teach the psychomotor skills essential in performing laparoscopic colorectal surgery. We also defined cognitive training elements to this curriculum, which consisted of a seminar-based video-instruction session, as well as a cadaver lab, which was designed to consolidate the psychomotor and technical skills that were learnt. In the final component of this study, we conducted a randomized controlled trial that demonstrated that residents who participated in the comprehensive curriculum showed superior technical performance in the operating room and superior cognitive knowledge compared to residents who received only conventional residency training.

6.1 Theoretical Framework for the Comprehensive Curriculum for Laparoscopic Colorectal Surgery

To date, current technical skills training programs in surgery are institution specific, are developed using local expertise, and are created in an ad-hoc basis rather than in a systematic evidence-based manner. More importantly, few comprehensive curricula have been described and validated in the literature for laparoscopic procedures, therefore there are few resources available for educators wishing to draw upon work that has been previously performed. The curriculum described in this study marks a significant departure from traditional methods of technical skills curriculum design. A significant strength of this study was the fact that the development of the curriculum followed a theoretical framework for curricular design and adhered to current educational standards of simulator training.
The development of this curriculum was informed by the framework for systematic training and assessment of technical skills described by Aggarwal et al., which was briefly outlined in the Introduction of this thesis. The first step of Aggarwal et al.’s framework is knowledge-based learning. Aggarwal et al. describe this step as consisting of acquiring information related to pre-procedure assessment and preparation, anatomic knowledge, post-procedure management, how to perform the procedure correctly, and how to anticipate and manage errors. In the curriculum described in this study, we limited the cognitive teaching to information on how to perform laparoscopic right and sigmoid colectomy correctly and how to anticipate and manage errors. Although pre-procedural and post-procedural considerations are essential to provide appropriate care to patients undergoing laparoscopic colorectal surgery, we chose to restrict our cognitive teaching to intra-operative technical considerations. Specifically, our goals were for the residents to learn the operative steps, in the correct order, as well as learn how to troubleshoot intra-operative difficulties such as difficult anatomy or bleeding. We chose to restrict the scope of the cognitive aspect of the curriculum for several reasons. First to facilitate the content being delivered in a feasible time frame; second to minimize the overlap between other weekly structured teaching sessions that all residents in our program were required to attend; and finally to facilitate post-intervention assessment.

The second step in Aggarwal et al.’s framework is to define a tool for assessment. The initial phase of this study was to develop a procedure-specific technical skills evaluation tool for laparoscopic right and sigmoid colectomy. These evaluation tools were created using Delphi consensus methodology. Ultimately, the rigorous nature of the Delphi process ensured that the final procedure-specific evaluation tool was reflective of international practice, and showed acceptable reliability and validity in the context of evaluating expert and novice performance. In its current form, the procedure-specific evaluation tool does not effectively discriminate between curricular-trained and conventionally trained residents. The likely role of the tool, however, is not in post procedure-assessment but rather in providing a source of constructive feedback to residents relating to their operating room performance.

The third step in Aggarwal et al.’s framework was to develop a training model in a laboratory environment. The ex-vivo training curriculum on a VR simulator that was developed through the course of this study reflects current educational principles of simulation-based learning. The components of the VR training program that we developed were also determined based on the
results of a Delphi consensus survey that involved international experts in simulation and laparoscopic colorectal surgery. This is important, as to our knowledge, the represents the first time that a Delphi survey has been used in this context. Our aim was to determine in the most evidence-based manner possible which tasks on the VR simulator were relevant to learning laparoscopic colorectal surgery. This is critical since a potential major barrier to simulators being utilized within residency training programs is the fact that there is a lack of consensus among educators which tasks should be used or practice, at what settings, and for how long. The settings for the tasks in the final VR curriculum were obtained from a European consensus document, which synthesized the available evidence relating to what an “easy”, “medium” and “hard” level was for each task\textsuperscript{178}. In addition, this study also delineated expert levels of proficiency for each curricular task ensuring that each curricular participant will have achieved the same degree of technical skill proficiency after completing the VR portion of the curriculum. Since learning curves for trainees can vary widely, this is especially important in ex-vivo training programs\textsuperscript{92,185}. This was reflected in our results where we showed that for certain tasks, it took some trainees only 1 or 2 trials to pass, whereas for the same task, it took other novices up to 8 trials. The VR training component of the curriculum also adhered to principles of distributed practice (residents were only allowed to practice on the simulator for an hour, once a day), deliberate practice, summary feedback (residents were shown the automatically generated feedback summary of their performance at the end of each task, and could see what they needed to improve on to pass), and practice at varying levels of difficulty. These elements have all been shown to be critical in evidence-based simulator training. The high cost of procuring and maintaining VR simulators underlines the fact that it is essential that evidence-based validated specific curricula on these simulators are developed in order to maximize their potential for use within residency training programs.

The fourth part of the theoretical framework is ensuring that the skills learnt in the curriculum transfer to the real environment. This was an integral component of the project described in this thesis and was described in Chapter 5. We conducted a randomized controlled single-blinded trial that demonstrated that participation in the curriculum resulted in improved technical performance in the operating room when performing a laparoscopic right colectomy, and superior cognitive knowledge related to laparoscopic colorectal surgery. Determining the transfer of curricular skills to the real environment is an essential step in ultimately implementing
the curriculum widely in practice. Although currently several virtual reality based curricula have been described for basic minimally invasive tasks and procedures, evidence is lacking relating to the transferability of the learned skills.94, 96, 116, 119.

The final component in Aggarwal et al.’s theoretical framework is to develop a method by which to grant privileges for independent practice. Although this is a reasonable ultimate goal in the development of a technical skills curriculum, at this point, the goal of the comprehensive curriculum described in this thesis is to provide an ex-vivo training method that allows trainees to surmount the early portion of their learning curve in a safe simulated environment, therefore maximizing their learning experience in the operating room. Specifically, the goal of curriculum participation is not to assess a trainees’ abilities and determine whether or not they have achieved a certain level of competence, but to provide them with the tools and a safe environment in which to develop a certain level of competence prior to operating room participation. At this point it is essential to differentiate between these goals. This is due to the fact that more work needs to be done to refine both the training and assessment components of the curriculum prior to determining standards used to determine technical competence. At this point, we cannot say that a trainee who is unable to complete the curriculum is “incompetent” – rather we know that they require more work to progress along the learning curve. The work described in this thesis provides evidence for the effectiveness of the curriculum in improving technical performance in the operating room. More work must be performed to potentially correlate participation in the curriculum with clinically relevant outcomes such as time in the operating room, or data on patient safety. This will help to provide evidence in the development of determining how to ultimately grant privileges for independent practice.

6.2 Training Using the Comprehensive Curriculum for Laparoscopic Colorectal Surgery

6.2.1 Time for Training

The median number of trials for the residents to reach proficiency on the virtual reality portion of the curriculum ranged from 2 to 10 trials, with the majority of tasks only requiring 2-3 trials to pass (Table 13). Although at first glance, 2 or 3 practice attempts per task may seem like a small number of trials to obtain expert proficiency, it must be emphasized that the virtual reality training component of the curriculum is designed only to teach psychomotor proficiency.
Although residents who pass the tasks are as proficient as experts on the simulator, this “expertise” is restricted to psychomotor performance on the simulator. This data is consistent with previously demonstrated learning curves on the virtual reality simulator, with the majority of residents achieving proficiency between 2 and 10 trials\textsuperscript{185}.

The average amount of time for trainees to complete the virtual reality portion of the comprehensive curriculum was four hours and fourteen minutes (with a standard deviation of four minutes). Adding this time to the time required to deliver the cognitive part of the curriculum (approximately 1.5 hours for the video-based learning session and 3 hours for the cadaver lab), this gives a total average time per trainee of eight hours and fourteen minutes to complete the training program in its entirety. Since residents could only practice on the simulator for an hour at a time, and the cadaver lab and cognitive teaching could occur only on different days, the average number of days required to complete the curriculum is 7 (5 days for VR training, and 2 separate days for cognitive teaching). In this study, the VR training and cognitive teaching was delivered over a 4 month period (VR training over 3 months, and cognitive training over 1 month). The time commitment for ex-vivo VR training is similar to that described for the time to achieve expert proficiency levels in the FLS training curriculum described by Ritter and Scott\textsuperscript{114}. It took novice medical students 11.4 hours at the University of Texas Southwestern, and 10.1 hours for students at the Uniformed Services University to pass this proficiency-based curriculum\textsuperscript{186}. This did not include the time required for the cognitive aspect of the curriculum. There is little data available for the time required to pass the VR curricula for laparoscopic skills described in the literature. The curriculum for basic laparoscopic skills on the LapSim described by Panait et al. requires on average 238 practice repetitions to pass\textsuperscript{116}. Although the authors do not give details regarding what type of time commitment this number of practice attempts translates to, a conservative estimate of 2 minutes per trial gives a total of 7.9 practice hours, double the time required for the VR training portion of the curriculum described in this thesis. Although Panait’s group also developed a curriculum for advanced laparoscopy, currently we do not have information regarding the amount of time required for training to proficiency in this curriculum\textsuperscript{187}. In addition, although Aggarwal et al’s group provides learning curve data for residents participating in their curricula for both basic laparoscopic skills and laparoscopic cholecystectomy, no data regarding the time required to complete the curriculum is available in this current work\textsuperscript{94, 96, 119}. The few randomized controlled
trials that assess the effect of proficiency-based training on VR simulators on operating room performance, report the time spend training on the simulator report a range of 1.1 hours to 7 hours to achieve expert levels of proficiency. Based on the limited data available, the time required to train on the proficiency-based comprehensive curriculum described in this study is well within the range of what is currently described in the literature.

6.2.2 Pass Rate for the Virtual Reality Portion of the Curriculum

In the VR technical skills training portion of the curriculum, there were a total of 22 tasks (7 skills at 3 levels of difficulty, and 1 skill at 1 level of difficulty). Thirteen residents completed the entire proficiency-based curriculum. As part of the study protocol, residents could only practice each task a maximum of 10 times. Up to two residents (13%) could not pass four of the tasks, three residents (23%) could not pass the “fine dissection-hard level” task, and seven residents (54%) could not pass the “cutting-medium level” task. With the exception of the significant number of residents who were unable to pass the “cutting level-medium” task, these numbers are consistent with learning curve data reported in the literature. Grantcharov and Funch-Jensen describe 4 distinct learning curve patterns in surgical residents on a VR simulator. In their study, 37 residents performed ten repetitions of six tasks on a VR simulator. Their results were as follows: one group of residents (5.4%) demonstrated technical proficiency right from the start of the session, the second group of residents (70.3%) achieved expert levels of proficiency between 2 and 9 repetitions on the simulator, a third group of residents (16.2%) demonstrated a learning curve, but were unable to achieve expert levels of proficiency within 10 repetitions, and the fourth group (8.1%) under-performed from the beginning and did not demonstrate any learning curve. The total percentage of residents who were unable to reach expert proficiency after 10 trials of practice as reported by Grantcharov and Funch-Jensen was 24.3% (groups 3 and 4). This corresponds with the percentage of residents in our study that were unable to pass 5 of the curricular tasks.

Although it could be argued that we should have allowed for more than 10 attempts to pass each task, in order to facilitate the “group 3” residents to pass the curriculum, we elected to keep the cut-off at a maximum of 10 repetitions. This was based on the learning curve of the Group 3 residents in Grantcharov and Funch-Jensen’s study. The curve for these trainees shows a plateau after the third repetition, with little gain in proficiency seen after that point. We hypothesized...
therefore that it would be unlikely that additional practice attempts (over 10) would result in an increased number of residents passing the VR portion of the curriculum.

It is interesting to note that the exception for this task was the cutting medium level task which 54% of trainees in the study were unable to complete. This is somewhat surprising since the settings for this task were taken from a consensus document, which demonstrated the construct validity for this task at the settings that were used in the current study.\(^{178}\) In general, the cutting task was one of the more difficult tasks in the curriculum, with the median number of trials to reach proficiency for all three levels being one of the highest within the entire VR curriculum. Perhaps the significant proportion of junior level trainees with limited laparoscopic experience who participated in this study contributed to the fact that this task was quite difficult to pass. In potential future studies involving this curriculum, it is worth considering whether eliminating the cutting task at the medium level, or reevaluating the simulator settings for this task, may help to improve the pass rate to what is standard in the literature.

### 6.3 The Benefit of the Cognitive Aspect of the Comprehensive Curriculum

The curriculum developed in this study, which consists of both a cognitive training element as well as a psychomotor skills training element, is unique. Although opinion leaders in surgical education have long emphasized the importance of including cognitive training in a technical skills training program, there are few examples of this in the literature. Currently, to our knowledge, the FLS program is the only validated evidence-based comprehensive program that includes both a technical and cognitive training element for laparoscopic technical skills. The cognitive content of our training program goes beyond simply didactic teaching. Rather the goal was to provide basic background knowledge regarding the technical aspects of performing laparoscopic colorectal surgery, as well as provide residents with the tools to understand and anticipate the technical steps of the operation, or flow of the operation. We hypothesized that a greater understanding of how to technically perform the operation was equally as important as the necessary technical training, in order to result in the best possible technical performance in the operating room. As part of the cognitive aspect of the curriculum we first provided residents with basic background knowledge in the form of the relevant material from the ACS textbook, and the ACS/APDS curriculum. The second aspect of the cognitive portion of the curriculum
was a video training session. During this session residents participated in a facilitated video session. A representative laparoscopic right and sigmoid colectomy video was edited and subdivided into the critical surgical sub-steps that were identified by the relevant procedure-specific tools (Tables 5 and 6). The videos were paused after each surgical sub-step. At this point the trainees were required to brainstorm and determine what the appropriate next surgical step would be and how they would approach that patient’s particular anatomy. This session was facilitated by a staff surgeon who ensured that an appropriate amount of discussion and involvement from the trainees occurred. We hypothesized that the video review session would facilitate trainees visualizing the correct steps of the operation, in the correct order. This was informed by our current understanding of the role of mental practice in the acquisition of technical skills. In the field of sport it has been shown that mental practice, which is defined as “the cognitive rehearsal of a task in the absence of overt physical movement” can significantly optimize psychomotor performance. Theoretically, the success of mental practice is thought to be related to the fact that mentally rehearsing a motor task involves the same neural network as physically practicing the task. It has also been postulated that a combination of motor and mental training sessions are required to build a functional representation of a complex motor task, such as a surgical procedure. Several preliminary studies have demonstrated the potential role of mental imagery in the learning of surgical technical skills. In a randomized single-blinded controlled study involving medical students Sanders et al. demonstrated that technical skills training followed by mental imagery, was equivalent to additional technical skills training using a validated assessment tool on an animal model. A follow-up study demonstrated that mental imagery was more effective than learning from a textbook. Similar results have also been obtained on a bench-model. These studies, however, are limited by the fact that the authors do not provide details regarding the specific mental practice strategy utilized, nor do they assess outcomes in a real clinical environment. Conversely, recent work by Arora et al. describes in detail the type of mental imagery strategy used, and subsequently demonstrated in a randomized control trial that mental imagery resulted in improved technical performance on a virtual reality simulator. Although work needs to be done in order to confirm that mental rehearsal improves technical performance in a real clinical situation, these studies demonstrate the potential role of cognitive training in technical skills acquisition. Although our video review sessions were not specifically designed to provide the trainees with traditional mental imagery techniques as they were utilized in the aforementioned studies, they
were designed to facilitate trainees developing a mental image of the procedure, and understanding the flow of the steps of the operation in the correct order.

The cadaver lab component of the curriculum is the final aspect of the curriculum. This element of the training program was designed to allow the trainees to rehearse the operation prior to performing it in the operating room. Theoretically, this aspect of the curriculum allows the mental image of the procedure to be strengthened. Trainees have the opportunity to integrate their cognitive knowledge and their psychomotor skills and rehearse the operation in an analogous risk-free situation. This type of practice has the potential to both enhance technical skills learning, as well as reinforce the mental concept of the procedure, both of which are thought to be essential in the final performance in a real clinical situation\textsuperscript{190}.

Although participating in a comprehensive curriculum resulted in both an increasing knowledge as well as an increase in technical performance, we hypothesize that the effect of both the cognitive training and the psychomotor training are not linear, meaning that cognitive training potentially improves both cognitive skills as well as technical skills and vice versa. Although the relative effects of the psychomotor portion of the curriculum and the cognitive portion of the curriculum are impossible to ascertain, this is supported by theories of attention. Gallagher states the difference between a novice and an expert surgeon is that a master surgeon requires less attentional resources when performing an operating room procedure\textsuperscript{92}. On the other hand, when a novice is performing the same procedure, they require a significantly higher amount of attention to be focused on the task in order to perform the operation correctly\textsuperscript{92}. Cognitive training and technical skills training may both contribute to shrinking the amount of attention required in the operating room. Therefore, when actually performing an operation in the operating room, the pre-trained novice may be better primed to respond to external cues, anticipate difficulties, and consequently perform with a higher level of technical expertise.

\section{6.4 Concerns About Cost Effectiveness}

The comprehensive curriculum described in this study effectively resulted in an improvement in technical ability in the operating room for an advanced minimally invasive procedure compared to conventional residency training. Residents who participated in the curriculum not only had improved global rating scores in the operating room, but were also able to perform more of the procedure than a control group. While this represents large potential benefits with respect to
resident education as well as patient safety, implementing this curriculum in residency training programs requires a significant amount of resources; specifically a virtual reality simulator, cadavers for a cadaver lab, and faculty commitment for the video-feedback session. Although a cost analysis was not performed specifically as part of this study, an estimate of the materials utilized is not insubstantial. Indeed, the LapSim virtual reality simulator retails at approximately $54,500.00, the software licensing and haptic interface are $2,500.00 and $23,000.00 respectively. The cost of 6 cadavers to train 13 residents is $5,100 (estimate obtained from director of surgical skills lab in Toronto). Therefore the total estimated one time cost to train 13 residents in this curriculum was $85,100.00. It should be noted, however, that after the initial cost of the VR simulator, the annual cost of maintaining this program is substantially less since the cost for the VR simulator is primarily related to purchasing the system. Although it could be argued that the cost of implementing this curriculum is prohibitive, over the long term this is likely not the case. Many centres already own VR simulators that are underutilized. One of the common cited barriers to the use of these centres is a lack of formal curricula on the simulators. By clearly defining a curriculum to train in an advanced laparoscopic procedure, we are able to provide centres with training strategies and an evidence-based methodology to implement on VR simulators that they already own and are potentially underutilized. In addition, it has been shown that after a five year period, in residency programs that have greater than 10 residents, VR simulators are more cost effective than conventional residency training to learn an advanced laparoscopic skill. It is also important to note that VR simulators, unlike bench-trainers, do not require a faculty facilitator. As such, the time commitment required from faculty to implement this program is required only for the cognitive training and the cadaver lab. The use of cadavers is likely the most significant cost for this curriculum. We believe, however, that they are an integral portion of the curriculum since they allow for a simulated rehearsal of a procedure prior to performance in the operating room. Coordinating with other departments within a university and maximizing the potential use of the cadavers, for example having general surgery residents performing the laparoscopic surgery on the cadavers and the limbs being used by orthopedic surgeons and plastic surgeons, could potentially reduce the cost of the cadavers per department. Although initiating this curriculum is expensive, if it is well coordinated with the educational goals of the entire surgical department at an institution, the VR simulator and the cadavers that comprise the most expensive components of the curriculum can be shared among the multiple stakeholders thus decreasing the initial cost for one program.
6.5 Future Directions

Informed by a theoretical framework for curricular design, this thesis described the development of a comprehensive ex-vivo curriculum for laparoscopic colorectal surgery. In a randomized controlled trial, residents who participated in the comprehensive curriculum demonstrated superior cognitive knowledge and technical ability in the operating room compared to conventionally trained residents. This has the potential to significantly alter our current standard of residency training and has critical implications for patient safety in the operating room. It would be interesting to further define the specific gains provided by the curriculum. Indeed, comparing the learning curves in the operating room between curricular trained residents and non-trained residents would allow for a specific analysis of the advantages of curricular training. Also such a study would provide data that would allow for a cost analysis to compare curricular training and conventional training. In addition, it would also be interesting to conduct a qualitative analysis relating to the experiences of residents trained in the comprehensive curriculum. Does structured ex-vivo training improve their confidence in the operating room and their perceived competence? What feedback do they have regarding the delivery of the cognitive training information, or their experience on the virtual reality simulator? This information could potentially allow us to refine the structure and delivery of the curriculum. Similarly, it would be interesting to see if curricular training also had an effect on non-technical skills in the operating room as well as on technical abilities. Perhaps the sense of mastery and competence provided by the curriculum would allow residents to develop an improvement in inter-professional skills such as teamwork or leadership skills. Finally, the goal of this project is to begin to implement this curriculum in a systematic manner in residency training programs. If this is done, more work must be performed in order to further define levels of competency. Should trainees be required to pass the curriculum prior to performing laparoscopic colorectal surgery in the operating room? In addition to passing the VR portion of the curriculum, should a cognitive test based on the multiple-choice post-intervention test be developed? If so what would be an appropriate cut-off level for competency?

The previous era of Halsteadian surgical training has been supplanted by the current environment, which emphasizes systematic ex-vivo training. The goal of this is to develop “pre-trained novices”, individuals who have surmounted the early portions of their learning curve, and are able to maximally benefit from operating room teaching. In order to implement this idea into
current residency training programs, we must bridge the gap between what the data shows and how current surgical residency training programs function. In order to facilitate residency training programs incorporating simulation training in an effective manner into their residency teaching programs, current research needs to move beyond simulator validation and towards systematic curriculum development. The development and validation of this curriculum represents a significant departure from the preliminary curricula currently defined in the literature for laparoscopic procedures. More work must be done to continue to utilize the well-described curricular frameworks described in the literature as a starting point to develop and validate more ex-vivo curricula for both basic as well as advanced laparoscopic procedures.
References


Appendices

Appendix 1

Multiple choice test to assess cognitive knowledge related to performing laparoscopic colorectal surgery

**Laparoscopic Right Colectomy**

1) The appropriate port configuration for laparoscopic right colectomy includes
   a) one 10mm port and three 5mm ports
   b) two 10mm ports and three 5mm ports
   c) one 10mm port and four 5mm ports
   d) two 10mm ports and four 5mm ports

2) After the ports are inserted for a laparoscopic right colectomy, in general the patient should be moved into the following position:
   a) Trendelenburg with right side up
   b) Reverse-Trendelenburg with right side up
   c) Trendelenburg with right side down
   d) Reverse-trendelenburg with right side down

3) In the medial to lateral approach for right laparoscopic colectomy, division of the ileo-colic pedicle is one of the first steps in the procedure. In an obese patient sometimes it is difficult to initially identify the pedicle. What maneuver may be helpful in this situation?
   a) medial traction to the ileocecal junction
   b) moving the small bowel loops to the pelvis
   c) anterior-lateral traction to the ileocecal junction
   d) switching to a lateral to medial approach

4) Which of the following statements is INCORRECT?
   a) When performing a laparoscopic right colectomy, in the majority of cases the right colic artery branches off from the ileocolic artery meaning that the right colic artery does not need to be individually ligated.
b) It is appropriate to ligate the ileocolic artery with clips, the Ligasure device, or a vascular stapler

c) If a vascular stapler is used, you can ligate the ileocolic artery and vein together

d) If a vascular stapler is used, the correct staple height is 0.9mm

5) When performing a laparoscopic right colectomy, which of the following vessels should NOT be ligated:

a) left branch of the middle colic artery

b) right branch of the middle colic artery

c) right colic vein

d) ileocolic vein

6) Which of the following statements is CORRECT when performing a laparoscopic right colectomy:

a) An important step of the procedure is skeletonizing the right ureter in order to properly identify it.

b) The most common location for an injury to the right ureter is over the right iliac vessels

c) The most common step during which ureteric injuries occur is when mobilizing the hepatic flexure

d) Ureteric injuries occur more commonly during a laparoscopic right colectomy than during a laparoscopic sigmoid colectomy
7) When performing a laparoscopic right coloectomy, one of the first steps in the procedure is identification of the ileocecal pedicle, by tenting up the mesentery. As this step is performed, what structure can be visualized directly cephalad to the “tented” ileocecal pedicle?

   a) the right ureter
   b) the middle colic artery
   c) the duodenum
   d) the head of the pancreas

8) During a laparoscopic right colectomy, blunt dissection occurs near the head of the pancreas in order to effectively develop a plane near the middle colic vessels. As you are bluntly dissecting near this area, you notice significant bleeding from the head of the pancreas. The most likely source of the bleeding is.

   a) branch of the inferior pancreaticoduodenal vein
   b) branch of the inferior pancreaticoduodenal artery
   c) branch of the posterior-superior pancreaticoduodenal vein
   d) branch of the middle colic vein

9) Although many approaches are appropriate during a laparoscopic right colectomy including medial to lateral, inferior to superior, and lateral to medial, the medial to lateral dissection method incurs certain advantages. The following are all advantages to the medial to lateral approach as compared to the lateral to medial approach EXCEPT

   a) the tumour bearing area of the colon is manipulated less
   b) the only retraction needed is the upward elevation of the mesentery
   c) it is easier to remain in the correct plane between the mesocolon and the retroperitoneum
   d) there is a reduction in injuries to retroperitoneal structures such as the ureters
10) Several large scale randomized controlled trials have compared the laparoscopic approach to the open approach for colorectal cancer. These trials have found all of the following to be true of the laparoscopic approach EXCEPT
   a) a shorter duration of hospitalization post operatively
   b) slightly higher port site recurrence rates
   c) a overall lower cost of the procedure
   d) lower overall complication rates
Laparoscopic Sigmoid Colectomy:

1) In the medial to lateral approach for laparoscopic sigmoid colectomy, identification of the IMA (inferior mesenteric artery) is a critical step in the procedure. The initial dissection plane to identify the IMA is:
   a) superior to the IMA
   b) posterior to the IMA
   c) anterior to the IMA
   d) inferior to the IMA

2) Prior to dividing the IMA in a laparoscopic sigmoid resection, several nerves need to be moved out of the dissection plane. These include the:
   a) ileoinguinal nerves
   b) splanchnic nerves
   c) hypogastric nerves
   d) genitofemoral nerves

3) During a medial to lateral laparoscopic sigmoid resection, the left ureter should be identified before the IMA is transected. If you are having difficulties identifying the ureter which of the following is your BEST next move?
   a) Switch to a lateral approach and work on mobilizing the sigmoid
   b) Ligate the IMA as long as it is well skeletonized
   c) Continue working from the medial direction
   d) Convert to an open procedure
4) After the inferior mesenteric vessels are safely divided in a laparoscopic sigmoid resection, the next step of the procedure is to:
   a) divide the superior hemorrhoidal vessels  
   b) mobilize the mesorectum  
   c) divide the distal rectosigmoid junction  
   d) take down the lateral attachments of the sigmoid colon

5) Which of the following structures are NOT divided during a laparoscopic sigmoid colectomy?
   a) superior hemorrhoidal vessels  
   b) middle hemorrhoidal vessels  
   c) inferior mesenteric vein  
   d) splenocolic ligament

6) In a medial to lateral laparoscopic sigmoid resection, if the patient is obese, it can be difficult to identify the IMA. Tricks that can help you identify the IMA in this condition include all of the following EXCEPT
   a) retract the sigmoid out of the pelvis and then retracting it an anterior-lateral direction  
   b) note the location of the sacral promontory and start the dissection there  
   c) switch to the lateral approach  
   d) pull the sigmoid down into the pelvis which pulls the IMA up from the surface of the aorta

7) You are performing a laparoscopic sigmoid colectomy for colon cancer. The operation has gone well and you have effectively mobilized the left colon and divided the rectum. When checking the length of the remaining colon you realize that it is not long enough to reach the distal resection margin. What should you do at this point?
   a) exteriorize since it is easier to get extra length with the bowel out of the abdominal cavity  
   b) divide the IMV to create more length  
   c) do more distal mobilization of the rectal stump to allow it to come further out of the pelvis
d) continue the lateral dissection of the left colon to create more length

8) The Ligasure Device is commonly used during laparoscopic colorectal surgery. All of the following are true about the Ligasure EXCEPT
   a) it uses ultrasonic energy to seal and ligate vessels
   b) the energy delivery is automatically discontinued once the vessel is sealed
   c) the sealing and division of vessels occurs in a single manoeuvre
   d) the device can be used to ligate vessels up to 7 mm in diameter