Building Validity Evidence For The Advanced Laparoscopic Suturing Curriculum and Assessment (ALS)

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Conflict of Interest

As a result of this research, a collaboration between myself and Dr. Yusuke Watanabe has led to a discussion with industry for the commercialization of the advanced laparoscopic skills suturing tasks.

ABSTRACT:

Introduction: There is broad agreement in surgical education that we need to move away from the current time-based model of training to a proficiency-based model. One of the challenges to this lies in the ability to have valid assessments of proficiency at various stages of training. To this end, there has been success in developing fundamental assessments and curricula in general surgery training which include the Fundamentals of Laparoscopic Surgery (FLS), Fundamentals of Endoscopic Surgery (FES) and the Fundamental Use of Surgical Energy (FUSE). However, there are no advanced skill assessments or curricula. We describe our experience developing and validating an advanced laparoscopic skills (ALS) assessment and curriculum with the goal that it will become adopted in the proficiency-based model of surgical training.

Methods: We describe a series of projects which are used to build validity evidence for adoption of the ALS assessment and curriculum. We began with a nation-wide needs assessment of stakeholders. We then developed simulated tasks based on the survey, and began to build evidence of internal structure validity by assessing multiple levels of learners. Finally, we developed proficiency benchmarks for the curriculum.

Results: The needs assessment targeted minimally invasive surgery (MIS) fellows, past fellows and program directors and included 186 respondents for a response rate of 64%. The majority (73%) identified the need for an ALS curriculum and 78% identified laparoscopic suturing as the most needed portion such a curriculum. Next, a series of laparoscopic suturing tasks was developed. Based on our novel metrics, expert MIS surgeons out-performed surgery residents on the following tasks: needle handling, ($p = 0.04$) off-angle suturing, ($p < 0.01$) back-hand suturing, ($p = 0.01$) confined space suturing, ($p = 0.02$) suturing under tension ($p < 0.01$) and continuous suturing. ($p < 0.01$). Next, proficiency benchmarks of time and error were set based on data from a national sample of 17 expert surgeons from 7 institutions.

Conclusion: We have begun to build validity evidence for incorporating the advanced laparoscopic skills curricula and assessment into proficiency-based surgical training. Additional work is currently under way to improve several elements of validity including the internal structure, relationship to other variables and to determine how the curriculum and assessment can optimally be used. With that said, this project likely represents one of the most methodologically robust curriculum development processes in the literature.

Chapter 1: Introduction – Why we need valid assessments of expertise in surgery

All patients expect and deserve expert level surgical care. Unfortunately, there is no reliable way to measure surgical expertise, and instead, in the real world, we are left to rely on surrogate measures such as surgeon volume, patient opinion, and publicly available outcome measures, which are often flawed. (1) There are many reasons why published outcomes are not always reflective of surgeon abilities: Surgeons choose patients with different degrees of complexity – some refuse to operate on higher risk patients. It is difficult to account for surgical "degrees of difficulty" such as re-operative cases or patients who have been transferred from other providers for a variety of reasons. All of these variables are not accounted for in the commonly used risk stratification systems, be they administrative or clinical. In practice, most patients ask their friends or colleagues who they think is "the person" to see for a knee replacement or a gall bladder problem. Those that work in healthcare (especially in the operating room) have insider status and thus can provide better advice. The rest of the world is left to hope for the best. How do we change that?

Theoretical Framework – Defining Expertise

Skill acquisition from novice to expert has been extensively studied. The most popular description uses the Dreyfus and Dreyfus model (originally developed for fighter pilots and used in other skills like chess and driving a car) and adapts it to graduate medical education. (2,3) (Figure 1). According to this model, a learner undergoes gradual progression in skill development in sequential order: Novice → Advanced beginner → Competent → Proficient → Expert → ?*Master*. Depending how one interprets the Dreyfus model, expertise is either the highest or second highest level achievable, with some models – like Carraccio's - describing clinical skills *mastery*, going even beyond the point of expertise.

It is expected that most trainees do not achieve expert level performance at the conclusion of their residency training. It is assumed that they will reach that level during the early part of their careers. Currently, surgical residency programs have established competency as the minimal threshold for graduation. The American Board of Surgery, along with the Accreditation Council of Graduate Medical Education in the U.S., have developed an assessment process called "the milestones", which are used by all surgery training programs. It is the duty of the program director to state that the graduating resident is competent in the assessed domains. According to the ACGME:

> "The Milestones are designed only for use in evaluation of resident physicians in the context of their participation in ACGME-accredited residency or fellowship programs. The Milestones provide a framework for the assessment of the development of the resident physician in key dimensions of the elements of physician competency in a specialty or subspecialty."

Principles of the Dreyfus and Dreyfus Model of Skill Development Applied to the Development of a Physician's Competence

Novice

- Is rule driven
- Uses analytic reasoning and rules to link cause and effect
- Has little ability to filter or prioritize information, so synthesis is difficult at best and the big picture is elusive

Advanced beginner

- Is able to sort through rules and information to decide what is relevant on the basis of past experience
- Uses both analytic reasoning and pattern recognition to solve problems
- Is able to abstract from concrete and specific information to more general aspects of a problem

Competent

- Emotional buy-in allows the learner to feel an appropriate level of responsibility
- More expansive experience tips the balance in clinical reasoning from methodical and analytic to more readily identifiable pattern recognition of common clinical problem presentations
- Sees the big picture
- Complex or uncommon problems still require reliance on analytic reasoning

Proficient

- Breadth of past experience allows one to rely on pattern recognition of illness presentation such that clinical problem solving seems intuitive
- Still needs to fall back to methodical and analytic reasoning for managing problems because exhaustive number of permutations and responses to management have provided less experience in this regard than in illness recognition
- Is comfortable with evolving situations; able to extrapolate from a known situation to an unknown situation (capable)
- Can live with ambiguity

Expert

- Thought, feeling, and action align into intuitive problem recognition and intuitive situational responses and management
- Is open to notice the unexpected
- Is clever
- Is perceptive in discriminating features that do not fit a recognizable pattern

Master

- Exercises practical wisdom
- Goes beyond the big picture and sees a bigger picture of the culture and context of each situation
- Has a deep level of commitment to the work
- Has great concern for right and wrong decisions; this fosters emotional engagement
- Is intensely motivated by emotional engagement to pursue ongoing learning and improvement
- Reflects in, on, and for action

Figure 1. Translating the Dreyfus Developmental Model to the Learning of Clinical Skills. Carraccio, et al, Acad Med. 2008; 83:761–767.

We do not know how many surgeons continue to improve to expertise and or mastery after graduating from residency. It is possible that some surgeons never move beyond a certain level of performance and therefore achieve arrested development instead of expertise. (Figure 2) This is possible because simple experience is not sufficient for the development of expertise, as in the fact that doing something poorly over and over without correction will not lead one to progress. Instead, once needs to "*seek out practice activities that allow individuals to work on improving specific aspects with the help of a teacher and in a protected environment, with opportunities for reflection,* *exploration of alternatives and problem solving, as well as repetition with informative feedback*." (4) One can easily see that, in a real work surgical practice environment, these kinds of opportunities may not exist. In addition, we do not know who needs that training in the first place? Ideally, it would be possible to assess for expertise and have curricula that train people to expertise level performance for those that do not meet those standards. This represents the theoretical underpinning of this project.

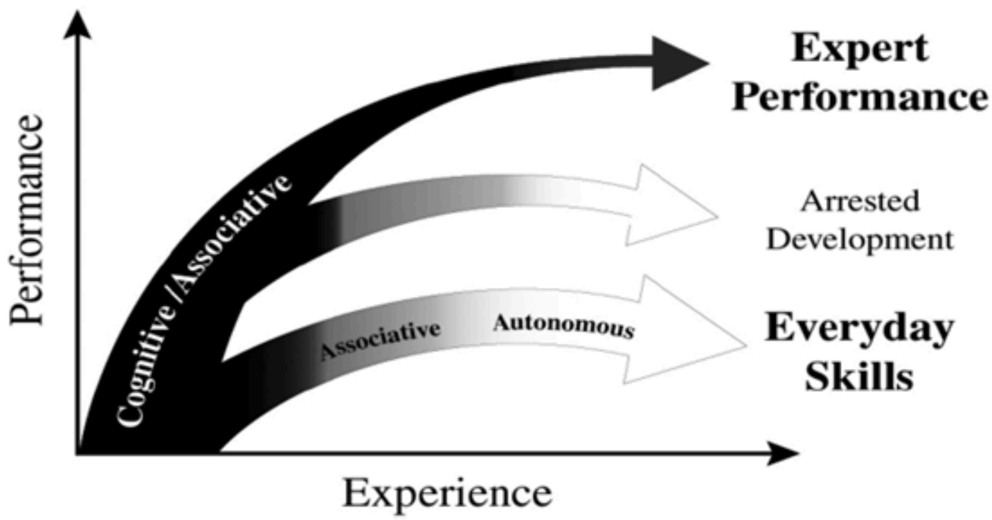

Figure 2. Ericsson K.A., "The Influence of Experience and Deliberate Practice on the Development of Expert Performance" The Cambridge handbook of expertise and expert performance (2006)

Assessment in Surgery – technical and non-technical skills

In surgery, education and assessment encompass two major domains – technical and non-technical skills. Both of these are important to patient outcomes and overall healthcare delivery. Non-technical skills include abilities to work well in teams, have good inter-personal skills, have excellent knowledge and make good decisions, be knowledgeable about systems of healthcare delivery, and be able optimize practice within the system, and realize the effects of the individual practice on the system, and display life-long learning behavior and continual self-improvement. It is easy to see how non-technical skills would be very important in having successful patient outcomes and optimal health care system function. However, one has to acknowledge that many of these skills are difficult to measure. The American Board of Surgery (ABS) focuses on the domains of knowledge, decision-making and life-long learning behavior for certification and re-certification purposes. They assess for knowledge via a high stakes multiple choice exam and continuing medical education (CME) through documentation of participation in self-directed learning.

Technical skills focus on the ability to properly perform procedures. This domain is very important and has been shown to correlate with patient outcomes in surgery. (5). In the literature, technical skills in surgery have been evaluated by over 100 different assessment instruments have been described in a meta-analysis by Ahmed et al. However, according to one of their findings, very few instruments can differentiate between competent and expert level performance. (6-12) In addition, the only high stakes technical skill assessments that are required for ABS certification is a fundamental level of competence in laparoscopic and endoscopic skills. Trainees must pass the Fundamentals of Laparoscopic Surgery (FLS) and Fundamentals of Endoscopic Surgery (FES) prior to sitting for their board exam. These benchmarks represent a *minimum* standard of performance, and are assessed only once, during the residency training process. Finally, and most disturbingly, technical skills are not assessed in any high stakes manner after completion of residency training, while non-technical skills are assessed every 10 years for re-certification via a written test and proof of CME. We feel that this is a major omission in how our system works to ensure high quality patient care. It is clear that, as new technologies are developed, surgeons are forced to learn new skills while maintaining existing ones, despite a natural deterioration that occurs with age. Therefore, one can assume that not everyone is able to maintain skills at an expert level or achieve expertise for the new skills required for modern surgical care. Every patient deserves a surgeon with expert level skills, and we should be able to verify via valid assessments that that is indeed the case.

Significance – Why should we care about technical skills?

Is there evidence that not all practicing surgeons are experts? There are multiple studies that demonstrate variability in patient outcomes based on the surgeon, such as the one by McArdle and Hole. (5) The most common variables that are analyzed to explain this difference are volume, specialization and location of practice (in a high volume vs. low volume center). However, these factors do not accurately account for all the differences – otherwise credentialing authorities would have established volume thresholds for all surgeries long ago. In addition, it is not practical. First, one has to obtain the necessary volume in the first place. Additionally, this volume-based system would punish good surgeons with good outcomes who do a particular procedure very well but in low volumes. And the reverse would also be true – in that poorly skilled but high volume surgeons would continue to operate unabated. We recall that expertise is not dependent on experience alone.

In a widely cited study by Brickmeyer et al., high-volume surgeons submitted videos of their bariatric surgeries for review. Patient outcomes were analyzed for those surgeons, and a high correlation was observed between intra-operative skill and decreased risk of postoperative complications. (13) Clearly, it would be better to assess the actual skill of the surgeons rather than just their volume – which is an incomplete process measure. Accurate assessment of technical expertise would allow for evidence-based credentialing, remediation and quality improvement. The overall result would be improved quality of surgical care for all patients so that they can be assured that their surgeon is an expert, and that their outcomes will be expected to fall within a predictable range. This approach would also lead to significant cost savings for the health care system for two reasons: First, there would be a reduction in the complication rate and associated costs, and second, there would be a lower reliance on expensive surgical technology (like the surgical robot) which assists surgeons in gaining laparoscopic expertise, but costs thousands of dollars more for each case compared to standard laparoscopy. Most surgeons use this technology to perform procedures that other surgeons routinely perform just as well without it.

Context – From Laparoscopic Suturing to Everything

Given the extremely broad degree of skills required to be assessed in all of surgery, it is not possible for any single group to develop the entire curriculum to teach and assess expertise. It is our hope that this project can encourage others to establish expert level curricula in other fields. Our curriculum focuses on the skill set of laparoscopic (minimally invasive or MIS) surgery. Within this domain, our needs assessment showed that the laparoscopic suturing skill set was found to be most significantly deficient amongst graduating surgery residents. There are other skill sets within laparoscopic surgery that are also important such as dissection, exposure, use of energy and staplers. However, laparoscopic suturing was felt to be the most lacking and most important skill required for trainees to be able to move from advanced beginner to proficiency. (14) Thus, this curriculum focuses on this competency.

The over-arching goal would be to develop a valid curriculum and assessment of expert level laparoscopic suturing skills, then build on this experience to expand it to all laparoscopic skills, and ultimately many other surgical skills. This would establish a true model of competency-based curriculum and assessment that could be used in training, remediation and credentialing.

Thesis Format

The current thesis project involves building validity evidence for an advanced laparoscopic suturing curriculum and assessment. The format of this thesis is manuscript based. The current chapter outlines the introduction, while the subsequent chapters describe published and un-published manuscripts outlining our case. Each chapter will have an introduction describing how it connects to the work as a whole.

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Chapter 2: Needs Assessment

In this chapter we describe the first step in developing this curriculum - a national needs assessment that was conducted to build evidence of content validity. We wanted to see if this type of curriculum was needed, and what type of skills an expert laparoscopic skills curriculum should have. We focused our survey on stakeholder surgeons who specialize in laparoscopic surgery as trainees, recent graduates and program directors. Based on the outcomes of this study, we picked laparoscopic suturing skills as the focus of our curriculum development, although many other needs exist and can be used by others to build on this work.

Identifying the need for and content of an advanced laparoscopic skills curriculum: results of a national survey

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Author Contributions:
Dmitry Nepomnayshy – Study design, manuscript preparation
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Shimae Fitzgibbons – Survey preparation, manuscript editing
Dimitrios Stefanidis – Survey preparation, data analysis, manuscript editing

Abstract

BACKGROUND: A recent survey of fellowship directors suggested significant deficits in the technical laparoscopic skills of graduated general surgery residents. Our aim was to define the need for and possible content of a simulation-based curriculum in advanced laparoscopic skills (ALS).
METHODS: An anonymous online survey was distributed to all Fellowship Council program directors (PDs), current fellows, and recent fellowship graduates. The survey was designed to assess the perceived need for, possible content of, and implementation challenges to an ALS curriculum. Recently developed simulation-based advanced laparoscopic tasks included off-angle camera work and restricted space suturing. Images and descriptions of these tasks were evaluated by respondents, and suggestions for modifications or improvements solicited via free text response.
RESULTS: Of 186 respondents (response rate: 64%), 40% were current fellows, 22% were fellowship graduates, and 37% were PDs. Respondents primarily self-identified as minimally invasive and/or bariatric surgeons (78%) and hepatobiliary surgeons (12%). Most respondents (73%) identified a need for an ALS curriculum. All 3 respondent groups cited laparoscopic needle positioning and suturing (78%) and bimanual coordination during dissection and retraction (72%) as the skills in most need of improvement. In addition, most of the responding PDs identified ‘‘lack of familiarity with anatomy and procedure’’ (74% of PDs) and ‘‘lack of proficiency at laparoscopic bowel anastomosis’’ (59% of PDs) as problem areas. Respondents felt that successful implementation of an ALS curriculum depended on both overall feasibility and the ability for repeated practice and should not be dependent on cost.

Thematic analysis of free responses revealed the following priorities for possible ALS skills and tasks: (1) difficult dissections and exposures, (2) forehand and/or backhand and suturing under tension, (3) non-dominant hand drills, (4) working with an off-set camera, and (5) suturing and handling fragile tissue with properties similar to peritoneum or bowel.

CONCLUSIONS: We present survey results identifying several specific ALS skill deficits among graduating general surgery residents, including advanced suturing, bimanual coordination, and managing difficult anatomy. Next, the results of this needs assessment will be used to develop an advanced laparoscopic curriculum for residents.

Background

Most of the graduating general surgery residents (80%) choose fellowship training after residency. A significant subset is pursuing minimally invasive surgery (MIS) fellowships. In 2013, out of 818 fellowship matches, 131 (16%) went into MIS and/or bariatric surgery, second only to hand surgery (153) and surgical critical care (132).[1,2] Although the reasons for pursuing MIS fellowships are likely multifactorial, some studies point to the perceived lack of graduating general surgery resident experience, confidence, and/or ability in advanced laparoscopic surgery.[3–6] A survey of 232 postgraduate 5th year residents from surgical programs in the northeastern United States revealed that only 52% felt confident practicing independently.[7] A survey focusing specifically on the laparoscopic skills of Canadian graduating residents found that after graduation, only 52% felt they would be able to perform a laparoscopic sigmoid resection, 41% a laparoscopic inguinal hernia repair, and only 6% felt that they would be able to perform a Nissen fundoplication.[8] It is consequently not surprising that a recent survey of Fellowship Council (FC) program directors (PDs) revealed that up to 60% of entering fellows were not proficient at laparoscopic suturing and that 30% were not proficient at laparoscopic cholecystectomy.[9]

The importance of improving MIS training has been recognized by the surgical profession. In 2007, the Accreditation Council for Graduate Medical Education increased the minimum number of basic laparoscopic cases needed to graduate to 60 and advanced laparoscopic cases to 25. In 2009, the American Board of Surgery required all residents to pass the Fundamentals of Laparoscopic Surgery (FLS) curriculum and examination, with the intention of ensuring a baseline proficiency in laparoscopic instrument handling and suturing for all general surgery graduates. Although this growing emphasis on basic laparoscopic skills training for surgical residents is notable, the technical skills required of MIS fellows are, by definition, more advanced. For this unique population of trainees, an advanced laparoscopic skills (ALS) curriculum could be used during residency and/or fellowship to help learners gain higher levels of technical expertise, allowing the fellowships experience to focus more time on transitions to independent practice rather than skills training.

To assess the perceived need for, potential content of, and expected implementation challenges to an ALS curriculum, we distributed an anonymous online survey to FC fellows, recent fellowship graduates (FGs), and PDs.

Methods

Survey development

A group of expert laparoscopic surgeons from the simulation committee of the Association of Surgical Education worked jointly to develop the survey. An expert in survey development assisted with the construction of survey questions. The questions gathered data related to respondent demographics; type of fellowship training; and the perceived need for, possible content of, and implementation challenges to an ALS curriculum. Before dissemination, the survey was piloted with 16 general surgeons, general surgery residents, and fellows in accredited fellow- ships in academic settings for clarity and response times. The feedback obtained from this pilot was used to adjust the survey questions.

Survey participants

The survey was disseminated to 286 surgeons via the FC research committee using SurveyGizmo (V3, V2005- 2014; Widgix, LLC, Boulder, CO). This anonymous online survey was distributed on February 2014 to all FC PDs, current fellows (CFs), and recent FGs who completed training within the prior 2 years and for whom the FC had working email addresses. Survey distribution lists were compiled and culled to exclude duplicates. This study was deemed exempt by the institutional review boards of the authors' institutions.

Data analysis

Summary and descriptive statistics were applied. The qualitative data collected as free text comments by survey respondents were analyzed for thematic content.

Results

The response rate was 64% generating 183 completed surveys. Responders included PDs, recent graduates, and CFs (Table 1). Respondents primarily self-identified as MIS and/ or bariatric surgeons (78%) and as hepatobiliary surgeons (12%), with fewer colorectal and thoracic surgeons. When asked about their clinical ALS experience, 51% of respondents felt it was ''good'' or ''excellent'' in residency, and 94% felt it was ''good'' or ''excellent'' in fellowship.

When asked about their residency simulation skills training experience, 67% of CFs and recent FGs described their non-FLS laparoscopic skills training as ''intermittent,'' ''rare,'' or ''never,'' whereas 33% described it as ''frequent'' (i.e., monthly) or ''extensive'' (i.e., weekly; Fig. 1)

When fellowship directors were asked why a fellow was not given the primary surgeon role during the first 3 months of fellowship, the most commonly cited reason was ''unfamiliarity with procedure'' followed by ''not proficient at bowel anastomosis and suturing,'' and, finally, ''not proficient at tissue handling'' (Fig. 2).

The most common technical skill deficiencies identified by responding PDs in their new fellows were laparoscopic suturing, followed by bimanual coordination and use of their non-dominant hand.
When asked to rank a list of proposed laparoscopic skills that could be emphasized in an ALS curriculum, the vast majority of respondents (77%) felt that a ''proficiency-based suturing and needle positioning curriculum'' and ''2-handed dissection and retraction training'' (71%) were desirable, whereas 47% of respondents felt that didactic instruction in anatomy and procedural steps were needed. (Fig. 3)
Overall, 72% of respondents felt that an ALS curriculum was needed.
When asked to rank the importance of various attributes of an ALS curriculum, ''feasibility'' was identified as most important by most of the respondents, followed by ''ability for repeated practice.'' Interestingly, ''cost'' was felt to be the least important factor under consideration.

Of the total 183 survey respondents, 37 submitted a free text response. The most common theme identified among these responses was that more operative cases were required to improve skills, as illustrated by the representative statement:
Most fellows can master the dexterity and manual tasks but have difficulty identifying dissection planes in the setting of severe inflammation and thinking through the cases that 'don't follow the rules.' It is easy to train people to do gastric bypasses since they follow fairly predictable set of steps. Much harder to teach them re-do's and odd cases where they need to fall back to basic anatomy and surgical principles and then solve a puzzle in terms of tactics and strategy of an operation. No substitute for experience.
The next most common theme related to specific skills sets was that fellows needed to improve their laparoscopic suturing skills with tasks that involve making an anastomosis, suturing under tension, working in tight spaces, using their non-dominant hand, and suturing backhand. Another common theme centered on working with difficult camera angles, as seen in the following representative statements:
working against camera, working left handed only driving camera and doing task at the same time. Working against camera training by placing mirrors.
Other respondent suggestions for skills to target in an ALS curriculum included practicing with tissues that were more realistic and teaching difficult exposure techniques and trocar placement: A representative statement is as follows:
suturing and handling fragile tissue that has properties similar to peritoneum or bowel tasks/didactics involving obtaining exposure like patient positioning and proper organ/tissue retraction.

Discussion

We report the results of a nationwide survey of FC PDs, CFs, and recent FGs designed to assess the perceived need for, possible content of, and implementation challenges to an ALS curriculum. The respondents were similarly distributed across the 3 main demographic groups (PD, CF, and FG) and were skewed to include more responses from bariatric and/or MIS fellowships. This is consistent with the fact that 80% of the FC is made up of members of bariatric and/or MIS programs.

Our 1st objective was to determine the perceived need for an ALS curriculum. Survey questions focused on the adequacy of current ALS training, as assessed by both surgical trainees and fellowship PDs. Results demonstrate that only half of responding trainees feel they had adequate ALS training during their residency and that very little of this training took place in the form of simulation-based practice. Conversely, 72% of all respondents felt that an ALS curriculum would be of value. Also, noteworthy is the relatively high response rate to this survey (64%), reflecting the evident importance of this topic to both surgical trainees and fellowship PDs.

Our 2nd study objective was to better define the possible content of a future ALS curriculum. To do this, questions focusing on the types of laparoscopic skills felt to be most deficient at the conclusion of residency training, as well as those skills considered most important to master before completion of fellowship training, were included in the survey. Responses clearly highlighted the need to improve laparoscopic suturing skills, particularly with respect to suturing a bowel anastomosis, and the use of one's non-dominant hand during 2-handed dissections. Free text responses provided additional detail with respect to desirable skills in advanced laparoscopy but overall continued to focus on suturing skills and use of the non-dominant hand. Additional skills cited as important included working with an off-angle camera, working in a tight space, working with fragile tissue, and learning how to achieve optimum exposure.

It is important to note that the most common free text response focused on the theme that ultimately, more clinical training in the operating room is needed to improve the advanced laparoscopic surgical skills of trainees. Although the authors agree that there is no substitute for clinical surgical experience, we should not overlook the opportunities we have to improve specific skills with deliberate, supervised practice in a cost effective and safe simulated setting. The goal of such practice is not to replace operative experience but to better prepare the trainee for optimal learning in the operating room. Instead of watching a fellow struggle with a difficult suturing move in surgery, for example, the attending can dedicate their intra-operative teaching to more complex, and more difficult to simulate learning points such as managing unanticipated findings or dealing with difficult exposure.

When asked questions regarding the design and implementation of an ALS curriculum, most of the respondents felt that it needed to be both feasible to deliver and capable of providing ample opportunity for repeated practice. Surprisingly, cost was not felt to be a particularly relevant issue despite the significant resource strain currently impacting graduate medical education and surgical training. This finding may reflect the acuity of the need for an ALS skills curriculum. Alternatively, the fact that these tasks were introduced as a potential ''voluntary'' curriculum, rather than a mandatory high stakes proficiency standard like FLS or Fundamentals of Endoscopic Surgery, may have deemphasized the issue of cost in the mind of respondents. Strengths of this study include a high response rate with a good mix of respondents across the various cohorts. Geographically, respondents represented 30 different states, with 44% coming from the East, 16% from the Midwest, and 13% from the West with the remainder coming from Canada and locations outside the United States. In addition, responses were reassuringly consistent across different question formats, repeatedly emphasizing the need to improve laparoscopic suturing skills in particular. Potential study limitations include the selection bias inherent in using the FC as a survey population. The FC represents roughly a 3rd of the fellowship positions in the United States and less than 20% of the total trainees that finish general surgery training each year. Because the FC does represent the largest number of trainees dedicated specifically to mastering skills in minimally invasive general surgery, one could argue that the results of this study are skewed toward a self-selected group of residents that perceive a weakness in their laparoscopic skills. On the other hand, a recent nationwide survey of 297 graduating chief residents found that 67% chose their fellowship because they were truly interested in that specialty and only 7% chose their fellowship because they were not comfortable with their skills[10] suggesting that the residents choosing MIS fellowships are no less skilled in laparoscopy than those choosing other specialties. The results of this needs assessment will guide the creation a simulation-based ALS curriculum intended to address the lack of adequate laparoscopic skills of incoming MIS surgical fellows. Successful completion of such a curriculum in the end of residency or beginning of fellowship will allow the fellows to focus more time on their transition to independent practice. They will be able to improve skills such as greater autonomy, management of unexpected findings, dealing with difficult patients, taking residents through cases and reoperative surgery rather than spending a lot of time on laparoscopic skills training and remediation.

Conclusion

This needs assessment has identified several specific laparoscopic skill sets, including advanced suturing, bimanual coordination, and managing difficult anatomy, that graduating surgery residents going into MIS careers need to improve. The development of an ALS curriculum to meet these needs is currently underway.

Table 1 Demographics

Respondent	Number	Percent (%)
Current fellow	74	40.4
Recent faculty, 1–2 y after fellowship	40	21.9
PD/associate PD	67	36.6
Other	2	1.1
Total	183	100

PD 5 program director.

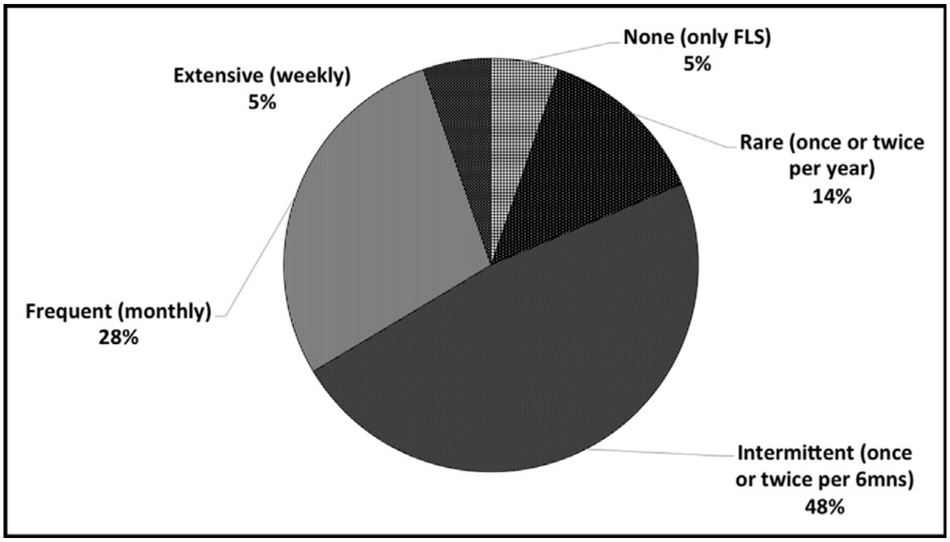

Figure 1 Frequency of laparoscopic skills simulation in residency, other than FLS training

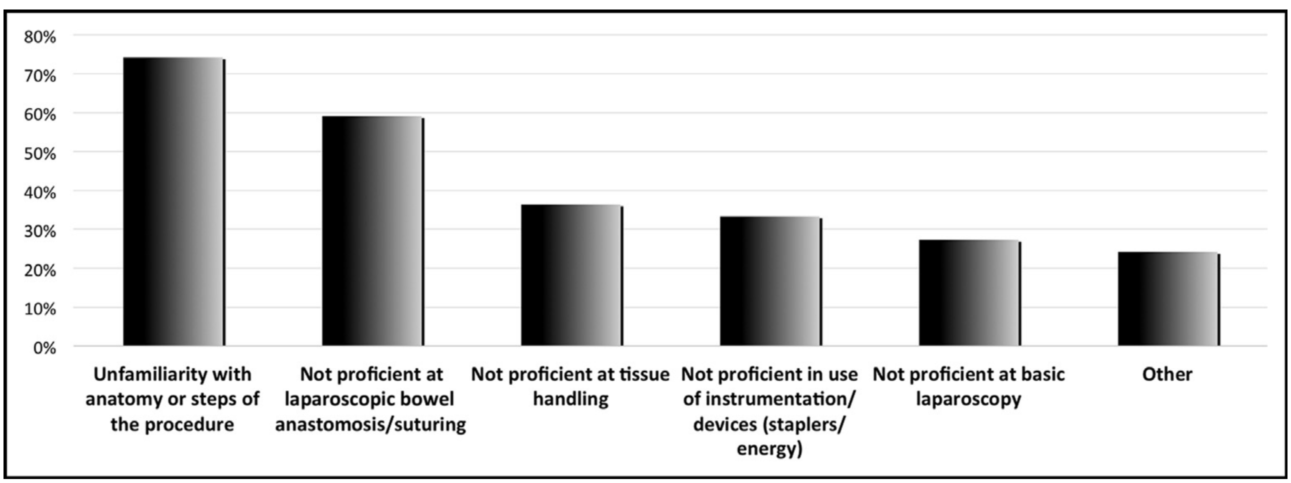

Figure 2 Reasons cited by responding PDs for why their fellows were not given the primary surgeon role in the first 3 months of fellowship

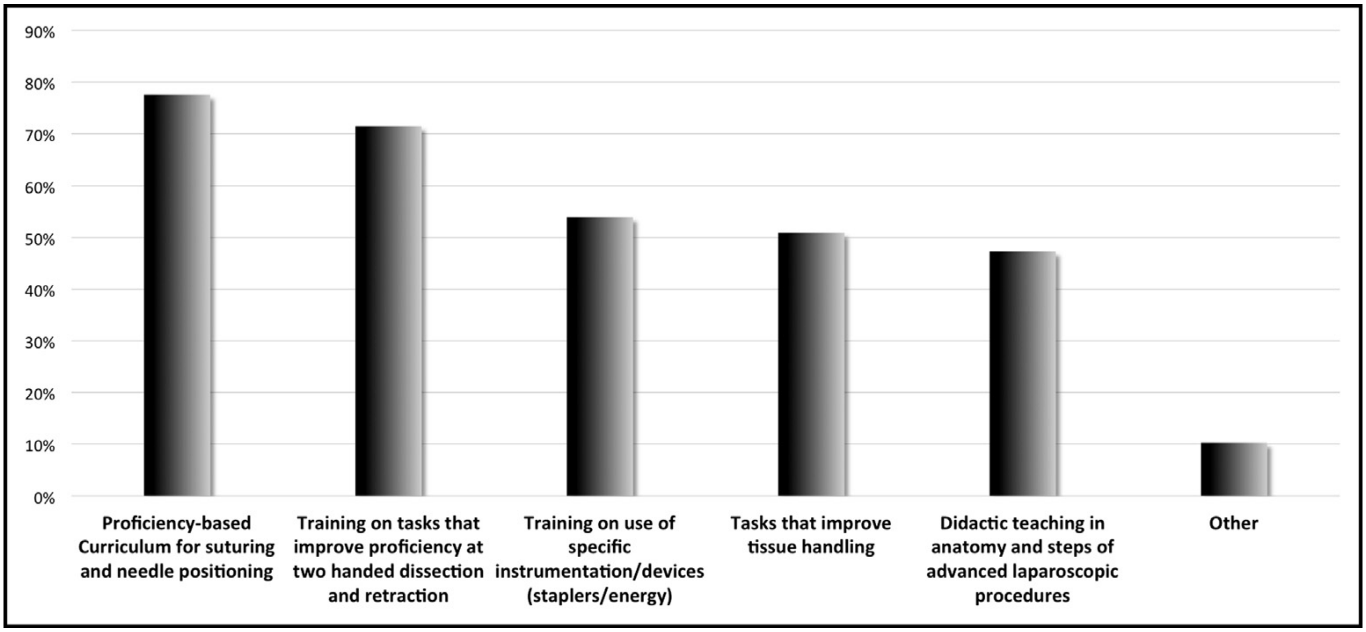

Figure 3 Tasks or skills identified by survey respondents as desirable in a potential advanced laparoscopic skills curriculum

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Chapter 3: Task Creation

In this chapter, we describe a pilot study exploring different tasks for use in an advanced laparoscopic skills curriculum. This study was performed around the same time as the national needs assessment described in Chapter 2 and includes additional tasks beyond just suturing, as the decision to focus on laparoscopic suturing was not yet finalized. This study adds validity evidence based on content and relation to other variables.

When designing ALS tasks, we wanted them to be based on an existing model that was widely available and already in use. We chose the standard FLS trainer box, and modified it to try to make the curriculum more realistic and difficult. (Figures 1-3) Our modifications were based on focus group feedback asking: "why trainees that achieve proficiency in FLS have problems with actual laparoscopic surgery?" In addition, we wanted our "novice" group to reflect a true advanced beginner according to the Dreyfus model, so we did not use medical students – only residents, fellows and attending surgeons. We also wanted to be broad in our definition of "expert laparoscopic surgeon" and include multiple minimally invasive specialties – GYN, Urology and General Surgery. Several interesting findings were obtained when we compared FLS and ALS performance:

1. Performance on FLS was not different between novice, intermediate and expert.
2. Performance of all tasks was better by general surgeons compared to GYN and Urologists – this finding underscored for us that any laparoscopic curricula would have to be specialty specific.
3. ALS task performance was able to differentiate expertise for general surgeons only, but not the whole group, likely relating to item 2.

<u>Evaluation of advanced laparoscopic skills tasks for validity evidence</u>

Surgical Endoscopy, 29:349-354, 2015

Author Contributions
Dmitry Nepomnayshy – Concept, study design, manuscript preparation
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Abstract

Background: Since fundamentals of laparoscopic surgery (FLS) represents a minimum proficiency standard for laparoscopic surgery, more advanced proficiency standards are required to address the needs of current surgical training. We wanted to evaluate the acceptance and dis- criminative ability of a novel set of skills building on the FLS model that could represent a more advanced proficiency standard—advanced laparoscopic surgery (ALS).

Methods: Qualitative and quantitative analyses were employed. Quantitative analysis involved comparison of expert (PGY 5+), intermediate (PGY 3–4) and novice (PGY 1–2) surgeons on FLS and ALS tasks. Composite scores included time and errors. Standard FLS errors were added to task time to create the composite score. Qualitative analysis involved thematic review of open-ended questions provided to experts participating in the study.

Results: Out of 48 participants, there were 15 (31 %) attendings, 3 (6 %) fellows and 30 (63 %) residents. By specialty, 54 were general/MIS/bariatric/colorectal (GMBC) and 46 % were other (urology and gynecology). There was no difference between experience level and performance on FLS and ALS tasks for the entire cohort. However, looking at the GMBC subgroup, experts performed better than novices ($p = 0.012$) and intermediates performed better than novices ($p = 0.057$) on ALS tasks. There was no difference for the same group in FLS performance. Also, GMBC subgroup performed significantly better on FLS ($p = 0.0035$) and ALS ($p = 0.0027$) than the other subgroup. Thematic analysis revealed that the majority of experts felt that ALS was more realistic, challenging and clinically relevant for specific situations compared to FLS.

Conclusion: For GMBC surgeons, we were able to show evidence of validity for a series of advanced laparoscopic tasks and their relationship to surgeon skill level. This study may represent the first step in the development of an advanced laparoscopic skills curriculum. Given the high degree of specialization in surgery, different advanced skills curricula will need to be developed for each specialty

Background

There is a general consensus among surgical educators of the need to improve the quality and uniformity of graduating surgery residents' skills [1, 2]. Resident experience varies widely and in many instances is inadequate. For example, for 63 of 121 ''core procedures'' in general surgery, the most commonly reported graduating resident experience was zero [3]. Survey results suggest that up to 30% of graduating residents do not feel confident operating independently [4, 5] and this may be one of the main considerations for the 80% who pursue fellowship training after residency [5–8]. Minimally invasive surgery (MIS) fellowships are one of most frequently chosen, but a recent Fellowship Council survey revealed that only 40% of the new fellows could operate independently for more than 30 min during major cases, 30% were

deemed unsafe to perform a laparoscopic cholecystectomy, and only 40% were proficient at laparoscopic suturing [9]. Simulation-based training has been increasingly used to improve and standardize the quality of surgical training. In 2009, the American Board of Surgery (ABS) began to require successful completion of the fundamentals of laparoscopic surgery course and test prior to the ABS Qualifying Examination. In 2012, The American College of Surgeons (ACS) and the Society for Gastrointestinal and Endoscopic Surgery (SAGES) released practice guidelines stating that all surgeons performing laparoscopic surgery should be FLS certified. In part, these recommendations were based on studies demonstrating that FLS proficiency improves operating room performance for surgical novices [10–13] and the need to standardize surgical training and improve patient safety [14, 15].
However, FLS is only designed to teach and assess a fundamental proficiency standard in laparoscopic surgical skills and is not intended or able to assess more advanced skills that might be reflective of surgical expertise. In a study by Okrainec et al. [16] looking at the first 5 years of FLS test data, attending surgeon skill on the FLS exam was not significantly different from junior residents. We pro- pose that there is a current need to teach and assess more advanced laparoscopic skills in residency and fellowship and have performed a pilot study in order to begin accumulating validity evidence for a novel advanced proficiency standard and curriculum—advanced laparoscopic surgery—which is based on the FLS model with modifications to address more advanced skills such as offset camera view, restricted space and difficult angles.

Methods

This IRB-approved pilot study used a convenience sample of advanced laparoscopic surgeons and residents recruited from two institutions and a national meeting. Over 80 % of the subjects came from one institution and over 90 % of the eligible laparoscopic expert surgeons at that institution participated in the study. Forty-nine subjects were recruited and 48 completed the study and were included in these analyses. Quantitative analysis involved comparison of performance on FLS and ALS tasks in order—FLS first ALS second. Groups were defined based on years of surgical experience as follows: expert (PGY 5 residents and higher— including fellows and attending surgeons), intermediate (PGY 3–4 residents) and novice (PGY 1–2 residents). FLS tasks included peg transfer, pattern cut and intra-corporeal suture. ALS tasks were created by modifying a standard FLS trainer as follows: Ports were placed together on one side of the trainer, while the camera was removed from its fixed position to a mobile stand (Fig. 1). This created the offset and reverse camera view tasks of ‘‘offset simple suture,’’ ‘‘offset backhand suture,’’ ‘‘offset peg transfer’’ and ‘‘180 degree ‘reversey’ peg transfer.’’ Additional modifications included a metal ring and plastic cup to restrict movement for the ‘‘confined suture’’ task (Fig. 2) and a wooden block to move tasks to a vertical plane for the ‘‘peg transfer on the block’’ and ‘‘circle cut on the block’’ tasks (Fig. 3).

Scoring: Time and errors were recorded for each task and used to generate a composite score. Standard FLS errors were assigned a penalty time (15 s for nonsuturing tasks and 30 s for suturing tasks) and added to task time to create the composite task score, with a lower score signifying better performance. Compound FLS and ALS scores for each participant were calculated by adding individual composite task scores together (i.e., the FLS compound score for subject A was the sum of FLS circle cut, peg transfer and suturing composite scores). Distributions of each score type were first plotted and then, because some measures were highly skewed, were compared between the three experience groups using a nonparametric Kruskal–Wallis test. When the omnibus test was significant at the p B 0.05 level, the groups were further compared as three sets of pairwise comparisons, still using the same test, and a Bonferroni-corrected threshold of p B 0.0167 (0.05/3) was applied to determine significance between the two groups within each pair. The Kruskal–Wallis test was also used for comparing the scores and times between surgery experience subgroups.

Times and composite scores were summarized for each group as medians and interquartile ranges. The SAS system for Windows version 9.3 was used for data analyses (reference: SAS Institute © 2002–2010, Cary, NC).

Qualitative analysis consisted of thematic review of open-ended questions provided to experts participating in the study after they completed all the tasks (Table 3).
Power was calculated based on prior task validation studies using standard deviations of 0.7–1.8 at a 95 % confidence interval and converted to calculate effect size. So to achieve 80 % power and a p = 0.0167, we calculated that between 9 and 35 participants per group were required depending on the standard deviation of the new ALS tasks.

Results

Table 1 summarizes the demographics of the 48 subjects that completed the study. There were 15 (31 %) attending surgeons, 3 (6 %) fellows and 30 (63 %) residents. Residents included 11 (23 %) novices, 12(25 %) intermediate and 7(15 %) fifth year residents. The median experience level of expert subjects was 12 years (range 5–27). By practice type, 26 (54 %) were general minimally invasive, bariatric or colorectal (GMBC) surgeons and 22 (46 %) were gynecologic and urologic surgeons.
Analyzing the entire cohort, we found no significant difference in performance between expert, intermediate and novice group in FLS (p = 0.40) and ALS (p = 0.47) (Fig. 4). We then performed a subgroup analysis to see if we could detect any differences between experience sub-groups based on our observation that some subjects significantly outperformed others. When we compared the performance of the GMBC surgeon subgroup to the gynecologic and urologic surgeon (Other) subgroup, we found that GMBC surgeons performed significantly better on FLS (p = 0.0035) and ALS tasks (p = 0.0027). When looking at specific tasks, the difference was significant for FLS suture (p = 0.0002), ALS offset peg transfer (p = 0.0331), ALS offset suture (p = 0.0036), ALS backhand suture (p = 0.0197) and ALS confined suture (p = 0.0074) (Table 2).

We then analyzed the performance of the general surgery subgroup (GMBC) on ALS skills. We found that there was a significant difference between novice and expert. (p = 0.01) (Fig. 4). However, when the GMBC subgroup was compared using the FLS task set, there was no significant difference in performance between novice and expert (Fig. 4). Twenty-five expert surgeons completed the questionnaire at the conclusion of the study. The findings are summarized in Table 3. The majority felt that the ALS tasks were more difficult and realistic, better representing specific clinical situations. Most of the negative responses focused on the reverse angle peg transfer task as being too difficult and unrealistic.

Discussion:

This study demonstrates discriminative validity of a novel system of laparoscopic skills testing developed to assess and teach more advanced laparoscopic surgical skills. It is based on current FLS models with simple modifications of some of the tasks which resulted in task conditions that were more difficult and arguably more clinically realistic for the subjects. ALS tasks were able to differentiate the performance of expert versus novice subgroups of general/bariatric surgeons, whereas FLS did not. In our study, novices were not naıve to FLS, in fact, many had already passed and/or practiced the surrogate proficiency standards for FLS as described by Ritter and Scott [17] making them FLS proficient. The fact that in our study, there was no difference between novice and expert performance on FLS is thus not surprising. In addition, early FLS external validity trials by Swanstrom et al. [18] showed that performance of third year residents was better than that of staff laparoscopic surgeons. Also, 5-year FLS testing data shows that attending surgeons do not perform better than PGY 2 and 3 residents, and actually perform worse than senior residents and fellows [16]. These findings are somewhat difficult to interpret without more specific information on the subjects and particularly the expert subjects whose behavior might be influenced by factors such as established practice (i.e., resistance to prescribed task demands), task naiveté´ or even age-related skills decrements. FLS was developed and deployed as a means to certify a fundamental level of skill and was not intended to assess much higher and advanced levels of surgical skill. In contrast, our study design was expected to parse out higher levels of skill from lower. The difference in ALS performance detected between novice (also FLS proficient) and expert general/bariatric surgeons strongly suggests that this skills testing scheme is a construct valid one and able to discriminate expected expert from non-expert laparoscopic performance. In addition, there was significant agreement among experts that many of the tasks in the ALS skill set were reflective of those used in actual clinical situations supporting the task validity based on content.

It is also notable that expert laparoscopic urologic and gynecologic surgeons do not perform as well on both FLS and ALS tasks as compared to expert laparoscopic general surgeons (GMBC). Although the reasons for this are not entirely clear, these findings might be attributed to task design, which was conducted by expert general surgeons and involved skills felt to be relevant to general surgery. One of the questionnaire comments from the ‘‘other’’ experience subgroup was particularly revealing: ‘‘As with all senior level residents, majority of MIS is done robotically.'' Indeed, a higher utilization of robotics for advanced laparoscopic cases might very well account for decrements in the purely laparoscopic skills tested in our study and underscores the fact that different specialties progress along lines of training that do not overlap in all areas. Proficiency standards in surgical training will play an increasing role in education and credentialing. FLS was one of the first and is expected to be followed shortly by fundamentals of endoscopic surgery (FES), which will also be required for ABS certification. Additional fundamental proficiency standards such as fundamentals of robotic surgery (FRS), essentials in minimally invasive gynecology (EMIG) and basic laparoscopic urologic surgery(BLUS) are also under study aiming for similar uses in certification.

The development of a more advanced level of proficiency standards and curriculum in laparoscopic surgery such as we have proposed, which go beyond the fundamentals, is a logical next step in the progression of surgical training and assessment for general surgical specialties. However, several important weaknesses must be acknowledged in this pilot study. The number of subjects in each arm of the GMBC subgroup is small and is mostly from a single institution. This could limit the generalizability of the findings. A more broadly applied multi-institutional prospective trial would be needed to address this. Like FLS, ALS tasks are scored based mainly on task time. This does not provide enough weight to factors such as precision, tissue handling and operative decision making, which are part of surgical expertise. In addition, ''expert'' status in our study was defined by years in practice, which may not always correlate with technical abilities. Analysis of actual surgical performance would be more accurate. We did not record FLS experience or certification as part of the study. However, this study was geared toward a more advanced skill set, and therefore, we purposely avoided including subjects that were likely FLS naive such as medical students. In addition, it is assumed that FLS exposure and training in residency is now ubiquitous and therefore is difficult to control in this study group. Also, we did not strictly control the testing environment (distractions, proctor and video quality) across various sites, introducing a possible confounding variable, although we feel this effect was relatively small.

Despite these limitations, we were able to demonstrate both a high degree of acceptance and good ability to discriminate expert from non-expert performance among general surgeons and general surgery trainees with this new advanced laparoscopic skills testing system. This may represent an important first step in the development of an advanced laparoscopic skills curriculum and proficiency standard.

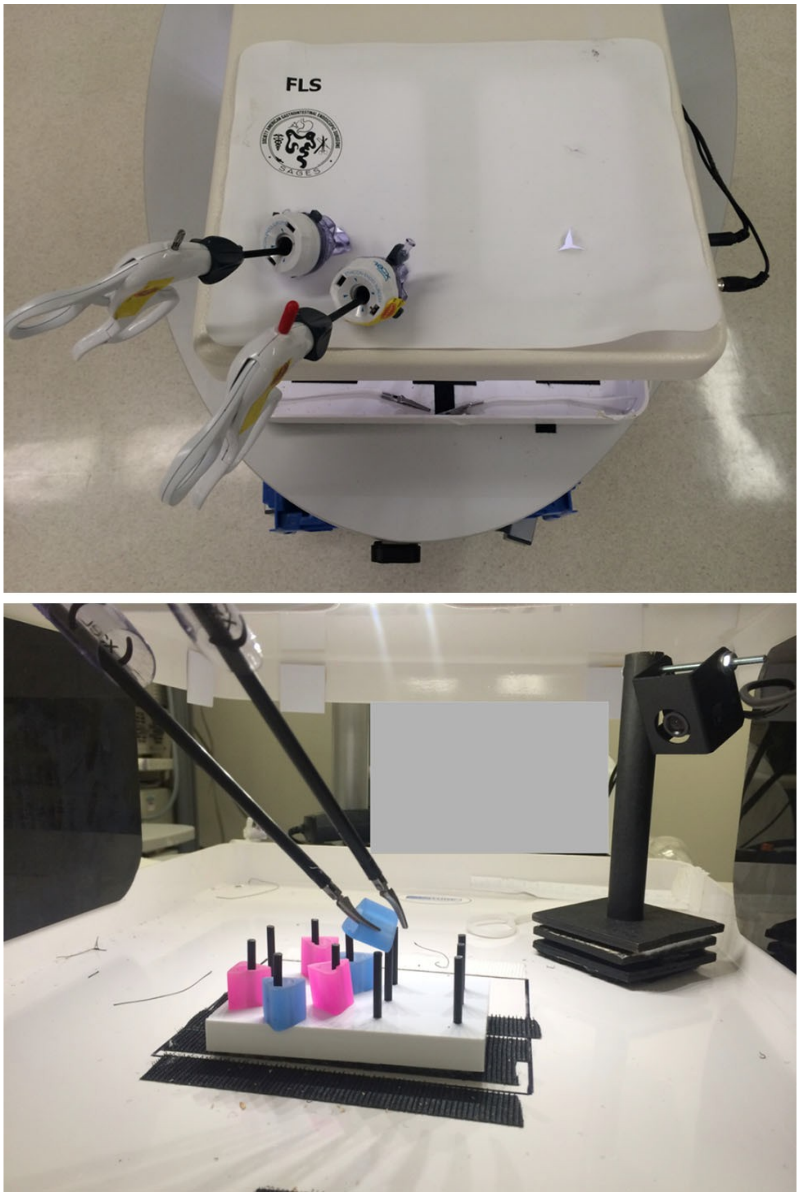

Figure 1 External and internal view of FLS trainer modifications

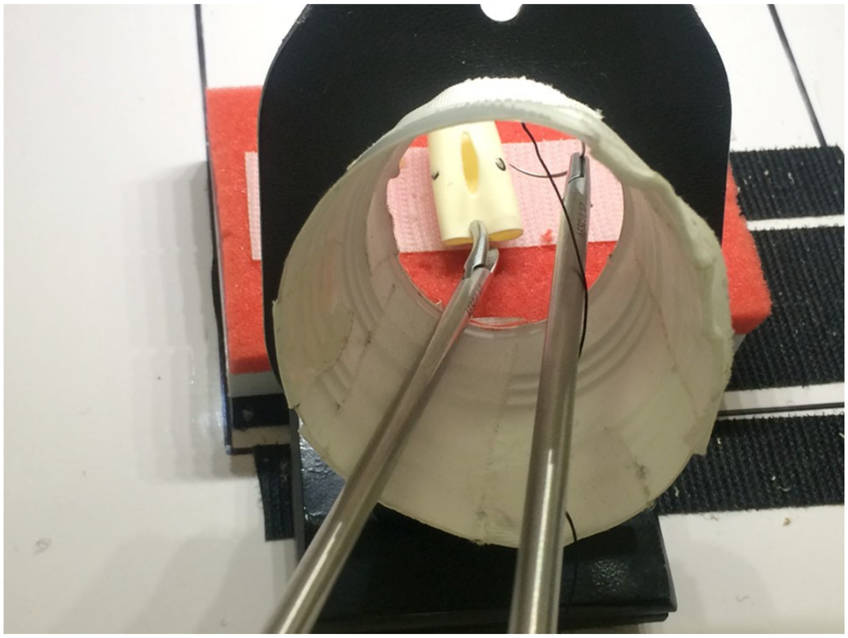

Figure. 2 Confined space suturing task

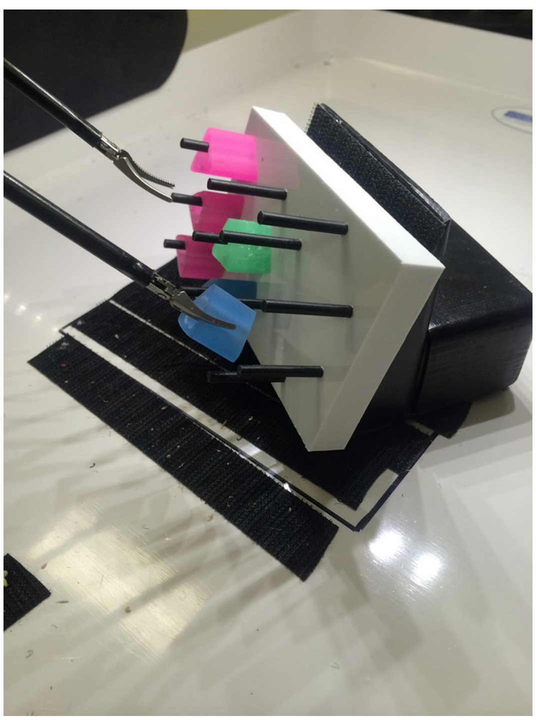

Figure 3 Peg transfer on the block in the vertical plane

MD type	Full cohort *N* = 48	Novice *N* = 11	Intermediate *N* = 12	Expert *N* = 25
Attending	31.3 % (15)			60.0 % (15)
Fellow	6.3 % (3)			12.0 % (3)
Resident	62.5 % (30)	100 % (11)	100 % (12)	28.0 % (7)
Years of experience median (min–max)	5.0 (1.0–27.0)	1.0 (1.0–2.0)	4.0 (3.0–4.0)	12.0 (5.0–27.0)
Practice				
Colorectal	4.2 % (2)			8.0 % (2)
GYN	10.4 % (5)			20.0 % (5)
General/MIS/bariatric	50.0 % (24)	45.5 % (5)	66.7 % (8)	44.0 % (11)
Urology	35.4 % (17)	54.5 % (6)	33.3 % (4)	28.0 % (7)

Table 1. Demographics

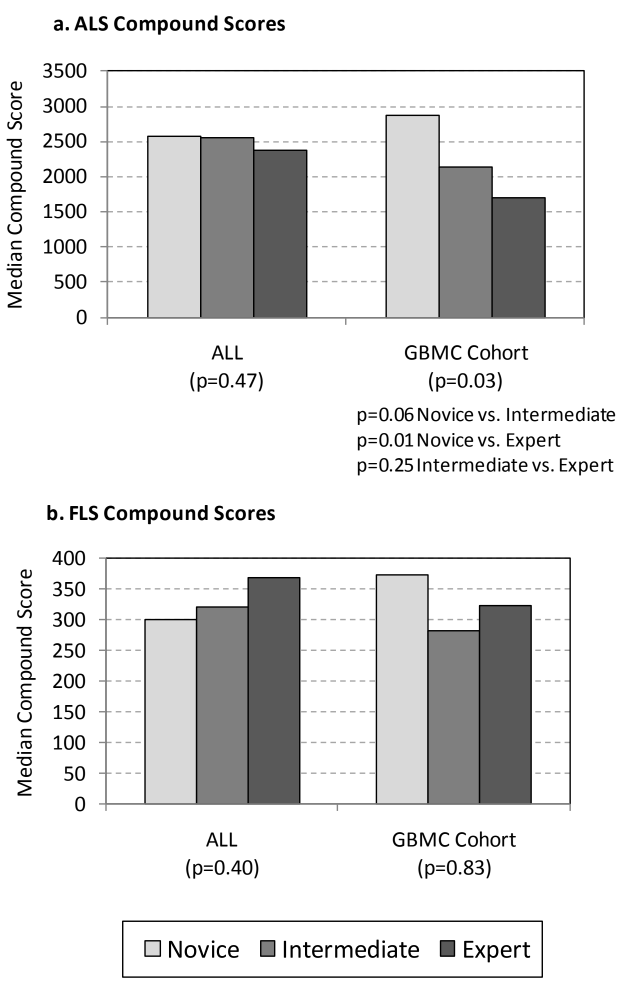

Figure 4. Combined FLS and ALS performance for entire cohort vs GMBC sub-group

1. *We need to improve on the current surgical skills training of residents.*

Vast majority agreed and felt that simulation lab practice time was essential to current residency training.

2. *I think that surgeons should be required to pass the FLS in order to practice surgery.*

Vast majority felt that it is necessary to demonstrate proficiency in baseline surgical skills.

3. *I think that FLS is a good representation of skills required for clinical laparoscopic surgery*.

Majority response was that it is a good representation of basic skills required in laparoscopic surgery. Secondary response was that the skills were too basic.

4. *I think that ALS is a good representation of skills required for clinical laparoscopic surgery*.

Majority response was that the skills were realistic and more challenging reflecting certain clinical situations. However, a few respondents felt that some of the tasks were too difficult and unrealistic.

5. *Which set of ALS skills was most relevant to training for real laparoscopic surgery?*

Majority felt that all the tasks were relevant, however, when specific tasks were mentioned, off-set camera and confined space were the most positively perceived tasks and the reverse angle peg transfer the most negatively perceived task.

Table 3 Thematic review of expert surgeon's responses (questionnaire questions/statements in italics)

Variable	General/MIS/Bariatric (N=26)	Others (N=22)	p-value**
Experience (yrs) median <q1-q3> (n)	4.5 < 1- 27> (26)	5 < 1- 27> (22)	0.7153
Experience (yrs) mean +/- std dev (n)	10.1 +/- 10.4 (26)	9.2 +/- 9.9 (22)	
Skill	N=26	N=22	0.5659
Expert	50.0% (13)	54.5% (12)	
Intermediate	30.8% (8)	18.2% (4)	
Novice	19.2% (5)	27.3% (6)	
MD type	N=26	N=22	0.2525
Attending	30.8% (8)	31.8% (7)	
Fellow	11.5% (3)	0% (0)	
Resident	57.7% (15)	68.2% (15)	
Practice	N=26	N=22	
General/MIS/Bariatric	92.3% (24)	0% (0)	
Colorectal	7.7% (2)	0% (0)	
GYN	0% (0)	22.7% (5)	
Urology	0% (0)	77.3% (17)	
Performance Metrics: median <minimum-maximum> (n)			
FLS Compound score	303 < 177- 742> (26)	450 < 207 – 1336 > (22)	0.0035
ALS Compound score	2157 < 1008- 4263> (26)	2818 < 1656- 4445> (22)	0.0027
FLS peg	61< 36-128> (26)	68.5 < 36 -143> (22)	0.1786
FLS circle	129 < 51- 450> (26)	135 < 49 - 300> (22)	0.4137
FLS suture	112 < 55- 296> (26)	182 < 122- 900> (22)	0.0002
ALS peg offset	122 < 65 - 231> (26)	163< 99- 246> (22)	0.0331
ALS peg block	153 < 107- 237> (26)	180 < 111- 450> (22)	0.0822
ALS reversey	585 < 123- 765> (26)	649< 378- 720> (22)	0.0639
ALS circle block	304 < 147- 450> (26)	324 < 159- 450> (22)	0.2815
ALS suture offset	247 < 92- 900> (26)	452 < 183- 900> (22)	0.0036
ALS suture backhand	266 < 119- 900> (26)	387 < 219- 900> (22)	0.0197
ALS suture confined	278 < 117- 900> (26)	559 < 244- 900> (22)	0.0074

** P-value chi-square test (md type) or
Kruskal-Wallis test (all other measures)

Table 2. Task performance by specialty

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Chapter 4: Choosing Tasks

In the previous chapter, we described the initial development of ALS tasks. In this chapter, which describes an un-published follow up study that we conducted, we build evidence of internal structure validity, by removing tasks that do not differentiate between levels of proficiency. In our initial study, we realized the need to focus our curriculum on general surgeons only, and thus we went back and recruited additional subjects just from this sub-set to increase our validity of response process and content. As a result, we identified 3 tasks that were able to differentiate levels of performance and represent the greatest opportunities for training. What we found the most interesting and gratifying was that the three tasks were laparoscopic suturing tasks! This further contributed to our content validity since the national needs assessment survey identified the same skills as being needed the most in an ALS curriculum.

Towards an Advanced Laparoscopic Skills Curriculum: Which tasks measure expert skill?

Author Contributions:

Richard Birkett – manuscript preparation, subject recruitment
Jim Whitledge – subject recruitment
Ted Delmonico - subject recruitment
Robin Ruthazer – statistical analysis
Dmitry Nepomnayshy – study design, manuscript preparation and editing

Abstract:

Background: In order to develop an advanced laparoscopic skills (ALS) curriculum, we previously described an initial validity trial of a novel fundamentals of laparoscopic surgery (FLS) based task set that was able to discriminate performance of minimally invasive (MIS) surgeon experts compared to novices, which the FLS tasks could not do. However, the entire task set took 6-7 times longer to complete than the FLS tasks. The purpose of this study was to isolate specific ALS tasks that could discriminate experience level in order to consolidate the entire skill set and focus ALS skills simulation training.

Methods: General surgery residents, fellows and MIS general surgeons were recruited at 2 national meetings and 2 institutions. Subjects were timed on a series of 10 tasks, 3 FLS tasks and 7 ALS tasks, using a previously described FLS-based scoring system of time and errors. Groups were defined as expert (PGY5+), intermediate (PGY 3-4) and novice (PGY1-2). Scores between groups were compared using a non-parametric Kruskall-Wallis test.

Results: 51 General/MIS surgeons completed the trial. 15 attendings (29.4%), 5 fellows (9.8%), and 31 residents (60.8%) were stratified into novice (n=14), intermediate (n=13), and expert (n=24) groups. Pairwise comparisons showed no differences of FLS tasks between groups. However, when pairwise comparisons of groups were carried out for ALS tasks, the experts out-performed the novices (P=0.0003) and the intermediate group out-performed the novices (P=0.0256). When analyzing tasks individually, only suturing tasks revealed a difference between groups: experts had significantly better scores than novices on offset forehand suture (P=0.0001), offset backhand suture (P=0.0163) and confined space suture (P=0.0099) tasks. In addition, experts had better scores than the intermediates on offset suture (P=0.0162) and backhand suture (P=0.0465) tasks.

Conclusion: Out of 7 ALS tasks, 3 of them discriminate performance differences between levels of expertise. These tasks focus on advanced suturing skills with an offset camera, backhand suture, and working in a restricted space. Our data supports the incorporation of these tasks when building an ALS curriculum.

Background:

Surgical education is shifting to a competency-based model from the apprenticeship model. One of the competencies is the successful completion of the Fundamental of Laparoscopic Surgery (FLS) (1). This requirement was in part due to studies of basic laparoscopic skills simulation, which demonstrated improved skills transfer to the operating room (OR) for novices. Few opportunities exist for residents and fellows to achieve expert-level skill in advanced laparoscopic skills (ALS). Similar studies in ALS suggest paralleled benefits of higher level laparoscopy training translating into the operating room (2-4).

Roadblocks to expertise for a surgical trainee have been extensively discussed; most exhaustively is the limitation of the 80-hour work week, but there are additional barriers to surgical skill proficiency in residency. In the setting of compliance rules and oversight, intraoperative training of residents faces challenges. Safety has been implicated in a trend towards decreased resident autonomy (5-9), and training residents in the OR has been deemed inefficient and expensive (10,11). In addition, published surveys suggest residency and fellowship graduates lack confidence in ALS (12,13); concern has also been expressed by faculty and program directors regarding inability of residents and fellows to perform advanced laparoscopy independently (14). Although most feel that graduates are well-trained in basic laparoscopy, many believe there is a deficiency in advanced laparoscopic cases, especially ones requiring intracorporeal suturing (15-20). Data suggests that training programs can enhance a trainee's intraoperative experience, affecting the learning curve of laparoscopic skills without affecting patient outcomes (26). Studies linking task training with decreased intraoperative mistakes by residents, efficiency in terms of learning curve and cost, and preferred way of learning by residents highlight the need of a curriculum for training residents in ALS (21,22).

In an effort to begin establishing an ALS curriculum, we previously described an initial validity trial of a novel FLS- based task set that was able to discriminate performance of minimally invasive surgeon (MIS) experts compared to surgery residents whereas FLS tasks could not (23). However, expert feedback highlighted shortcomings in the task set. The area of greatest concern focused on the fact that the ALS task set took 6-7 times longer to complete than the FLS tasks and some tasks were felt to be too difficult and unrealistic, such as 180-degree reverse peg transfer. In this light, the purpose of the current was to isolate specific ALS tasks that could discriminate experience level in order to consolidate and focus the entire skill set, and develop expert-level benchmarks to be included in an ALS training curriculum.

Methods:

This study is a follow up study to our original work with the ALS task set. It includes additional subject recruitment and sub-group analysis as follows. In our original study, there was a significant discrepancy in the amount of advanced laparoscopic experience and training between subjects from Urology and Gynecology compared to those in Minimally Invasive and Bariatric Surgery. This discrepancy precluded inclusion of these subjects into our "Expert" group; thus, all Urology and Gynecology subjects were eliminated from the data pool for the current study. Based on our original power calculations, additional recruitment was required. We recruited an additional 27 Minimally Invasive and Bariatric surgeons from 2 institutions and 2 national meetings to achieve our final subject count of 51.

All subjects were timed on the series of tasks. Data was compiled and analyzed as previously described. The series of 10 tasks included 3 groups of tasks in the following sequence: 4 peg transfer tasks, 2 pattern cut tasks and 4 suturing tasks. All subjects completed the tasks in the same sequence- with the FLS task followed by the ALS tasks, described in detail in our previous work (3). Time and errors were based on the FLS scoring system and penalties were recorded and added to the task time. Lower scores represent better performance. Subjects were divided into groups based on their years of experience defined as expert (PGY5+), intermediate (PGY 3-4) and novice (PGY1-2).

A non-parametric Kruskal-Wallis test was used to compare the FLS and ALS tasks, as well as to compare each individual task between groups. When the omnibus test was significant at the $p \leq 0.05$ level, the groups were further compared as 3 sets of pairwise comparisons, still using the same test, and a Bonferroni-corrected threshold of $p \leq .0167$ (.05 / 3) was applied to determine significance between the 2 groups within each pair. Times and composite scores were summarized for each group as medians and interquartile ranges. The SAS system for Windows version 9.3 was used for data analyses [reference: SAS Institute © 2002-2010, Cary, NC.]

Results:
A total of 51 subjects from General, Bariatric, Minimally Invasive and Colorectal Surgery specialties completed the study: 15 attending surgeons (29.4%), 5 fellows (9.8%) and 31 residents (60.8%). Divided into 3 groups by experience, there were 14

novices (27.4%), 13 intermediate (25.5%) and 24 experts (47.1%). The mean experience of GBMC experts was 14.5 years +/- 9.1 (range 5-27). (Table 1). Analysis of FLS tasks and ALS tasks separately revealed differences in overall performance between experience groups only in the ALS tasks; no difference was found between experience levels in the FLS tasks ($p = 0.7081$). Comparison of ALS task times between experience groups demonstrated the intermediate group out-performing the novice group ($p = 0.0256$) and the experts outperforming the novice group (0.0003). No significant difference in performance was demonstrated between the intermediate and expert groups on the ALS tasks ($p = 0.0605$). (Table 2). Comparison by task revealed a significant difference in performance in 3 of the 7 ALS tasks: offset forehand suture ($p = 0.0001$), backhand suture ($p = 0.0163$) and confined-space suturing (0.0249). All other tasks failed to demonstrate a significant difference in performance based on experience. Further analysis in these 3 tasks found experts to have significantly better scores than novices in offset forehand suture ($p = <0.0001$), offset backhand suture ($p = 0.0163$) and confined space suture ($p = 0.0099$). In addition, experts had better scores than the intermediates in offset suture ($p = 0.0162$) and backhand suture ($p = 0.0465$). We did not find performance differences between the novice and intermediate groups in these 3 tasks. (Table 3).

Discussion:

The results of the study demonstrate 3 advanced laparoscopic tasks that were able to stratify performance by expertise level, which focused on intracorporeal suturing skills. Modification of trocar and camera position resulted in greater time required for novice and intermediate group subjects to finish the tasks, whereas the more experienced surgeons completed these tasks in comparable time. This suggests that tasks mimicking realistic intraoperative conditions where trocar and operative site positions are not in an equal midline plane, require more advanced laparoscopic aptitude for faster times.

The offset suturing task was best able to discriminate the laparoscopic expert from both the intermediate and novice surgeons. Although not statistically significant, the compound score in the offset suturing task for novice subjects was 492.2 seconds, compared to 313 seconds in the intermediate group ($p = 0.0750$). Compared to the other 2 ALS suturing tasks, the offset suturing task came closest to discriminating the novice from the intermediate, thus reinforcing the conclusion that this task could most accurately stratify the trainee by skill level. The failure for the 3 ALS tasks to find a significant difference between the lower 2 skill levels could be a reflection of the learning curve in advanced laparoscopy, with a greater discrepancy in skill level between mid-level residents and experts, versus novice and mid-level trainees. This could be an opportunity to study further task modification for skill assessment of the 2 non-expert levels.

Box-trainers have been demonstrated to be effective tools in training residents in basic laparoscopy, and have been the standard of laparoscopic proficiency in general surgery residencies (24-27). This type of trainer is comparable to a simulator in developing advanced suturing skills and is more cost effective (28). In our study, we showed that when elements of off-midline camera positioning, restricted space, and close hand positioning were introduced, suturing tasks were able to differentiate between skill levels. In development of a laparoscopic training curriculum, tasks focused on intracorporeal suturing could be included not only to develop trainees' skills but also to create milestones for determining proficiency in advanced laparoscopy.

There are limitations to our study. It was impossible to recreate identical testing environments for all testing sites, as subjects were tested in different locations. In addition, there were a total of 3 different timers used for the study. All timers were instructed and trained together at the same site; however, timing was completed by only 1 timer per subject which could potentially lead to score variability between timers.

Moving forward, we would like to see creation of an ALS curriculum for development of skills that are transferable to the operating room. We believe that advanced intracorporeal suturing tasks would be an integral component to such curriculum and could be used to train laparoscopic surgeons to expertise. Important in the development of such a curriculum would be the establishment of expert proficiency standards. Once tasks that show promise for inclusion into an ALS curriculum are identified, further research should develop scoring and assessment tools to define these proficiency goals. Ultimately, we hope for a randomized controlled trial to investigate the effects of training with use of an ALS curriculum on operative performance

MD Type	Full Cohort N = 51	Novice N = 14	Intermediate N = 13	Expert N = 24
Attending	29.4 % (15)			62.5 % (15)
Fellow	9.8 % (5)			20.8 % (5)
Resident	60.8 % (31)	100 % (14)	100 % (13)	16.7 % (4)
Years of experience mean +/- SD	8.1 +/- 8.8	1.1 +/- 0.4	3.7 +/- 0.5	14.5 +/- 9.1
Practice				
Bariatric	2.0 % (1)			4.2 % (1)
Colorectal	3.9 % (2)			8.3 % (2)
MIS/Bariatric	47.1 % (24)	35.7 % (5)	61.5 % (8)	45.8 % (11)
Gen Surg/MIS	11.8 % (6)			25.0 % (6)
Unspecified	35.8 % (18)	64.3 % (9)	38.5 % (5)	16.7 % (4)

Table 1. Demographics

	Compound Score (Seconds) N = 51	Novice N = 14	Intermediate N = 13	Expert N = 24	Overall P value	Novice vs. Intermediate P value	Novice vs. Expert P value	Intermediate vs. Expert P value
FLS median (min-max)	323 [161-742]	331 [200-662]	287 [177-742]	331.8 [161-742]	0.7081	0.6275	0.3968	0.8486
ALS median (min – max)	2231.0 [726.0-4263.3]	2906.9 [2069.0-4030.0]	2180.0 [1619.0-3565.0]	1781.3 [726.0-4263.3]	**0.0006**	0.0256	0.0003	0.0605

Table 2: FLS vs ALS performance

Task	Compound Score (Seconds) N = 51	Novice N = 14	Intermediate N = 13	Expert N = 24	Overall P value	Novice vs. Intermediate P value	Novice vs. Expert P value	Intermediate vs. Expert P value
FLS peg	66.0 [35.8-164.0]	58.3 [37.8-128.0]	67.0 [35.8-164.0]	68.4 [36.2-128.0]	0.1827	0.3957	0.0766	0.3398
FLS circle	117.0 [42.0-450.0]	124.0 [78.0-186.9]	115.0 [63.0-450.0]	121.5 [42.0-240.0]	0.9372	0.7340	0.7853	0.8987
FLS suture	126.0 [55.0-390.0]	170.5 [73.0-390.0]	126.0 [55.1-222.0]	114.5 [55.0-340.0]	0.1341	0.3318	0.0458	0.3991
ALS peg offset	139.0 [64.8-265.0]	144.5 [78.0-265.0]	139.0 [80.0-207.0]	133.2 [64.8-206.6]	0.4108	0.4966	0.2146	0.4641
ALS peg block	170.0 [92.0-450.0]	191.0 [107.0-450.0]	161.0 [120.4-229.0]	156.0 [92.0-258.0]	0.5376	0.3197	0.3328	0.8237
ALS reversey	660.0 [123.0-765.0]	675.0 [506.3-720.0]	645.1 [123.0-701.3]	556.8 [144.0-765.0]	0.1022	0.0846	0.0425	0.8719
ALS circle block	250.0 [88.0-450.0]	289.0 [189.0-450.0]	235.0 [127.0-450.0]	240.5 [88.0-450.0]	0.0883	0.1323	0.0293	0.7502
ALS suture offset	296.0 [89.0-900.0]	492.2 [167.0-900.0]	313.0 [131.2-900.0]	193.7 [89.0-900.0]	**0.0001**	0.0750	**<.0001**	**0.0162**
ALS suture backhand	288.0 [81.0-900.0]	423.0 [173.0-900.0]	355.0 [155.0-900.0]	223.5 [81.0-900.0]	**0.0163**	0.4069	**0.0099**	**0.0465**
ALS suture confined	336.0 [117.0-900.0]	518.5 [241.1-900.0]	358.0 [127.1-900.0]	277.0 [117.0-900.0]	**0.0249**	0.3315	**0.0099**	0.1098

Table 3: Performance comparison by task

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Chapter 5: Setting Expert Performance Score for ALS

This work described in this chapter started with a little serendipity that resulted in a productive collaboration. As our group was working on the ALS curriculum, we were honing in on laparoscopic suturing tasks as the most important first step. Another group at McGill University, working on a similar project, was also coming to the same conclusion that a more advanced curriculum in laparoscopic suturing was needed. They started with similar ideas of having an inexpensive task models that can be added to any laparoscopic box trainer. But they focused on 3 different – and turns out complementary - tasks that we did not have in our curriculum, but we felt to be important. These tasks were developed as part of a separate needs assessment and expert focus group opinion and included: needle handling, suturing under tension, and continuous suturing. (1) Together, we combined our efforts, and added their tasks to our tasks (off-angle suturing, back hand suturing and confined space suturing) together to make a six task ALS suturing curriculum. (Figure 1.)

The next step was to establish expert performance benchmarks for this curriculum. We conducted a multi-institutional study with 17 expert surgeons at 7 different institutions across the U.S. and Canada. Experts were defined as surgeons that performed at least 25 laparoscopic suturing operations per year without the use of assisting devices like the surgical robot or Endostitch™. The proficiency benchmarks were reported in time and error (Table 1) with very few errors conducted by experts. As a result of this study, we were able to provide trainees with goal directed learning, as well as a valid representation of ALS expertise.

Task	Mean time (95% CI)*	Median accuracy scores (25th-75th percentile)
Needle handling	169 (149-189)	0 (0-0) needles dropped outside field of view
Offset-camera forehand suture	158 (134-181)	1 (0-2) mm off from the dots 0 (0-0) mm gaps in closure 0 (0-0) knot security error
Offset-camera backhand suture	189 (154-224)	
Confined space suture	181 (156-205)	1 (0-2) mm off from the dots 0 (0-0) mm gaps in closure 0 (0-1) knot security error
Suturing under tension	379 (334-423)	0 (0-0) mm off from the dots 0 (0-0) mm gaps in closure 0 (0-0) knot security error
Continuous suturing	416 (354-477)	1 (0-3) mm off from the dots 0 (0-0) mm gaps in closure 0 (0-0) knot security error 0 (0-0) skipped dots

*Time reported in seconds

Table 1. Performance-based proficiency benchmarks (Bilgic et al.)

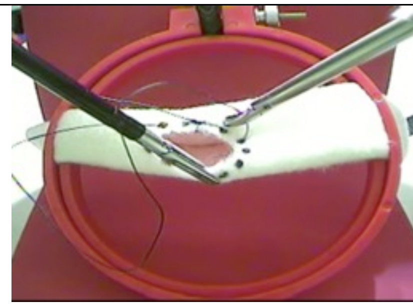
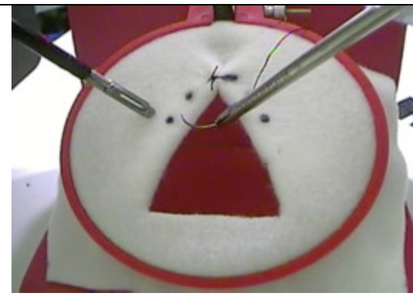
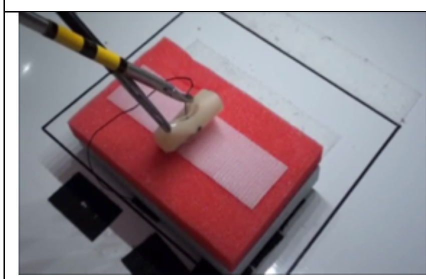
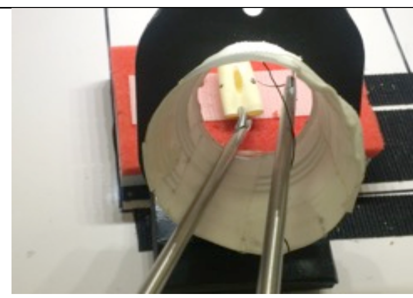
 Needle handling	 Continuous suturing
 Off-set forehand suturing	 Suturing under tension
 Off-set backhand suturing	 Suturing in a confined space

Figure 1. Complete Set of Advanced Laparoscopic Skills (ALS) Tasks

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Chapter 6: Conclusion

As we transition to a proficiency-based model of surgical education, we have identified a need to teach and assess more advanced laparoscopic skills. The evidence for this need is well documented in previous chapters, and stems from surveys of residents, fellows and program directors about the skills and readiness of graduating chief residents to operate independently. (chapter 2) The Advanced Laparoscopic Skills (ALS) curriculum is being developed to address this need. Based on previously published needs assessments, the greatest need exists in teaching and assessing laparoscopic suturing skills, and this is the domain that the curriculum currently addresses in a set of 6 tasks: needle positioning, offset forehand suturing, offset backhand suturing, suturing under tension, suturing in a confined space and continuous suturing.

This thesis demonstrates evidence of validity for this curriculum according to the modern validity framework based on the Standards of Educational and Psychological Testing (1). Evidence of content validity has been shown by the fact that multiple experts, from the U.S. and Canada have provided input on the tasks. The experts were queried by different investigators at different time points using different instruments (surveys and focus groups) to arrive at the current ALS task set. Chapter 2, 3 (2,3) Evidence of response process validity lies in the fact that we use the same scoring rubric of time and error that exists for another well validated curriculum – Fundamentals of Laparoscopic Surgery (FLS). Our curriculum is created to be used with the same equipment as the widely used FLS box, needle holders and suture, with several minor modifications. In addition, we have shown high (0.99) inter-rater reliability in scoring the ALS tasks (4). Next, we have demonstrated evidence of internal structure validity by analyzing performance on ALS tasks, and removing the tasks that did not differentiate performance. (chapter 4) We also demonstrated evidence of relation to other variables by showing that performance on these tasks can differentiate between advanced beginners, competency and expertise in the domain of laparoscopic suturing. (chapter 3) (5). We also documented evidence of relating to consequences, in that we set proficiency standards for the curriculum, with the intention that eventually, a pass/fail determination could be made as part of a high stakes assessment. (4) Although we do not have enough data to have a valid high-stakes assessment at this time, this work represents the first series of steps in that direction.

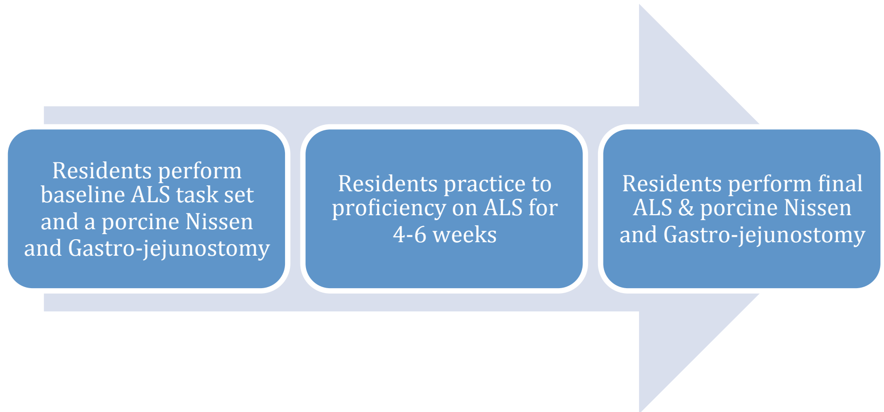
The ultimate goal in having a valid high-stakes assessment for advanced laparoscopic suturing would be to use it for certification, credentialing and re-credentialing. It is reasonable to assume that a given surgeon's scope of practice in their job may be different than their residency or fellowship training. As an example, a surgeon completing a colorectal fellowship may join a practice where they do all the abdominal wall hernias and cover trauma call. Therefore, we should expect the surgeon to demonstrate the skills necessary for their job, as they change jobs and as their practice changes in a given job. In addition, we know that many domains of surgical expertise develop after completion of residency. Therefore, assessing for expertise should also occur after residency training – possibly in fellowship or in practice - where one has been allowed to develop those skills to a sufficiently expert level. The proposed use of the ALS assessment and curriculum would include objectively assessing the domains of expertise in laparoscopic suturing for anyone who seeks to perform an operation which requires laparoscopic suturing. These would include bariatric surgery or any advanced GI surgery including hernia surgery. Ideally, all surgeons should demonstrate those skills prior to obtaining privileges to perform those procedures in their place of employment. The time to achieve expertise will be variable, and will require supervision by an expert surgeon until those skills have been assessed as being at an expert level for the trainee surgeon. This can be done in fellowship or in practice. In addition, a surgeon's on-going ability to demonstrate skills required to perform certain operations should be re-assessed periodically during their career. Practice patterns change in a given job and certain cases become less common. People take time off for personal or military responsibilities. Technical skills deteriorate from lack of practice or as a result of the normal aging process or illness. An objective and valid assessment of the skills would address those concerns and provide clarity on when someone is still "fit for duty".

This thesis describes evidence of validity for using the advanced laparoscopic skills curriculum (ALS) by addressing all components of the modern validity framework – evidence of content validity, evidence of internal structure validity, evidence of relation to other variables and evidence of relating to consequences (6,7). It represents one of the methodologically most rigorous examples of curriculum development in the literature. However, in order to build evidence for wide-spread adoption and ultimately it's use as a high stakes assessment, additional work is needed to build evidence of how ALS relates to other variables, specifically does practicing on ALS lead to clinical expertise in the domain of laparoscopic suturing?

Future Directions – The Next Study

In order to build additional validity evidence of how the ALS curriculum relates to other variables, specifically clinical performance, we want to see if training on the ALS curriculum improves clinical performance, and if ALS performance correlates with clinical performance. We will use a porcine tissue model to assess for clinical performance. (Figure 1,2) This type of model has been used in the past, (8) for suturing assessment, and the authors have experience using this model for routine simulation education as part of the training curriculum for surgery residents. We will have subjects perform two advanced suturing operations, (Nissen fundoplication, and entero-enterostomy closure after a bowel anastomosis) focusing on just the suturing portions from those procedures to allow for curricular alignment with ALS. Therefore, the "clinical" tasks consist of placing 3 stitches for the Nissen fundoplication wrap, and a running suture closure of a gastro-jejunostomy anastomosis. Performance on the porcine tasks will be recorded, deidentified, and analyzed by 3 expert raters using an existing suturing assessment instrument (9). (Figure 3)

Proposed Study Protocol



All residents will perform the six ALS task to assess their baseline abilities as well as a porcine Nissen and a Gastro-jejunostomy. Then, the residents are instructed to practice on their own to proficiency. Baseline and final ALS performance will be recorded and assessed using previously established metrics of time and error (Chapter 5). Trainees will also be assessed on the Nissen and Gastro-jejunostomy tasks prior to ALS practice and at the conclusion of practice. Performance on the clinical tasks will be compared before and after ALS practice. We hope that the results of this latest study will contribute to the overall validity of the ALS curriculum and lead to it's widespread adoption.

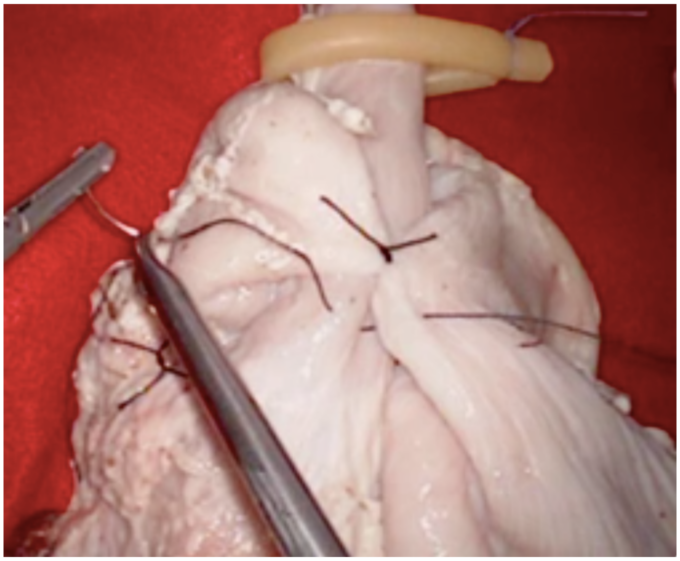


Figure 1. Porcine model of Nissen fundoplication

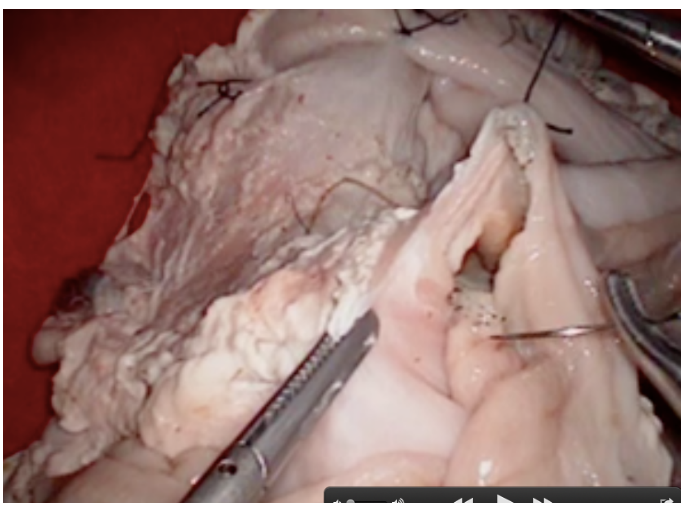


Figure 2. Porcine model of gastro-jejunostomy

			Yes=1, No=0
Needle position-1	1	Held at ½ to 2/3 from the tip	
	2	Angle = 90° ± 20°	
	3	Uses tissue or other instruments for stability	
	4	Attempt at positioning (3 or <3)	
Needle driving through tissue-1 (entry to incision)	5	Entry at 60°-90° to the tissue plane	
	6	Driving with one movement	
	7	Single point of entry through tissue	
	8	Removing the needle along its curve	
Needle position-2 (incision to exit)	9	Held at 1/2 to 2/3 from the tip	
	10	Angle- 90° ± 20°	
	11	Uses tissue or other instrument for stability	
	12	Attempts (3 or <3)	
Needle driving-2 (incision to exit)	13	Driving with one movement	
	14	Removing the needle along its curve	
Pulling the suture through	15	Needle on needle holder in view at all times	
	16	Using pulley concept or walking along the suture	
Technique of knots	17	Two-handed overwrap/underwrap followed by same or if one-handed, one followed by the other	
	18	Correct C loop (no S or O loops)	
	19	Smoothly executed throw, no fumbles	
	20	Correct inverse C loop (no S or O loop)	
	21	Smoothly executed throw, no fumbles	
	22	Knot squared (capsized reef/surgical)	
	23	Correct third C loop (no S or O loops)	
	24	Smoothly executed throw, no fumbles	
Knot slippage	25	Knot left loose to slip	
	26	Knot slippage attempts 3 or <3	
Knot quality	27	All throws squared	
	28	Not too tight or too loose	
	29	All knots laid on the side (not over the incision)	
		Total Score (maximum 29)	

Figure 3. Suturing assessment instrument (Moorthey et al.)

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