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A Novel Virtual Reality Curriculum Improves Laparoscopic Skill in Novices

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A Novel Virtual Reality Curriculum Improves Laparoscopic Skill in Novices

A Thesis Submitted to the
Yale University School of Medicine
in Partial Fulfillment of the Requirements for the
Degree of Doctor of Medicine

By Michael Joel Martinez

Yale School of Medicine – Graduating Class 2009

Thesis Advisor: Andrew J. Duffy, MD, Assistant Professor, Department of Surgery

A NOVEL VIRTUAL REALITY-BASED CURRICULUM IMPROVES LAPAROSCOPIC SKILL IN NOVICES. Michael Joel Martinez, Andrew John Duffy. Department of Surgery, Yale School of Medicine, New Haven, CT.

Surgical skills training, facing work hours restrictions and increasing numbers of procedural skills to master, requires an innovative approach to ensure success. We developed a novel basic laparoscopic skill, virtual reality-based simulator curriculum on the LapSim (Surgical Science, Goteborg, Sweden), with a training module and a skills exam enabling trainees to develop a minimum skill level. We hypothesize that unskilled trainees' laparoscopic skills performance will improve when compared to controls. Also, those who are able to successfully complete our training curriculum and pass the exam will demonstrate higher skills levels compared to non-passers during the training period. We anticipate that skills will begin to degrade after a period 30 days without repetitive training. We expect that individual trainee performance will correlate with past experience with video games, sports, or musical instruments.

Thirty-two novice, pre-clinical medical students were randomized to various training schedules. All students trained on the curriculum with the goal of completing the practice drills and passing the skills exam. Students' laparoscopic skills were assessed at baseline and at monthly intervals using two tasks from the Fundamentals of Laparoscopic Surgery (FLS) curriculum that are known to correlate with operative laparoscopic skill. Additional FLS testing was performed after a one month layoff to evaluate short-term skill degradation. Objective skill FLS scores were compared between training and non-training groups, and between passing and non-passing groups at the completion of the study. All participants prior experiences with video games, sports and musical instruments were correlated with study performance.

Training improved FLS performance for all participants. There was significantly greater skill development in passers versus non-passer ($p < 0.05$). Skills did not degrade after a 30 day layoff but continued to improve for all participants even reaching a statistically significant improvement on one task. Performance was not correlated with past video game, sports, or musical instrument experience.

Trainees who successfully completed the our curriculum demonstrated significantly higher laparoscopic skills. These skills should translate to improved operative performance. Skills were retained after the last training session and demonstrated improvement at 30 days. We demonstrated no performance correlation with prior video game, sports or musical experience.

Acknowledgements

This work is dedicated to the loving memory of my father (May 25, 1950 - Aug 30, 2007) who taught me about love, honor and dignity. My family, specifically my mother, brother and sister, were and are instrumental in all my accomplishments and continue to be a driving force on my journey in medicine and life. Jessica, thank you for your love and support.

My advisor, Dr. Andrew Duffy, has been a mentor in the truest sense of the word. He has taught me by example the ideals of professionalism, hard work, and reinforced the importance of life perspective. Lucian Panait, MD was instrumental in this thesis as was statistician James Dziura, PhD. Former Dean Ruth Katz gave me the chance to come to this incomparable institution and I am forever grateful. Dean Nancy Angoff, Terry Tolson, Richard Silverman, and other administrators and staff gave me unwavering support in the midst of my loss.

My many classmates as well, made me feel as though I was part of a real family (Vinita). Last, but not least, thank you to my best friends Lou and Dario for all their assistance (professional and otherwise). Because of all these people and so many others, the people of South Texas will someday (hopefully) have a physician and an advocate that does them justice.

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Section 1 – Introduction

The field of surgery has had its greatest period of advancement over the last 50 years, specifically over the last 20 to 30. But that advancement in the practice of surgery has not translated into advancement or innovation in the training of surgeons. Now that the need for innovative ways to train residents has become obvious, it has also become increasingly difficult [1]. Several factors have conspired to necessitate a true shift in the delivery of general surgical education. As the mantra goes, “see one, do one, teach one”. This has served as the basis for much of formal surgical education since the days William Stewart Halsted first began formally training surgical residents in the United States in the late 1800’s. A Yale alumnus, Halsted, is considered the most influential American surgeon due in part to his many advances in techniques (first emergency blood transfusion, 1882, and extensive use of sterile surgical techniques), equipment (first surgical gloves, 1889), and his mentorship of influential pupils (fellow Yale alumnus Harvey Cushing, the father of modern neurosurgery) [2, 3].

While there is no denying that Halsted’s approach of seeing, then doing, then teaching continues to have a place in modern surgical and medical education, there is also no denying that we are at a point in time where it is no longer sufficient in and of itself. Specifically, the approach to abdominal surgery has been significantly changed by the advent of endoscopic techniques (laparoscopy). Though endoscopy has enabled great progress to be made in many fields (gynecology, thoracic surgery, etc), for the purpose of this paper and discussion we will focus on laparoscopy (which is specifically endoscopy of the abdominal cavity). What was once merely a diagnostic tool with unknown treatment possibilities has evolved to become the standard of care treatment for many

specific abdominal procedures. Abdominal laparoscopy has been around since the early 1900's, used for basic procedures in animals. It has been continuously refined since then and has been in widespread use for a variety of procedures since the 1990's [4].

Innovations in surgical instruments (e.g. graspers, scissors, and clip appliers) have made laparoscopic techniques mainstream. The first widespread, and still most common, procedure for the laparoscopic surgeon is the laparoscopic cholecystectomy or removal of the gall bladder. We can use the evolution of this procedure as a microcosm for the current need for innovations in surgical education. It is also fitting that we mention this particular operation as Halsted performed one of the first cholecystectomies in America on his own mother [2].

Removal of the gall bladder is a procedure that has lent itself to developments in laparoscopy. In laymen's terms, the gall bladder can be described as a balloon with a duct system designed for the storage and, at the appropriate time, release of bile into the gastrointestinal tract. Removal of the gall bladder had not changed much in principle or form since the days of Halsted. The purpose of the procedure was to get adequate visualization so that you could tie off the blood supply and duct system, then cut out the gall bladder and close the patient. Until the advent of laparoscopy, this meant a 20-30cm incision along the right upper quadrant and flank of the abdomen. The gall bladder would then be visualized behind the liver and the procedure would be carried out. In modern laparoscopy, it is now routine that 2-4, 0.5-1cm incisions will accomplish the same goal [3], while surgeons in larger centers, such as here at Yale, have even begun to perform single incision operations (or even operations with no external incision, more on that later).

The benefits of laparoscopy go far beyond the aesthetics of a smaller scar(s). Patients have reduced blood loss during procedures and, in the case of abdominal surgeries, less adhesive scarring which may hinder subsequent procedures or even lead to complications such as bowel obstruction. Smaller incisions mean less pain and decreased need for narcotic pain medications. Patients often resume a normal diet and activity level more quickly. While procedure times can be longer than the “open” versions of the surgeries, the post-operative hospital time is often drastically less for patients undergoing laparoscopic procedures [5-8]. While there are many benefits laparoscopy is not without its specific risks as well.

The most glaring difference between laparoscopic and traditional “open” surgery is the surgeon’s dependence on laparoscopic instruments instead of traditional instruments and their hands. There is no direct ability for tactile feedback. Until the advent of laparoscopic surgery, the surgeon’s hands had been in contact with the operative field of the patient since the beginning of time. Visualizing the operative field meant looking right down into the area where your hands were working. Visualizing an obscured structure meant pushing another out of the way, often using your sense of touch to feel for tension so as not to apply too much force. Cutting, sewing and stapling were done with instruments that represented only the slightest extension of the finger tips, the scissor, a needle driver, or stapler.

This is simply not the case in laparoscopy. Visualization now means looking away from where your hands are working and towards a video screen. The screen is a two-dimensional representation of the three-dimensional space in which you are working [9-11]. You can no longer directly feel the organs with your finger tips nor simply reach

into move something out of the way. The formerly slight distance of a couple of inches from fingers to structures is now over a foot away. When once your actions with an instrument were directed straight towards a target, you now must compensate for such unique phenomena as the fulcrum effect [12]. This is the effect of using an instrument over a pivot point, in this case the trochar or the abdomen itself, which creates opposite directions of movement between the hand and the distal tip of the instrument (if the hand moves down the instrument tip moves up, etc.). Once the novice surgeon masters these techniques they will find that they are still beholden to the skills of open surgery as well. Adhesions from prior abdominal surgeries can make laparoscopic abdominal approaches difficult or entirely too dangerous. When complications do arise, or adhesions threaten the safety of a laparoscopic approach, surgeons may have to revert back to the “open” or traditional, non-laparoscopic approach.

It may seem obvious that laparoscopy involves a unique set of skills, but does the data bear this out or are the skills of open surgery applicable to mastering the skills of laparoscopy? Figert, et al, [13] used the skill of intracorporeal knot tying to examine so called “transfer of training”, or whether or not more advanced open surgical skill translated into more laparoscopic skill. They used interns with limited open or laparoscopic skill, junior residents with recent or current open and laparoscopic experience, and senior residents with remote and limited laparoscopic experience, but the highest level of ongoing open experience. The junior residents had fewer errors than the senior residents and were significantly faster than the interns. There was no significant difference between interns and senior residents in either error or time. The authors

concluded that open surgical experience did not transfer to laparoscopic skill and that specific training for laparoscopic techniques was necessary.

Herein lies the challenge for surgical education, the surgical resident must be taught the traditional, open method (of the cholecystectomy, for example) as well as this fairly new approach which is increasingly becoming the standard of care and the evidence says that the technical skills of one technique do not apply to the other. Teaching residents was a difficult enough task when laparoscopy offered alternative approaches to the cholecystectomy, appendectomy, or even inguinal hernia repairs. But laparoscopy now offers alternatives to complex foregut procedures (e.g. Nissen fundoplication for intractable gastroesophageal reflux disease), liver and gall bladder procedures, small and large bowel procedures (e.g. colectomies), abdominal wall procedures (e.g. prosthetic mesh placement for incisional hernia repairs), and even bariatric procedures for the treatment of obesity [4]. The trend is such that more procedures will continue to be approached laparoscopically making acquiring these skills a vital part of general surgical education.

The field of laparoscopic surgery is not satisfied with its current state of affairs either. Surgical innovation in instrument technology is now allowing for some procedures to be done through a single incision (so-called single port surgery). The future may even include no external incisions as various groups on the forefront of surgery are now attempting surgical approaches through natural anatomical orifices. NOTES stands for natural orifice transluminal endoscopic surgery. An endoscope may be passed through the mouth, urethra, vagina, or anus and an internal incision be made through the stomach, bladder, vaginal wall or colon. A group in India has performed

transgastric appendectomies. In 2007, a group performed the first transgastric cholecystectomy in humans [14, 15]. Transvaginal cholecystectomies have also been attempted and here at Yale, our own Dr. Kurt Roberts has already performed a transvaginal appendectomy. NOTES may very well represent the next great paradigm shift in abdominal surgery the way laparoscopy changed surgery in 1980's and 1990's [16-20].

However, despite the increased need for evermore specialized procedural proficiency, residency training is shorter in actual hours than it once was (owing to the 80 hour workweek restrictions). This is to say nothing of the ethical concerns regarding young surgeons gaining basic laparoscopic operative experience on actual patients or the tremendous costs of increased operating room time used to teach completely novice surgeons these rather foreign skills. Now more than ever the surgeon must hone ambidextrous skills to be able to operate tools efficiently in a very limited working space [21-23]. The response to these factors mentioned above has been to pursue surgical education innovations targeted at efficiently training new surgeons the specific skill sets they will need to be competent laparoscopic surgeons. The bulk of advancement in this endeavor has come through surgical simulation.

Animal models, box trainers and virtual reality simulators have all been proposed and tried as methods for training surgical trainees. Animal models involve using anesthetized animals which offers the most realistic non-human anatomical and tissue experience for the surgical trainee [24]. The pig abdomen roughly approximates the human abdomen in size and foregut anatomy and can be used for procedures such as cholecystectomy [25]. A canine model is often used as well. Though these models

offer certain benefits, there are distinct drawbacks to be sure. While ethical concerns can and should be addressed, it is cost that most likely prevents animal models from gaining widespread acceptance into the surgical curriculum [26]. There is significant cost associated with maintaining animals, facilities, and the appropriate staff that can undermine the practicality of this opportunity for residents.

The box trainer is essentially a box that approximates the size of the abdominal cavity and uses real laparoscopic tools, including camera and video setup. They allow for certain drills and activities to be done in the box (such as basic grasping and cutting or more advanced knot-tying) [27-29]. This experience simulates the motions, visual and tactile feedback (of grasping and tying, etc.), and allows the use of actual instruments. While the equipment itself is real, the objects being handled are far from real. Cadaveric tissue samples can be used for tasks such as knot tying and suturing, but the majority of drills are done with inanimate objects offering little in the realm of reality. Box trainers cost little to obtain and maintain though, which makes them a widely available training tool. Box trainers are the platform for drills that have come to be known as the Fundamentals of Laparoscopic Surgery (FLS) (more on FLS later) [28].

Virtual reality simulators, on the other hand, offer the ability to see virtual anatomical structures more approximate to what would be seen in an actual operative setting. There is also no chance of patient morbidity nor are there the ethics issues of animal models while climbing the learning curve on a virtual trainer. But perhaps the biggest advantage to virtual reality based simulators is the ability to track the progress of trainees by tracking such factors as errors, time to complete tasks, and attempts required to become proficient. Additionally, computer-based training modules on virtual reality

simulators can be tailored for the specific skill levels of the trainees using the system [30-34]. But this system is hardly perfect either. While advances continue, creating realistic virtual experiences remains a challenge given the costly technology in such areas as tactile feedback to the user. Haptic technology or force-feedback systems have and are being developed and refined, but they remain a work in progress [35, 36]. As the technology becomes more mainstream it is not a stretch to imagine, and is already becoming a reality, a cost-effective virtual reality-based system that provides simulations of entire procedures. Virtual reality simulation is the basis of our training curriculum.

Here at Yale, Dr. Andrew Duffy, the Associate Program Director of the Yale General Surgery Residency and the Director of the Yale Surgical Skills and Simulation Center developed a virtual reality-based curriculum for all residents to use prior to entering the operating room for laparoscopic cases. What was unique about our curriculum was the fact it was customized to benchmarked standards using Dr. Duffy and other fellowship-trained minimally invasive surgeons in the department. The parameters for the individual tasks were then set based on this information. The simulator that was used was the LapSim simulator (Surgical Science, Göteborg, Sweden). LapSim, like other commercially available simulators (e.g. Minimally Invasive Surgical Trainer – Virtual reality [MIST-VR], Mentice, Göthenburg, Sweden or LapMentor, Simbionix, USA Corp., Cleveland, OH) comes with preset metrics or parameters for its training exercises. But LapSim offers the ability to customize the metrics and exercise parameters over a wide range of settings, more than the current offerings from other manufacturers. Most of the literature contains data garnered from testing virtual reality trainers using the manufacture's preset settings [37-39].

The goal of the curriculum was to develop two handed coordination and depth perception in junior residents. The construct validity, or ability of the curriculum to differentiate various levels of skill, has been demonstrated previously [40]. More work is necessary to demonstrate that the curriculum actually improves skills in trainees. It is essential that this skill development translates to improved operative performance. We chose to test this by correlating performance on our curriculum with a validated proxy for operative performance, in this case tasks from the FLS.

The FLS is a teaching tool that uses both a written exam and box trainer drills to teach and assess the basic principles of laparoscopic surgery [41]. The FLS skills curriculum was based on work out of McGill University in Montreal, the McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS) program. It has been repeatedly validated as an objective measure of laparoscopic skill that correlates with operative performance [28, 29, 42-47]. A review from 2008 in the *Journal of Gastrointestinal Surgery* by Fried, the innovator responsible for MISTELS, discussed the rigorous scrutiny that has led to such an effective and widely accepted program. The FLS metrics have been tested and found to have reliability between raters (interrater reliability) as well as reliability between repeated testing of the same individual. An internal consistency of 0.86 was reported, higher than the cutoff of 0.80 generally required for important standardized tests [41]. The validity of the FLS skills curriculum (formerly MISTELS) has been rigorously scrutinized in many domains as well.

Content and face validity were assessed using minimally invasive surgical experts to establish whether or not the testing curriculum evaluated appropriate content and

contained an appropriate breadth of content. A global rating scale was used to confirm the validity of the curriculum content. Construct validity was also assessed. 215 surgeons from 5 different countries participated in studies that stratified surgeons by training level, experience, or self-assessed competence and found that the FLS metrics discerned appropriate differences in proficiency. Criterion or concrete validity, a measure of how well a variable can predict outcomes shows the extent to which various measures are related to “concrete” or real world criteria. It is further categorized into concurrent validity (how well a particular measure correlates with concrete criteria assessed simultaneously) and predictive validity (how well a measure predicts future outcomes). Studies involving the use of live animal simulation, objective intraoperative skill assessment, and technical skill evaluation reports concluded that FLS meets high reliability and validity standards [41].

FLS has evolved to become a proctored, objective exam that is now mandatory for all surgical residents. In 2008, the American Board of Surgeons announced that it would now require FLS certification in addition to Advanced Cardiac and Advanced Trauma Life Support (ACLS and ATLS) for all general surgery residents completing residency after July 1, 2009 (though it had been recommended since 2004 by such groups as the American College of Surgeons and the Society of American Gastrointestinal and Endoscopic Surgeons) [48]. Accepting that FLS can serve as an appropriate proxy for operative performance based on the evidence presented, we chose to use two basic tasks from the FLS skills curriculum against which to measure individual skill acquisition after training on the Yale virtual reality curriculum.

Section 2 – Purpose, Aims, Hypotheses

This study tests the acquisition and maintenance of basic laparoscopic skills from the Yale University Basic Laparoscopic Skills Curriculum, developed by Dr. Duffy, on a population of novices (in this case, first and second year medical students). Does the successful completion of our curriculum translate into improved operative skill as measured by two selected Fundamentals of Laparoscopic Surgery tasks? We answer that question and others.

The study will first address whether training in the curriculum has any significant benefit beyond that of becoming familiar with the laparoscopic equipment and FLS tasks. This is done by comparing a randomized training group with a randomized control group who is not allowed to train but will receive all orientation and familiarization with equipment and procedures as that of the training group. Following the training versus non-training control phase of our study, then all participants will be asked to attempt the curriculum with the goal of successful completion.

During this phase of the study we will compare those who pass our curriculum (passers) against those who do not (non-passers). We will explore whether or not any difference in skill can be quantified among those two groups. Assessing a difference between passers and non-passers is the most important aim of the study, because our curriculum is proficiency-based as opposed to being dependent on repetition. The Yale curriculum was designed with the goal of improving operative skill for junior residents upon successful completion of the curriculum.

A final phase of the study will determine the amount of skill drop-off after a specified period of not training. Questionnaires distributed before the experiment will be used after all data is acquired to assess for qualities common to those who demonstrate a more advanced level of proficiency. The purpose of this is to find out whether or not specific past experiences (video game playing, sports, musical instrument playing) that are thought to enhance coordination, translate to increased ability to acquire or maintain skill using our curriculum.

The Yale Basic Laparoscopic Skills Curriculum was designed by Dr. Andrew Duffy, MD, and is a virtual reality-based curriculum that is performance or proficiency-based as opposed to repetition driven. This means, that in order for participants to advance in the curriculum they have to proceed through progressively more difficult tasks. The goal of training in our curriculum is completion of all curriculum tasks and the post tests.

Hypotheses

1 – Our hypothesis is that one month of training in our curriculum, regardless of curriculum completion or not, will result in significant skill improvement compared with a randomized control group as measured by two basic FLS tasks (block transfer and pattern cutting).

2 – Successful completion of our curriculum in its entirety will result in significantly higher skill for those who pass, versus those who do not pass, as measured by FLS tasks.

3 – After a minimum 30 day non-training period away from our curriculum, we will begin to see skills degrade for all participants (passers and non-passers alike) as measured by FLS tasks.

4 – Participants who are able to complete our curriculum in its entirety will have had more experience with video games, sports, and musical instruments, based on self reported answers to a questionnaire given to all participants when compared with those who are unable to complete our curriculum.

Section 3 – Methods

Volunteers

Prior to beginning the study, a full HIC application was submitted and approved by the Yale HIC for our project to include human participants. All potential participants were given consent forms approved by the HIC prior to volunteering (Appendix 1). Volunteers were taken from 1st and 2nd year medical school classes, many of whom expressed interest in surgery through participation in a surgical interest group. All students, regardless of surgical interest group participation were allowed and encouraged to participate in our study. An email explaining the study was sent to the entire 1st and 2nd year medical school class. All students who expressed interest received informed consent forms detailing the study, its risks and its payment schedule (\$50 upon completion of the study in its entirety). Eventually, 38 first and second year students elected to participate in the study and were entered based on criteria that they had no surgical or simulator experience with laparoscopic equipment or procedures. Four volunteers withdrew from the study due to unwillingness to complete the entire study protocol, while 34 completed the first arm of the study in its entirety. Two more volunteers were disqualified for not adhering to the terms of their randomized group (the participants trained during a period of time when they were not supposed to be training), leaving 32 participants who completed all phases of the study in its entirety.

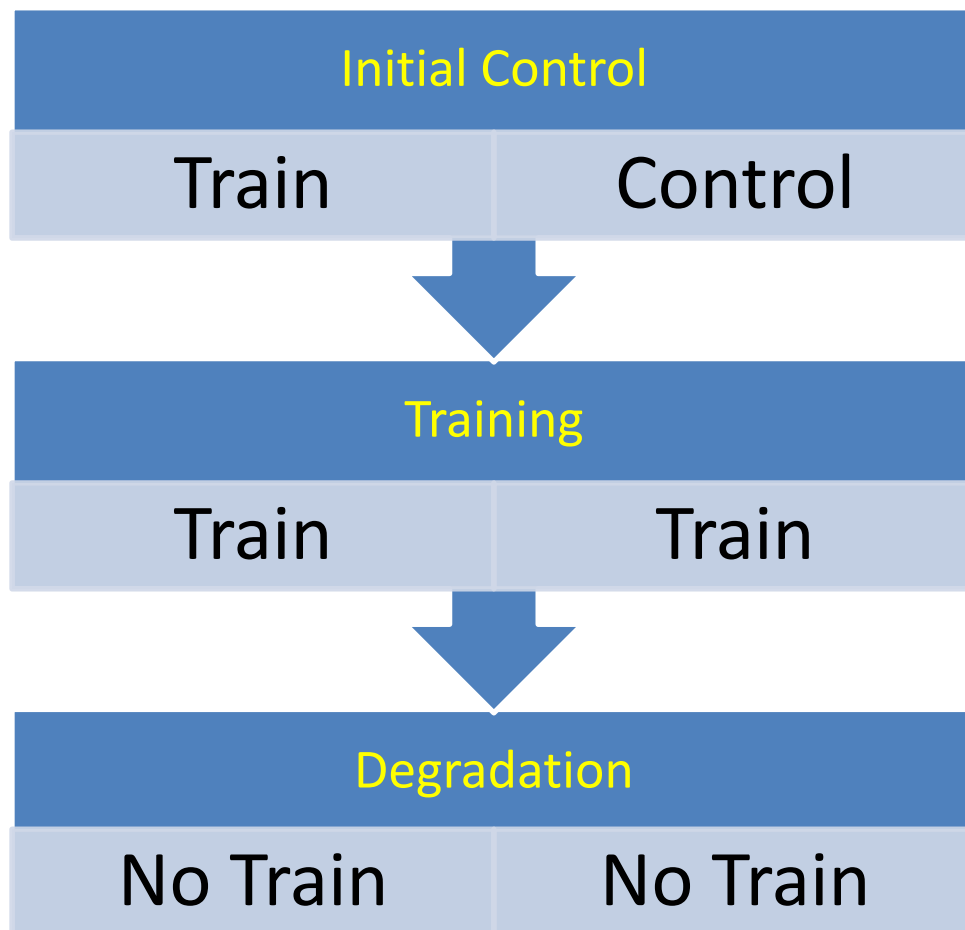
Volunteers were prospectively randomized into various training schedules as will be explained in further detail. All volunteers, regardless of randomized group were familiarized with all appropriate equipment and procedures prior to initiating the study.

Baseline FLS testing was performed on all volunteers prior to study regardless of group designation and at monthly intervals to monitor progress throughout the study. All participants filled out a questionnaire regarding personal characteristics, prior laparoscopic experience and experience with video games, sports and musical instruments.

Study Design

Fig 1, Flow Chart of the study design

-Familiarization with all equipment, Baseline FLS Training and Initial Questionnaire (Appendix 2) given to all participants



-Monthly FLS Testing Between Phases, Final FLS Testing and Exit Questionnaire (Appendix 3) given to all participants

Volunteers were initially randomized into one of two groups, “control” or “study” group (Fig 1, first box labeled “Initial Control”). Both groups were given a questionnaire regarding such characteristics as handedness, exposure to playing video games, exposure to playing musical instruments, etc (Appendix 2). Both groups were tested using two Fundamentals of Laparoscopic Surgery (FLS) tasks, to establish a baseline of skill level prior to the study. The two FLS tasks chosen to examine the volunteers’ progress were the pattern cutting and block transfer tasks. Pattern cutting involves using a laparoscopic grasper and a laparoscopic scissor to cut out a pattern on a piece of gauze, in this case a circle. Scores were based on time to complete exercise and errors (the area in cm^2 off the guideline). The gauze is suspended in a box trainer using alligator clips. Participants were not allowed to look down at the gauze, but instead were required to look at a video monitor that displayed the images from a laparoscopic camera setup in the box trainer (mimicking actual laparoscopic operative conditions). They were given 3 attempts and their best score was recorded.

The block transfer task uses a similar box trainer and camera setup. The task involves using two laparoscopic graspers to transfer rubber blocks from one peg to another with a mid-air transfer of the block from one hand to the other. The blocks have holes that allow them to fit over the pegs. To complete the task, all six blocks have to be picked up, one at a time, and transferred in mid air from one hand to the other, and then replaced on the pegs. This is repeated for both left to right and right to left hand transfers. This task is measured for time and mistakes made (dropped blocks, failure to

transfer from one hand to another prior to replacing the block, etc.). The two FLS tasks chosen for our study were the two most basic tasks of the FLS and were chosen specifically for their emphasis on two handed coordination and depth perception as well as their appropriateness for our novice study participants.

Initial Phase of the Study – “Train” group versus “Control” group to examine the effects of exposure to training using our curriculum (refer to Fig1). The “train” group was asked to train a minimum of 1hour per week (no maximum limit to training) using the curriculum for one month. Individuals training time was monitored by sign in/sign out timesheets that were checked against computer login records. The “control” group was not allowed to train during this month. The control group was, however, given the same orientation to all equipment, same questionnaire and same baseline and end of the month FLS testing.

Second Phase of the Study – All students are re-randomized to train with the goal of completing our curriculum. This phase was over the course of 2 months with continued monthly interval FLS testing to monitor progress. During this phase of the study participants were compared based on whether or not they passed the curriculum (passers versus non-passers). Throughout the 2nd phase all participants trained using various randomized training schedules (some participants trained for one month, some for two straight months).

Final Phase of the Study – All students are kept from training to examine skill degradation. A final month of the study involved no training for a minimum of 30 days. All participants were given a final evaluation using the two FLS tasks and an exit

questionnaire (Appendix 3). Comparison of participants' best performance on the FLS tasks while training versus their best performance after 30 days of not training was the comparison made to examine skill degradation.

Curriculum Design

As previously mentioned, the curriculum was designed by Dr. Andrew Duffy using fellowship-trained minimally invasive attending surgeons to benchmark the parameters of the curriculum. The particular system used was the LapSim simulator and software. One of the particular benefits of this program is that it allows the administrator to customize various parameters of the training modules making a customizable, resident level appropriate curriculum an attainable goal. Parameters for time to finish tasks, as well as acceptable mistake limitations were configured into the individual tasks on the curriculum. The curriculum consisted of two versions (a basic and advanced) of the following tasks: camera navigation (Fig 2), instrument navigation (Fig 3), coordination (Fig 4), grasping (Fig 5), cutting (Fig 6), clip applying (Fig 7), and lifting and cutting (Fig 8). Participants who passed all tasks opened up a testing block at the end of the curriculum. They were given a test in each of the seven areas that was slightly more difficult than the advanced version of the task. Participants were allowed five attempts per test to pass and could continue to access the practice portion of the curriculum for additional practice as they saw fit. Inability to pass any one of the tests after 5 attempts would result in having to navigate through the curriculum in its entirety in order for the tests to become available again. This feature was able to force adequate practice repetitions and to decrease the likelihood of a “lucky” passer and yet allow adequate attempts to compensate for a poor effort. The curriculum was designed to be proficiency based. There was no minimum number of repetitions required to complete the curriculum. There was also no maximum number of attempts per task so that participants could continue to practice on a task that they had passed, but perhaps not yet mastered.

Figures 2 – 8 below correspond to actual images from the virtual reality simulator drills used in our curriculum:

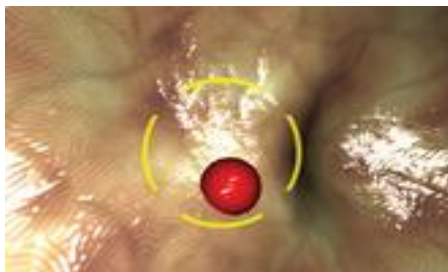


Fig 2 – Camera Navigation

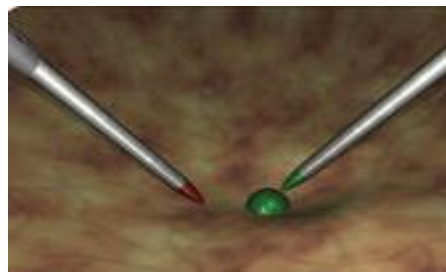


Fig 3 – Instrument Navigation

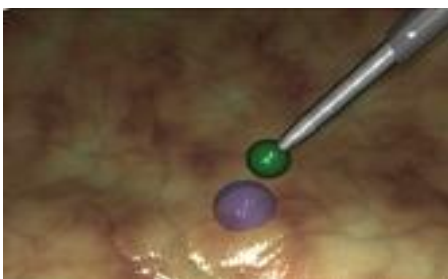


Fig 4 – Coordination



Fig 5 -Grasping



Fig 6 – Cutting

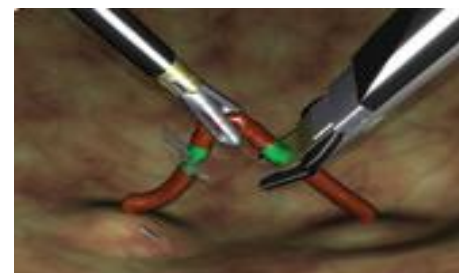


Fig 7 – Clip Applying

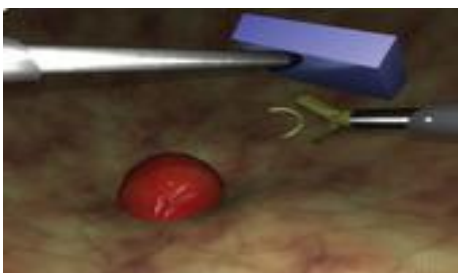


Fig 8 – Lifting and Grasping

Statistical Analysis

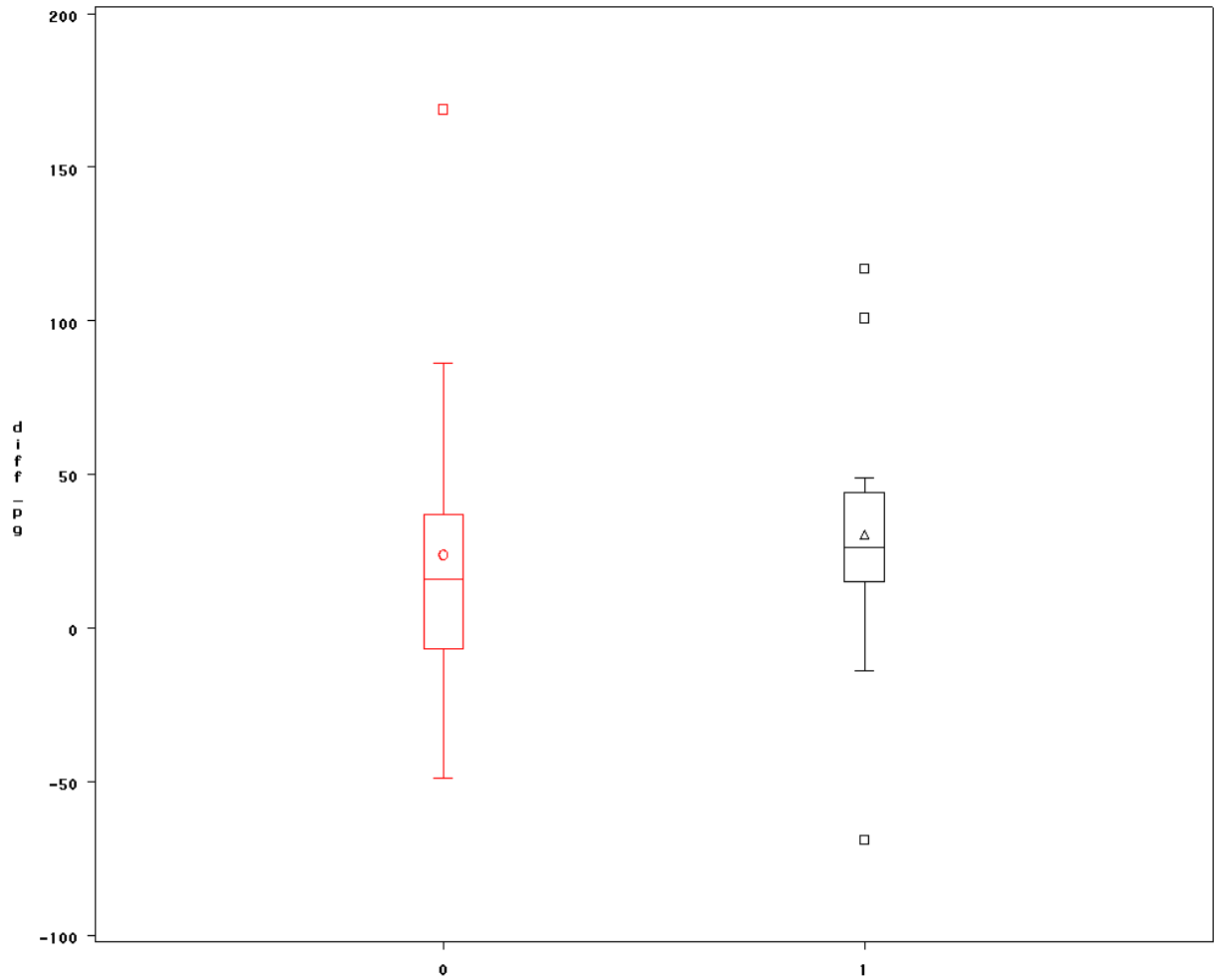
Statistical analyses were carried out with the assistance of biostatisticians at Yale. Most notably, James Dziura, PhD was integral in the application of statistical methods that allowed us to both properly design our study and carry out the examination of our data. We used analysis of covariance and two sample t-tests assuming unequal variance with adjustments made for baseline test scores (especially applicable during phase one of the study looking at score changes to baseline scores after one month). We also used a statistical method known as exact inference. Exact inference is specifically designed to look for correlations in data from small sample sizes and was used to examine possible correlations between our groups (passers versus non-passers, in phase two of our study) and prior experiences with video games, sports and musical instrument playing. FLS scores were compared both within and across groups for differences in improvement throughout training interventions. We used a p-value <0.05 as our cutoff for establishing statistical significance of our findings. Statistical significance will be noted in the results figures with an asterisk.

Section 4 – Results

Phase 1 – Control versus Training group

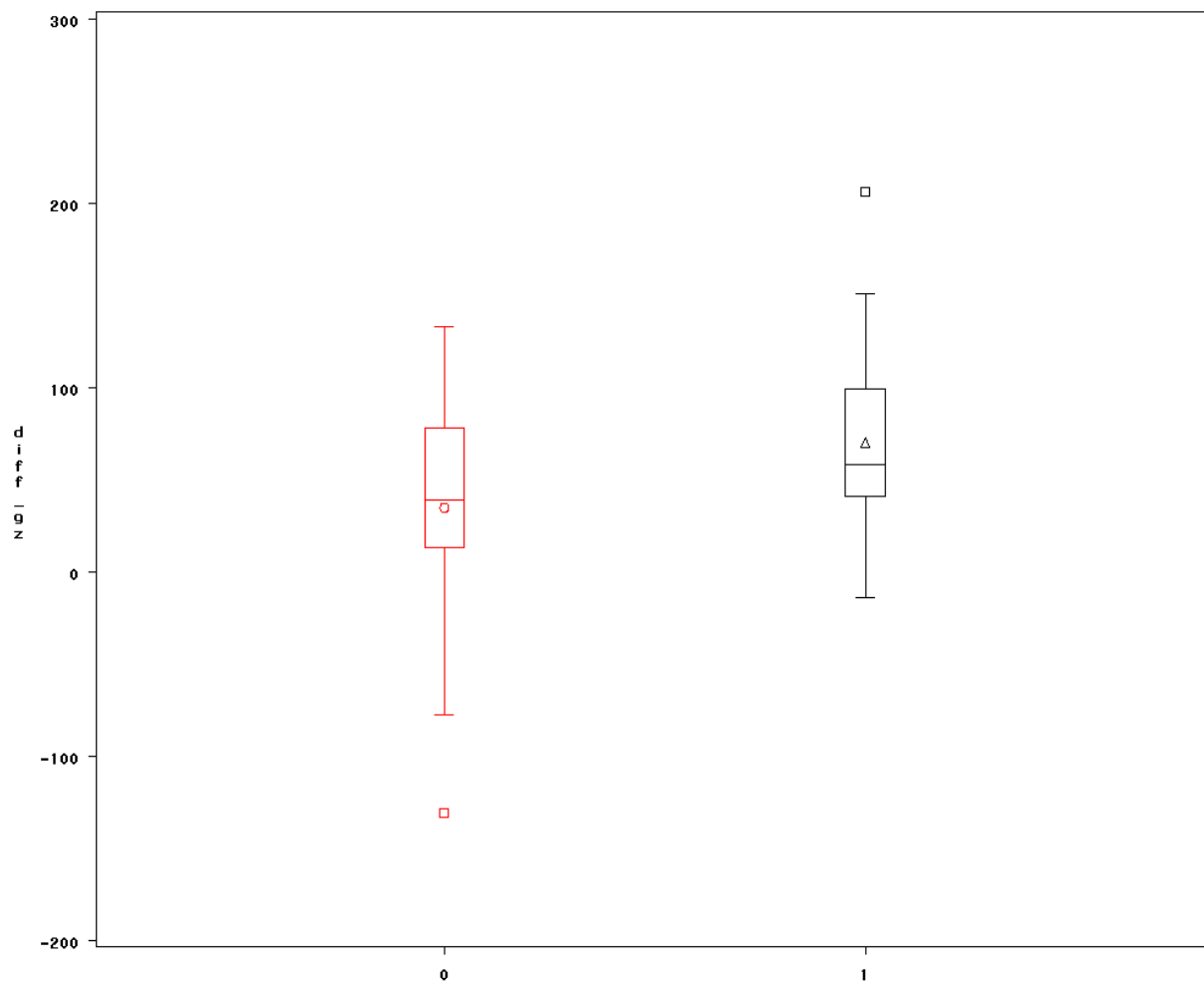
The purpose of this portion of the study was to determine whether or not the curriculum had any benefit beyond familiarizing participants with the equipment and FLS tasks. One-month changes in FLS scores for the two tasks were compared using analysis of covariance with adjustment for baseline test scores. The FLS uses a proprietary scoring system with regards to time to complete tasks and error counting. The training group was compared with the control group. We looked at the improvement of the FLS scores from baseline to one month. Improved training group performance on the block transfer task did not reach statistical significance (141 versus 130) ($p = 0.2986$) (Fig 9). In gauze cutting, the training group showed significantly higher mean FLS scores at 1 month (138 versus 91) ($p = 0.0333$) (Fig 10) and significantly greater improvement from baseline (79 versus 33) in FLS scores (Fig 11). Refer to Fig 9-11 below.

Fig 9 – Box plot Depicting Original Data of Training group versus Control in Block Transfer Task (baseline to 1 month)



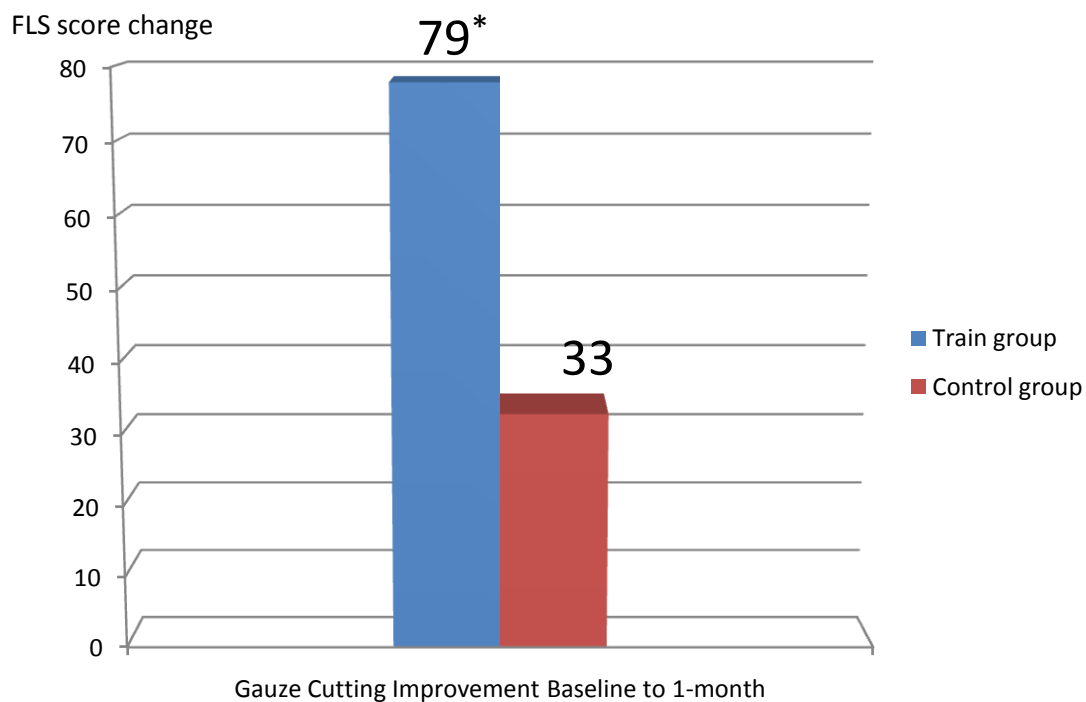
The left distribution (red) represents the control group (no training). The right distribution (black) represents the intervention group (training). The numbers on the x-axis represent FLS scores from baseline to one month. $P = 0.2986$ indicates that there was no statistically significant difference between FLS scores of the training group compared with the control group.

Fig 10 – Box Plot Depicting Original Data of Training group versus Control in Pattern Cutting Task (baseline to 1 month)



The left distribution (red) represents the control group (no training). The right distribution (black) represents the intervention group (training). The numbers on the x-axis represent FLS scores from baseline to one month. $p = 0.0033^*$ indicates a statistically significant difference in scores between groups (training group higher than control)

Fig 11 – Net change in FLS score for Gauze Cutting Task, training group versus control (baseline to 1 month)

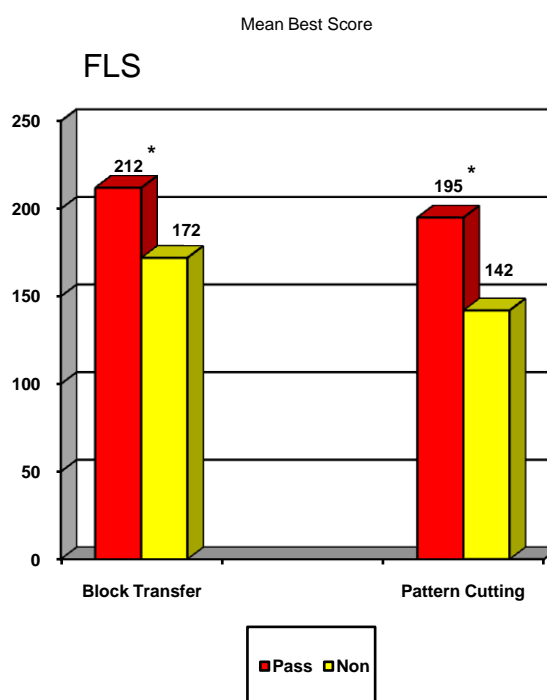


This graph represents the average net change in score (improvement) for the training group (blue) compared to the non-training control group (red). Statistically significant improvement in FLS scores in gauze cutting exercise from baseline to one month was demonstrated ($p = 0.0418$).

Phase 2 – Participants Train with Goal of Completing Curriculum in its Entirety (Data Comparison is now Passers versus Non-Passers)

This phase of the study should demonstrate whether or not completion of our curriculum results in higher skill as measured by FLS testing. All participants had the chance to train with the goal of completing our curriculum in its entirety. 10 passed (passer group) and 22 did not pass the curriculum (non-passer group). We examine difference in performance (Fig 12) and difference in improvement from baseline (Fig 13) between groups.

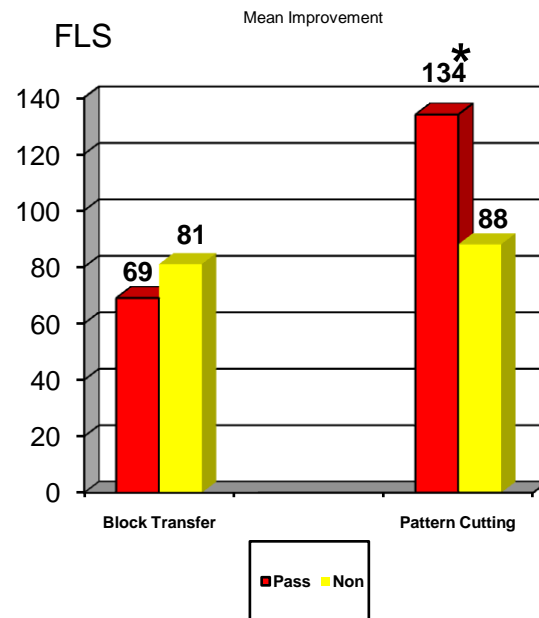
Fig 12 –FLS Scores in Block Transfer and Precision Cutting Tasks comparing Passers and Non-passers



For Figure 12 above, a 2-sample T-test assuming unequal variance was used to examine mean best FLS scores in both the block transfer and precision cutting tasks. The passer group (red) performed significantly better than non-passers in both the Block

Transfer ($p = 0.001$) and the Precision Cutting task ($p < 0.001$). Significance noted by asterisk (*).

Fig 13 - Mean IMPROVEMENT of FLS Score in Block Transfer and Precision Cutting Tasks comparing Passers and Non-passers

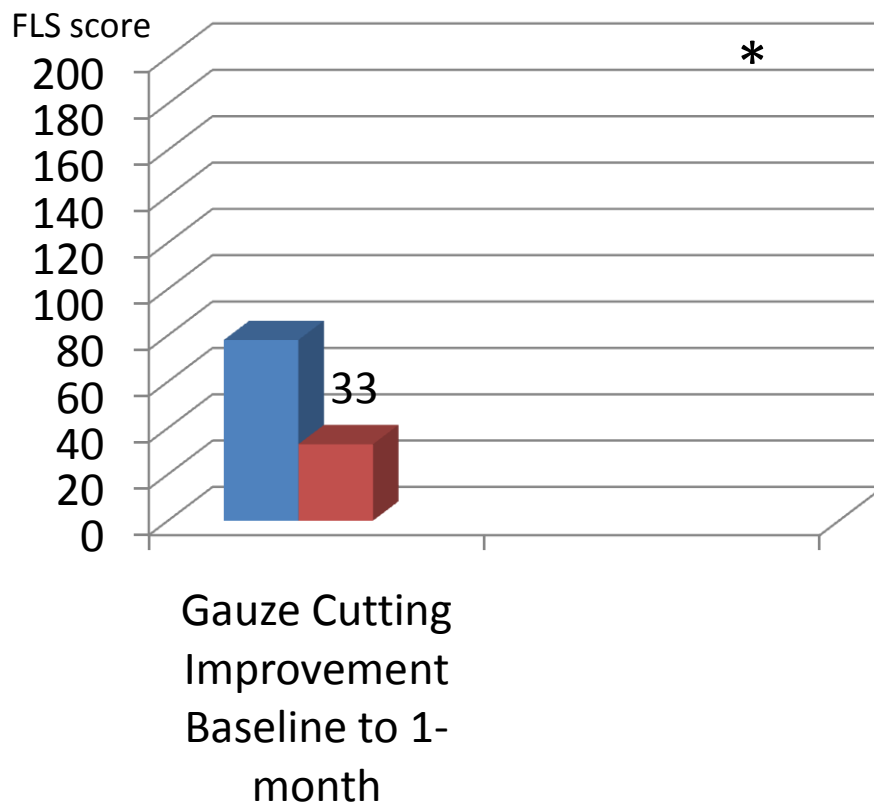


For Figure 13, above, in order to examine mean improvement, baseline FLS scores were subtracted from the mean best score achieved by the participants during training. Statistical significance was not achieved for the block transfer task ($p = 0.229$), but was achieved for the precision cutting task ($p = 0.013$). Significance noted by asterisk (*).

Phase 3 – Skill Degradation

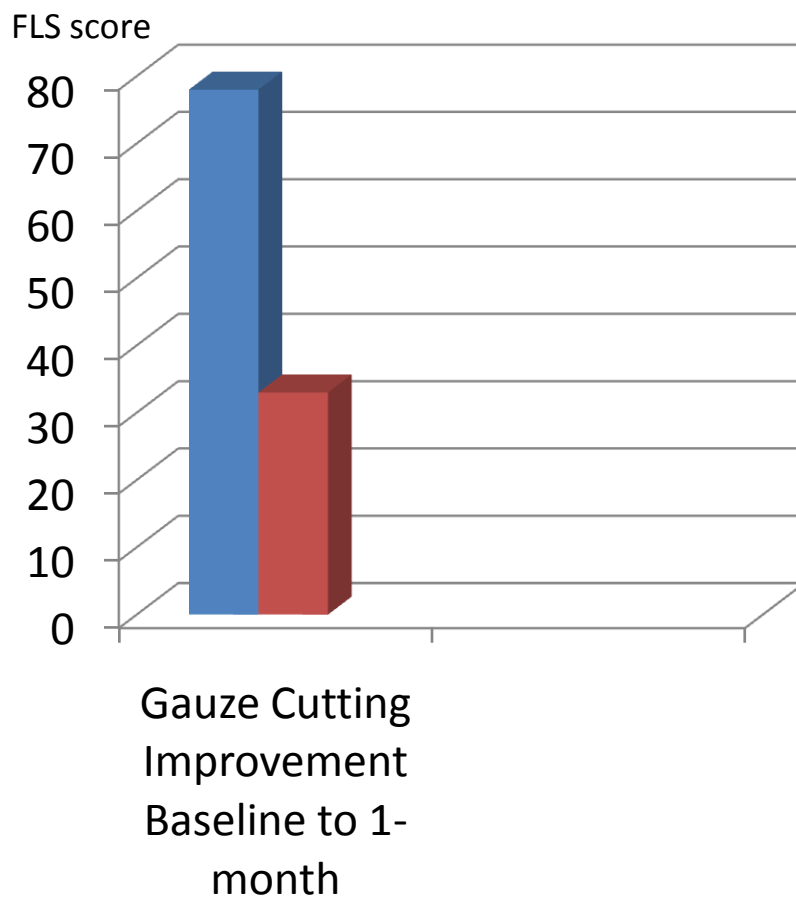
Below are figures from our skill degradation data. All participants were kept from training for a minimum of 30 days. At that time they were retested using the same two FLS tasks we used throughout the study. We looked at ALL participants together and compared their best score while training to their score after a 30 day layoff for each task (Fig 14, 15). We then examined their net change in score for the same two tasks (either improvement or degradation) (Fig 16). Lastly, we split the data back into passer versus non-passer groups to discern any possible difference in skill degradation between the groups (Fig 17).

Fig 14 – FLS scores for ALL Participants in Pattern Cutting Task, best score during training compared to best score after 30 days with no training



Skill degradation was not demonstrated, instead mean scores improved for all participants (158 to 180) in pattern cutting task and achieved statistical significance ($p = 0.002$). Significance noted by asterisk (*).

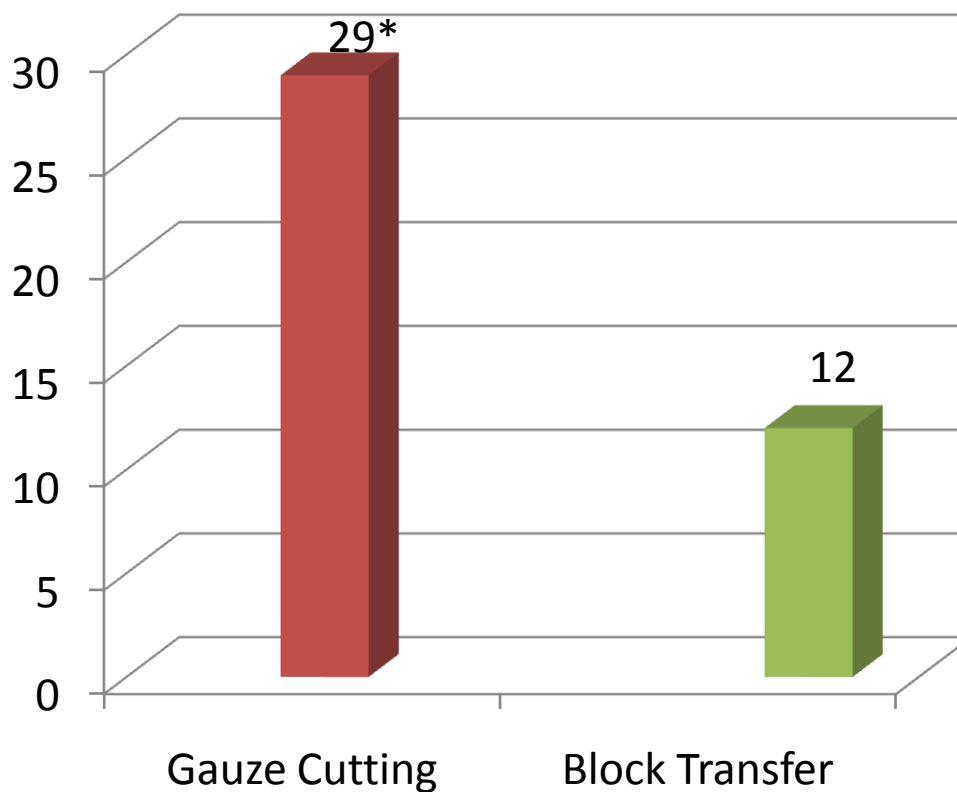
Fig 15 - FLS score for ALL Participants Block Transfer Task, best score during training compared to best score after 30 days with no training



Again, skill degradation was not demonstrated. Again mean scores increased for all participants (188 to 198) in block transfer task, but score increases did not reach statistical significance ($p= 0.069$).

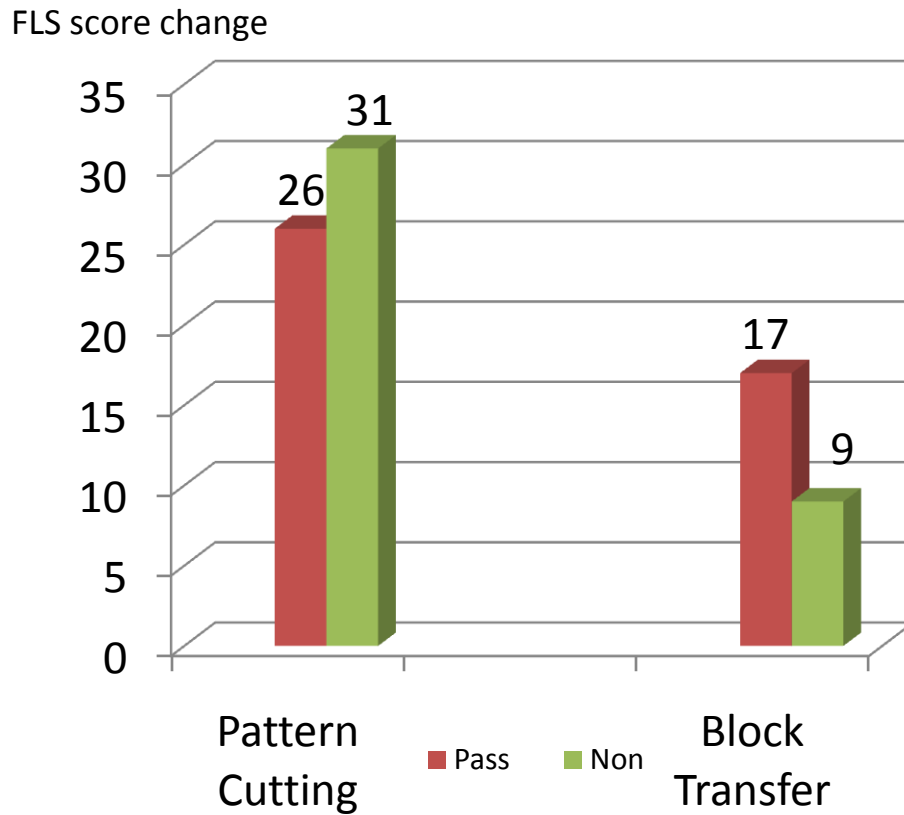
Fig 16 –Net Change in FLS scores for ALL participants after 30 days away from the trainers in Gauze Cutting Task (Red) and Block Transfer Task (Green)

FLS score change



This is a graphical representation of the two previous slides combined, demonstrating a net improvement after a 30 day layoff for both the pattern cutting (red) and the block transfer task (green). Statistically significant improvement, for all participants was seen in the pattern cutting task ($p=0.002$), but not for block transfer ($p = 0.069$). Significance noted by asterisk (*).

Fig 17 – Net change in FLS scores comparing Passers vs Non-passers in both Pattern Cutting Task and Block Transfer Task after 30 days with no training

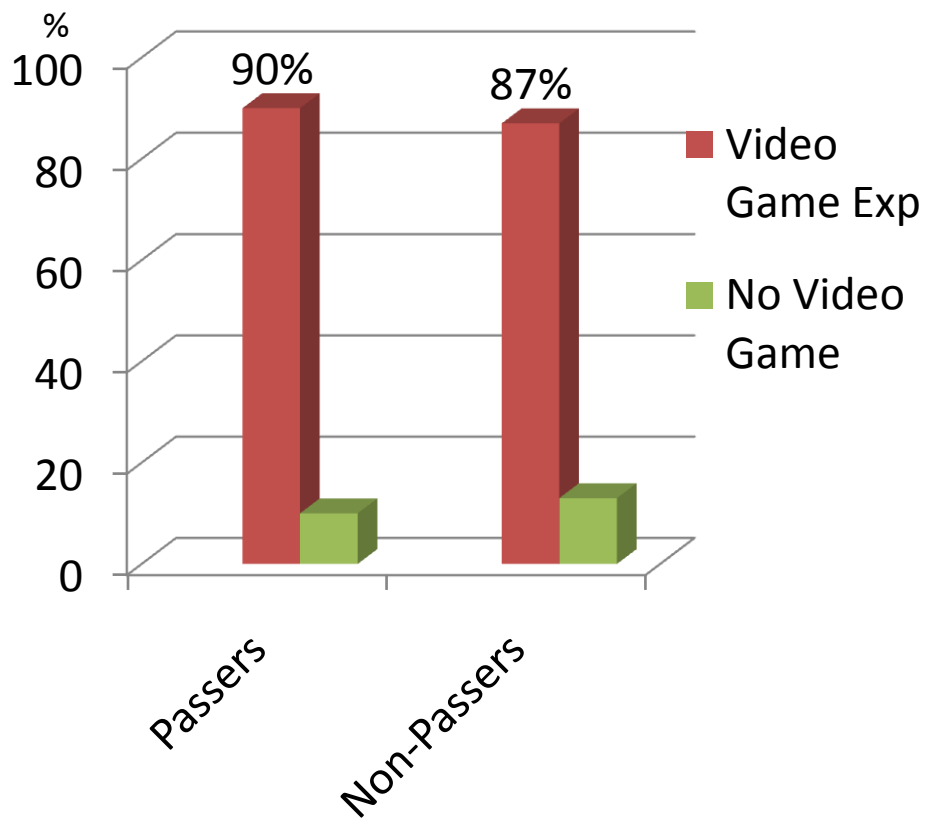


This graph depicts differences in skill degradation between those who completed our curriculum in its entirety (passers, red) and those who did not (non-passers, green). There was no statistically different level of skill improvement or degradation when comparing passers to non-passers for either task. Both passers and non-passers showed increased FLS scores on both tasks.

Phase 4 – Differences in Characteristics of Passers and Non-passers

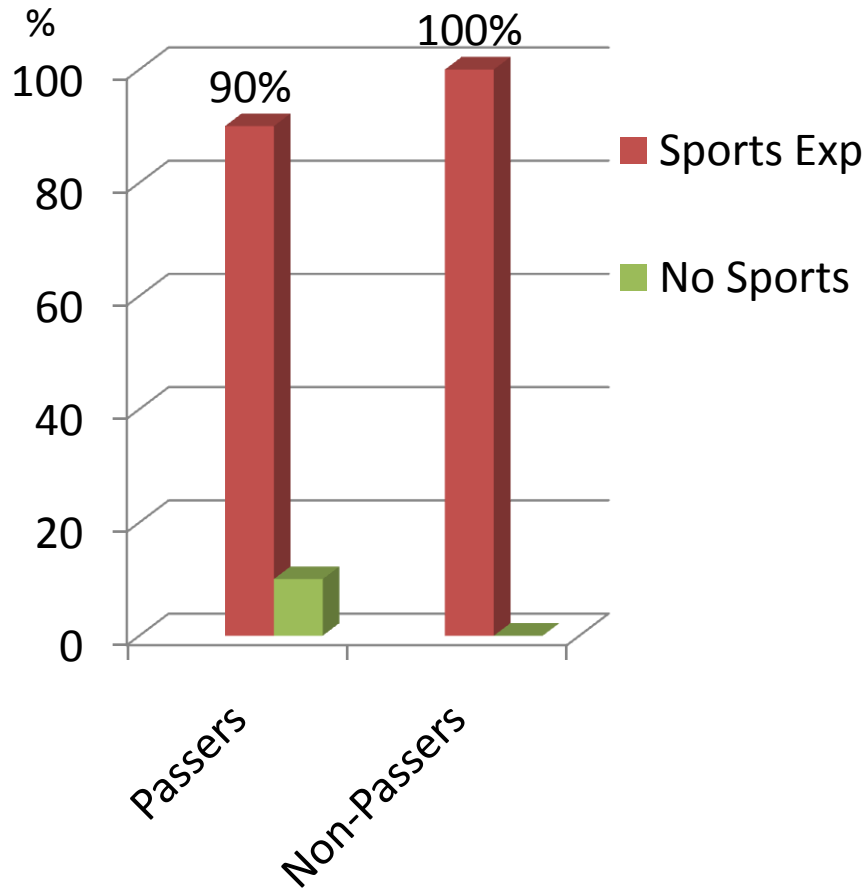
Data was collected from the pre and post questionnaire forms looking at video games, sports, and musical instrument playing (Appendix 2 and 3).

Fig 18 –Percent of Participants with Video Game Experience (red), Passers versus Non-passers



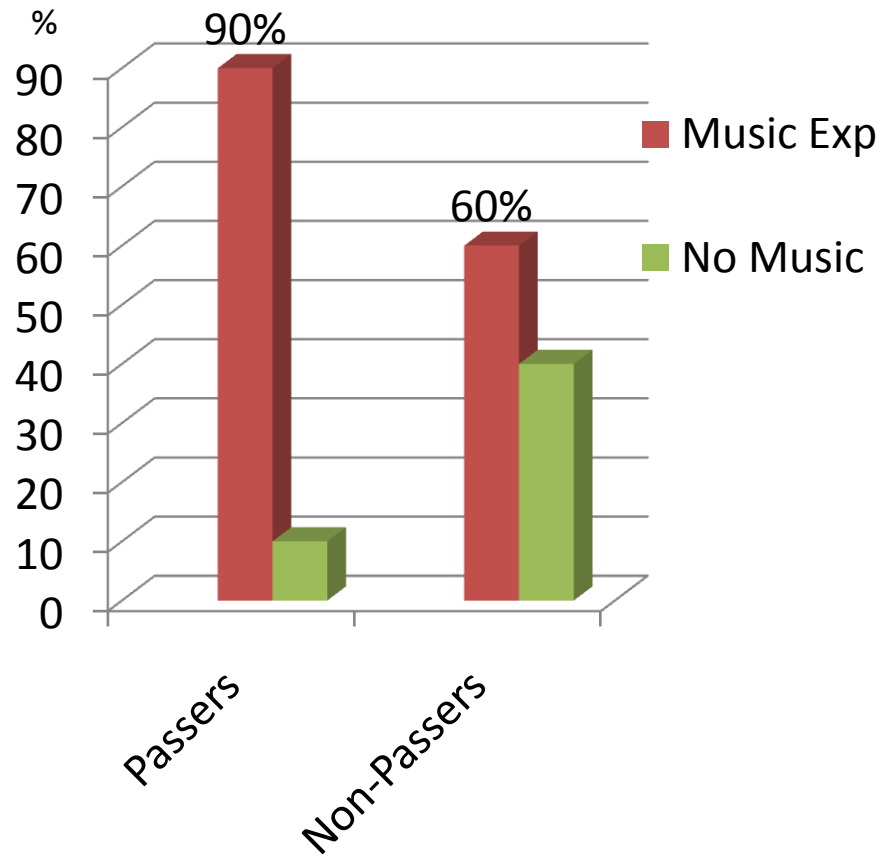
Percentage of video gamers in the Passers and Non-passers was essentially equal across groups. Hence, no correlation between video game experience and performance on our curriculum was demonstrated.

Fig 19 –Percent of Participants with Sports Experience (red), Passers versus Non-passers



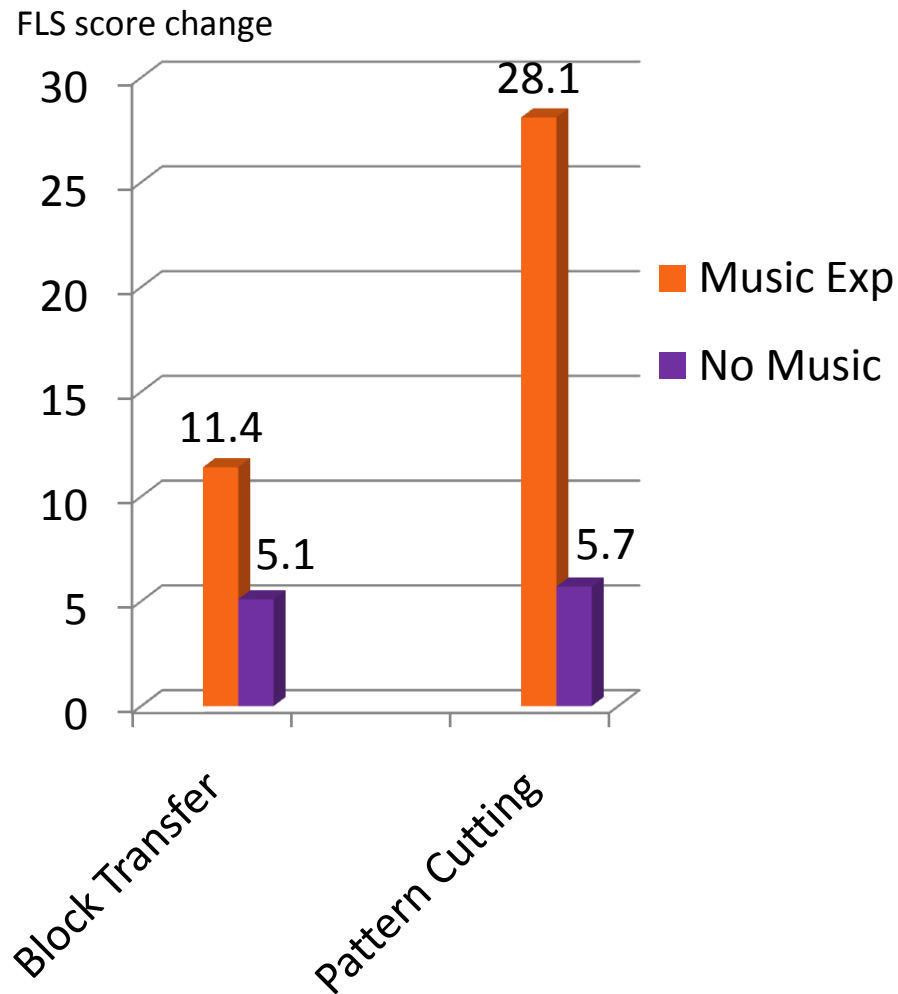
Participation in sports was proportionally almost equivalent among both groups. No correlation between sports experience and performance on our curriculum was demonstrated.

Fig 20 –Percent of Participants with Musical Experience (red), Passers versus Non-passers



Despite a greater percentage of musicians in the passer group statistical significance was again not demonstrated to correlate with performance on our curriculum.

Fig 21 – Net Change in FLS scores, by task, using Musical Instrument Experience versus no Musical Instrument Experience as group designation



This final figure of the set attempts to look more closely at musical instrument playing by reorganizing the data based in musical experience. The impetus for this was the difference in the percentage of passers with musical experience (90%) compared with non-passers (60%) in Figure 20. Data was not statistically significant for either task but appears to show a trend towards performance benefit to musical experience.

Section 5 – Discussion

The study demonstrated several findings, ultimately leading to the validation of a viable curriculum for our junior residents. Initially, students participating in our curriculum showed improved FLS test scores in two separate measures of laparoscopic technical skill (block manipulation and gauze cutting), achieving statistically significant improvement in gauze cutting (Fig 11). Participation alone, and not completion of the curriculum, was responsible for these changes, as none of the participants in the training group were able to complete the curriculum during the first month. Using individual participants as their own controls, it was clear that all participants showed meaningful improvement in their own individual FLS scores when given the opportunity to train in Phase 2 of the study.

Successful completion of our curriculum is the ultimate endpoint of the training. It is the most important endpoint to us, because we intended to develop a curriculum that consistently demands a minimum proficiency level in order to be completed. That proficiency must also be transferable to the operating room. What are the factors that go into a successful curriculum? There is now substantial literature touting the benefits of simulator training for surgical residents [49-54], but there remains no consensus on the best curriculum for accomplishing this goal. Factors that affect the efficacy of simulation training of residents include, but are not limited to, simulator location relative to the hospitals, mandatory as opposed to voluntary training schedules [55], and the benefits of multiple, regular training sessions as opposed to massive and less frequent practice sessions [56, 57].

Evidence has shown that a didactic or cognitive component enhances the effectiveness of a skills curriculum [58]. Both the American College of Surgeons and the Association of Program Directors in Surgery have included a teaching component in their skills curriculum [59]. In addition to the cognitive component of a skills curriculum (which we did not address in this work), it enhances learning when the users of the curriculum are given feedback throughout their training [60]. The effects of this user feedback are further enhanced by the presence of experts to assist in implementing that feedback [61]. This speaks to the issue of proper funding and staffing to maximize the benefit of a simulation center, but that is a discussion for a different day. What is certain is that devoting time to observe residents during their training and then offering expert feedback has a positive effect on performance and may prevent the formation of detrimental habits.

But what specifically about the skills curriculum makes it more or less successful? Training goals that motivate the trainee are essential and are at the heart of proficiency-based curricula. Proficiency-based curricula set training goals using experts as benchmarks. In our case, Dr. Duffy used himself and several other fellowship-trained minimally invasive surgeons. Once the benchmarks are established, then the curriculum should be tailored to the specific needs and skill level of the trainees [62]. This is a particular advantage to the simulator software that we use. The LapSim simulator offers the ability to customize the individual drills based on the metrics established by its administrator. Many of the other currently available simulators that have been tested have rigid pre-set drill settings and metrics [62]. Another advantage of a proficiency-based curriculum as opposed to requiring a specific timeframe or number of training

sessions is that trainees with higher level of skill prior to training will not be forced to waste time in training that does not improve their proficiency. By the same logic, those with lesser skill at the outset will not be cut off from training before proficiency is reached merely because they have fulfilled their required number of attempts or training sessions.

The data demonstrate that successful completion of our basic laparoscopic skills curriculum and exam results in improved novice skill development as measured by improved FLS scores. Figure 12 demonstrates our most important findings. In both FLS tasks, the group that passed the curriculum significantly outperformed the group that trained but did not pass. The results represented by figure 13 serve to reiterate that all participants, regardless of passing status, showed great improvement in both tasks. In a practical application, our proficiency-based curriculum would allow us to identify those that were improving but had not yet reached competence, and we would be able to offer them further training and guidance. As participants progress through the curriculum, error sensitivity is greater, and error tolerance is less. The time to complete tasks also decreases as efficiency of movement is a highly prized skill. Though training alone improved skill beyond familiarization with equipment, and beyond merely doing the two FLS tasks, passing our curriculum improved skill even further. The FLS scores bear out this reality, and suggest that our passers should have skills that translates into improved operating room proficiency [63-66]. McCluney et al. demonstrated that FLS simulator performance could in fact predict intra-operative laparoscopic skill performance. The group found that FLS scores significantly correlated with Global Operative Assessment

of Laparoscopic Skills (GOALS) [63]. GOALS is a previously validated and objective measure of laparoscopic skills in the operative setting [67].

During Phase 3 of our study we examined skill degradation. We set out with the idea of finding the point at which it appeared that skills began to degrade (FLS scores decrease) so that we could use that information to establish a useable re-training or maintenance schedule. After a 30 day layoff, skill degradation was not demonstrated, in fact, on average for all participants, skills continued to improve significantly (Fig 14-16). We assumed, incorrectly, that skills would at least plateau after 30 days away from training. It may seem that the 30 day non-training window is a rather quick or arbitrary cutoff, but we wanted to continue the standard one month interval between retesting on the two different FLS tasks as we had used throughout the study. We had no real sense of how durable the skills our trainees developed were, given their novice status and the fact that our curriculum was brand new. We were surprised to find that skills had not decreased, nor had they reached a plateau, they actually had improved (Fig 14 – 16). This was the case for all participants, regardless of passer status (Fig 17). We were encouraged to see these unexpected findings. Since the study did not continue past one month of no training, it would be inappropriate to speculate how long it would take for skills to show significant erosion. What is certain is that our skills are maintained in the absence of training for at least one month's time.

Studies in the literature report immediate post-training skill drop-offs, with a longer-term maintenance of sub-maximal skill [68]. Other literature has demonstrated skill erosion after one to six months time, but it is not consistent [69, 70]. Additionally, time frames from other studies are not directly applicable, since they were not using our

specific curriculum. It is, however, widely accepted is that there is a need for maintenance training to maintain proficiency. Studies have shown that regular maintenance training improves simulator performance compared to trainees who reached proficiency but were not allowed to maintenance train [70]. The timeframe for such maintenance may be specific to each individual curriculum or even individual trainees. With a proficiency-based curriculum like ours, we can afford to do regular testing, using FLS tasks, for example, and only ask those who demonstrate a lack of proficiency to re-train. This more individualized approach would appear to be the most efficient to implement. While we do not have a concrete explanation of why we saw continued improvement, what is also certain is that none of the participants trained during that 30 day interval. This was verified by the computer log- in system which recorded each time a particular participant logged into train.

The last portion of our study focused on the effects past and current experience had with ability to perform on our curriculum. Extensive experience with video gaming, athletics, and musical instruments showed no significant correlation with the ability to successfully complete our laparoscopic virtual reality skills curriculum (Fig 18-20). There have been many studies and popular news articles touting the effects of video game playing or music, etc. on laparoscopic proficiency. This would appear on the surface to have some validity. After all, many video games, for example, require ambidextrous manual dexterity and do mimic the interaction with video monitors used in laparoscopic surgeries. Sports and musical instrument playing may also require or enhance psychomotor reflexes as well as hone visual-spatial abilities [71]. Most of these tasks, however, do not ask the user to use their hands in a limited spatial field while focusing

your attention in a different direction. The fulcrum effect (the effect of using your instrument over a pivot point) is also difficult to mimic outside the world of laparoscopy and is a reminder of the specific challenges facing laparoscopic trainees.

Many in the literature have sought to correlate video game performance with laparoscopic skill by grading the two separately and running correlational statistical analyses [71]. The results have been mixed, one study even finding that video game experience was inversely correlated with performance of surgical skills [72]. This is fundamentally different from our approach. We were looking to correlate past experience or exposure, not current skill level, with performance on our curriculum. A recent study by Madan, et al. did question novice participants about prior experience with non-surgical skills (including music, computer games and chopstick usage, etc.). They then randomized them to perform in either a virtual reality simulator or a box trainer. They found increased performance in virtual reality simulator for those with higher self-reported skill, but this did not reach significance. They found, however no correlation with drills in the box trainer [73].

Our data did not indicate a significant correlation between performance on our curriculum and past or current experience with video games, musical instrument playing or sports (Fig 18-20). We were intrigued by the results depicted in Figure 20. We felt there was enough of a difference between passers (90%) and non-passers (60%) with musical backgrounds that we decided to look at the data in a different way. Figure 21 compares those with musical experience versus those without musical experience (as opposed to passers and non-passers). We looked at their performance and found an obvious difference with musical participants outperforming non-musical. It is important

to keep in mind that the sample sizes for the groups were drastically different once we combined musicians versus non-musicians, the musician group roughly three times as large. This may have accounted for the insufficient power to show significance for this data despite a seemingly obvious difference in FLS scores. Possibly a more diverse study cohort could demonstrate a difference.

It appears the natural evolution of medical education is shifting towards more assessments of practical skill. The National Board of Medical Examiners is now requiring medical students to take a USMLE clinical skills exam as part of their licensing. In 2004, the FDA stepped in for the first time to mandate performance based proficiency be demonstrated by physicians using certain intravascular carotid stenting devices [74, 75]. Our own anatomy and physiology curriculum for medical students has begun to include presentations of the anatomy as would be encountered via endoscopy. As fantastic and limitless the possibilities for simulation appear, it will ultimately take a comprehensive approach, beginning in medical school, and continuing on through fellowship training to produce surgeons with the highest level of endoscopic skill. The development of an efficient skills curriculum is one rather large spoke in that wheel.

Though the study did prove to aide in the creation of a workable curriculum there is no doubt that there were limitations to the information it provided. First, and perhaps most obviously, the sample size for the study was limited. This is almost always a viable criticism in studies of this nature, and is certainly appropriate for us as well. For example, during the second phase of our study we compared “passers” with “non-passers” and examined both mean FLS scores (on our two tasks) and mean improvement. Participants in both groups showed great improvement, however it was clear from the

data that “passers” (those who completed our curriculum in its entirety) showed greater improvement. In the precision cutting task, the greater improvement was statistically significant, while in the block transfer task, there was a trend approaching but not reaching statistical significance. Had we the luxury of a greater number of participants, perhaps we would have demonstrated statistical significance in both tasks.

Another limitation of the study has to do with our examination of skill degradation. We set out thinking that 30 days with no training on our curriculum would lead to a decline in performance as measured by our two FLS tasks. We presumed that in such novice participants the skills obtained would be fragile in nature and prone to decline without consistent training. We assumed that the level of skill degradation demonstrated would give us an idea of the need for retraining and that would help us to implement a schedule for the actual curriculum. When we looked at the data, however, we were surprised to see that overall skills were still improving after 30 days without training. This was true when we looked at all participants and when we broke it down into passers versus non-passers. This was also true of both tasks. It would have been beneficial to our goals to be able to continue looking at all the students each month (30 day intervals) until we got to a point in time when we did actually see skills begin to degrade. Only then could we have made a reasonable recommendation for a retraining schedule. It is possible that this day would never have come. It is possible that, since our curriculum is designed for the purpose of imparting basic skills of two-handed coordination and depth perception, skills may never have dropped to any appreciably significant level. We simply cannot say given the limitations of our data gathering.

Lastly in the fourth phase of our study we examined the characteristics of the passers and non-passers looking for specific qualities that may have predicted or indeed influenced performance. Going back to the initial criticism of the study looking at sheer number of participants, we simply did not have the power to definitively find any differences. It looked promising with regards to musical experience, but nothing significant was able to be discerned. Additionally, our study was not ideally designed to examine such parameters. If we had separated groups of participants by experiences (musicians versus non-musicians, video gamers versus non-video gamers, etc) then run a prospective trial, perhaps then we would have been able to draw more relevant conclusions.

For the sake of academics it would be nice to rerun the study to address some of the concerns mentioned in the above sub-section. But the point of this study was not merely an academic exercise. This study was done for the purpose of validating a new tool for training residents. Whenever the discussion of training surgical residents begins we are ultimately discussing improving operative performance, and hence, the quality of patient care. Our surgical skills curriculum should be looked at as any other tool for training: a living organism that must evolve to continue to meet the needs of those for whom it is designed. All further study should be aimed at examining the curriculum's effectiveness in improving surgical skill and should take into account improvements in technology that may enhance the training. Work in the field of virtual reality haptics (force feedback) has begun to show the promise of decreasing the learning curve [35, 36]. With regard to necessary self-criticism for the sake of improvement, our group has recently published work detailing the construct validity of each of the individual drills in

the curriculum, or the ability for these drills to differentiate between various skill levels [62]. Various levels of surgeons from junior residents up to fellowship trained minimally invasive surgeons were asked to perform in the curriculum. We determined that certain tasks were better at correlating with operator skill. This curriculum should be considered version 1.0 in what will hopefully be a continuously evolving and ever more effective way to train our residents. This curriculum should also be a model for others who hope to train residents and attendings alike. This can only be accomplished with rigorous and regular quality control and a global approach to skill acquisition, which should be addressed by further study.

Section 6 – References

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Appendix 1 – Informed Consent

CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: Virtual Reality Based Laparoscopic Skills Acquisition & Maintenance

Principal Investigator: Andrew J. Duffy, MD, Department of Surgery

Funding Source: Charles Ohse Grant

Invitation to Participate and Description of Project

You are invited to participate in a research study designed to look at how people acquire and maintain the skills to use laparoscopic surgical tools. You have been asked to participate because you have expressed interest in assisting with our research experiment. We are hoping to find 40 medical students who will be able to conveniently access the laparoscopic research laboratory in FMB 221 (near Yale-New Haven Hospital) to assist in our project.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to participate in this study, you will be asked to first fill out a questionnaire that asks questions about handedness and hobbies that might be beneficial to acquiring the skills to use laparoscopic tools (hobbies such as playing video games, playing a musical

instrument, etc.). You will then be given a standardized test of basic laparoscopic skill, using the instruments to manipulate objects and using the instruments to cut out a design. After this standardized test is given you will be randomized to one of two groups. In one group you will be asked to practice a minimum of one hour per week, at your convenience, for one full month on a laparoscopic virtual reality simulator. At the one month mark you will be retested using the same standardized test you were given before. You will then be asked to either continue training as you were before or NOT to train for a period of one month. At the end of this month you will again be retested. If you were in a group that was still training you will be asked to go one full month without training and then again be retested. It is also possible that you will start in a group that does NOT test at all for the first month, but then will be asked either to train or remain untrained, etc. Some version of this pattern will continue for 3 or 4 months depending on group assignment with monthly tests for all groups.

Risks and Inconveniences

There are no reasonable expectations of any physical risks involved in this study. We do, however, recognize the risk that students may feel compelled to participate or may feel that their participation or performance may have some bearing on their future as medical students (via evaluations, etc). To guard against these risks we assure all participants that there will be no adverse consequences to deciding NOT to participate in our study. Additionally there will be no evaluation made of students based on the data collected. All the data that is collected will be coded in such a way that it will not be traced back to students' names. All data will also be stored in a protected format (i.e. password protected and coded to maintain the confidentiality of participants and assure that such data would not be used to evaluate students in any way) and destroyed after the study is complete so that it will not be able to be misused in any way.

Benefits

Your participation in this study may help to advance knowledge about how certain skills necessary to laparoscopic surgeons are acquired and maintained. It may also contribute to the design of more efficient and standardized curricula for surgeons in training.

Economic Considerations

There are NO costs to participants in this study.

Participants will receive \$50 for COMPLETION of the study. There will be NO prorated amount given for partial participation.

Treatment Alternatives/Alternatives

This study does not involve treatments. Alternatives are to choose not to participate.

Confidentiality

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. All data will be coded and stored under password protection with direct access available only to those directly involved in conducting the study. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained. Once the study is published and the data has served its purpose it will be completely destroyed.

Representatives from the Yale Human Investigation Committee may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

In Case of Injury

We anticipate no risk that you will be injured as a result of your participation in this study.

Voluntary Participation and Withdrawal

You are free to choose not to participate and if you do become a subject you are free to withdraw from this study at any time during its course. If you choose not to participate or if you withdraw it will not harm your relationship with your own faculty, doctors, or with Yale-New Haven hospital.

The researchers may withdraw you from participating in the research if necessary. You may be withdrawn if you do not meet your obligations as a subject in the study (e.g. practicing a minimum of 1 hr/week if assigned to do so, etc).

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

Authorization

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

Name of Subject: _____

Signature: _____

Relationship: _____

Date: _____

Signature of Principal Investigator

Date

or

Signature of Person Obtaining Consent

Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Andrew J Duffy MD at (203)764-9060. If you have any questions concerning your rights as a research subject, you may contact the Human Investigation Committee at (203) 785-4688.

*THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX
HAS BEEN COMPLETED IN THE HIC OFFICE*

THIS FORM IS VALID ONLY FROM: _____
UNTIL: _____

HIC PROTOCOL #:

INITIALED:

Appendix 2 - Questionnaire**Laparoscopic Skills Questionnaire**

Name: _____

Clinical PGY-Level: I II III IV V

Age: _____

Gender: Female MaleHandedness: Right LeftHave you had previous experience with surgical simulators? Yes No

If yes, please specify:

How many laparoscopic operations have you performed/assisted in total?

 0 1-10 10-50 50-100 >100Did you play video games as a child/adolescent? Yes No

Which video game system(s)? _____

How often did you play on average?

daily

weekly

monthly

less than monthly

Did you have your own video game machine (Atari, Commodore, Nintendo, Playstation, Sega, X-box etc.) as a child/adolescent?

Yes No

Which system(s)? _____

Do you currently play video games? Yes No

Which system(s)? _____

How often do you play on average?

daily

weekly

monthly

less than monthly

Do you currently have a video game machine? Yes No

Which system(s)? _____

Did you play sports as a child/adolescent? Yes No

What sports did you play and at what level (beginner..pro)? _____

How often did you play sports on average?

daily

weekly

monthly

less than monthly

Do you currently play sports? Yes No

What sports do you currently play? _____

How often do you play sport on average?

daily

weekly

monthly

less than monthly

Did you play a musical instrument as a child/adolescent? Yes No

Which instrument(s)? At what level? _____

How often did you play on average?

daily

weekly

monthly

less than monthly

Do you currently play a musical instrument? Yes No

Which instrument(s) at what level? _____

How often do you play on average?

daily

weekly

monthly

less than monthly

What kind of car do you drive?

automatic

stick shift

don't drive a car

Do you do any 3D-artwork (woodcarving, sculpturing, etc.)? Yes No

What kind? _____

Do you do any 2D-artwork (painting, photography, etc.)? Yes No

What kind? _____

Can you think of any skill you possess that could enhance your surgical simulator skills that has not been mentioned above? Yes No

If yes, please specify:

Do you think the surgical simulator will improve your operative performance?

strongly disagree

disagree

neutral

agree

strongly agree

Thank you for your participation!!!

Appendix 3 – Published and Presented Abstracts

A. New England Surgical Society, Fall 2007 (Poster Presentation)

A Novel Virtual Reality Based Curriculum Improves Laparoscopic Skills in Novices

M. Martinez, K.E. Roberts, R.L. Bell, J. Dziura, D.Eisenberg, W.Longo, A.J. Duffy

B. 3rd Annual Academic Surgical Congress, Feb 2008 (Oral Presentation)

Passing a Virtual Reality Based Curriculum and Skills Exam Improves Laparoscopic Skills in Novices

M. Martinez, K.E. Roberts, R.L. Bell, J. Dziura, L. Panait, A.J. Duffy

C. Society for Laparoendoscopic Surgeons Annual Meeting, Sept 2008 (Oral Presentation)

Skill Acquisition From a Novel Virtual Reality Based Experience and is Maintained At Least 30 Days After Training

M. Martinez, L. Panait, K.E. Roberts, R.L. Bell, J. Dziura, A.J. Duffy