Development of a Proficiency Based Skills Curriculum for the Fundamentals of Endoscopic Surgery

Primary Investigator: E. Matthew Ritter MD FACS*
Associate Investigators: James R. Korndorffer MD FACS# and Jonathan P. Pearl MD FACS^

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Statement of Funds

Funds for this project are not currently on hand, thus the reason for the grant application. Each of the participating institutions do have in place considerable resources to contribute to the success of this proposed project. The Uniformed Services University, Tulane University, and the University of Maryland all have American College of Surgeons Accredited Education Institutes in which this type of skills based educational research has been previously performed. Thus, there is considerable infrastructure available to support this protocol in terms of research space and personnel (technicians, IT / AV support, etc., see included Letters of Institutional Support) Additionally, all three centers are currently certified FLS test centers and all have either a Simbionix GI Mentor II or Bronch Mentor available. All have plans to become an FES test center as that process evolves. Finally, each facility has access to dedicated standard flexible endoscopy equipment and AV equipment for use in this protocol. Finally, the Uniformed Services University Joint Office of Technology Transfer is executing a Collaborative Research and Development Agreement (CRADA) with both Kyoto and Limbs and Things for the commercial production of the S.C.O.P.E. platform. Since this involves only minor modifications to the current Kyoto colonoscopy simulator, it is expected that a production quality version of the S.C.O.P.E platform would be used for the study and be commercially available prior to the completion of any research.

Summary

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) has devoted significant resources to the development of the Fundamentals of Endoscopic Surgery (FES) program. Much like the Fundamentals of Laparoscopic Surgery (FLS), FES consists of both a high-stakes didactic examination and a skills test. If the FES program follows a trajectory similar to that of FLS, it will be widely disseminated and may become a requirement for American Board of Surgery Certification [1]. Because of the high stakes associated with FES, it is necessary to develop a training program that would best prepare the learners for the skills examination, as well as provide a curriculum for skills remediation for those who are initially unsuccessful.

Based on the success of the previously developed FLS skills training curriculum[2-5], we will develop a proficiency based skills curriculum using the low-cost, non computer based Simulated Colonoscopy Objective Performance Evaluation (S.C.O.P.E) platform. This will be done in 3 phases. In phase 1, experience endoscopists will define the performance goals that will be used in the curriculum. In phase 2, novice endoscopists will train on each of the S.C.O.P.E. tasks until they reach the performance goals. Their endoscopic skills will be assessed both before and after training with 3 different validated assessment tools, FES, S.C.O.P.E. and the Global Assessment of Gastrointestinal Endoscopic Skills for Colonoscopy (GAGES-C). Finally, for phase 3, the durability of skills acquisition will be evaluated with both 6 month and 12 month follow up for the novice endoscopists.

Background

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) has devoted a significant amount of resources to the development of the Fundamentals of Endoscopic Surgery (FES) program[1]. Much like the Fundamentals of Laparoscopic Surgery (FLS), FES consists of both a high-stakes didactic examination and a skills test. If the FES program follows a trajectory similar to that of FLS, it will be widely disseminated and may become a requirement for American Board of Surgery Certification in Surgery. Because of the high stakes associated with FES, it is necessary to develop a training program that would best prepare the learners for the skills examination, as well as provide a curriculum for skills remediation for those who are initially unsuccessful.

Proficiency based training has proven useful in preparing for FLS testing. In proficiency-based training, learners train to expert levels prior to high-stakes testing. Our group has been instrumental in the development of proficiency-based training for FLS. After completion of the proficiency based training program for FLS, learners have 100% certification pass rate. The skills acquisition was durable and learners were able to return to high levels of performance on simulators even after a lengthy hiatus from training[2-5]. An analogous proficiency-based training program for FES would likely demonstrate similar utility.

FES relies on a computer-based platform for skills testing. A commercially available virtual reality (VR) endoscopy simulator with software modifications will be used to administer the examination. VR simulators such as the one used for FES have several limitations: high maintenance costs, suboptimal durability, and difficulty mimicking the feel of performing live clinical cases. Furthermore, the start-up costs of the simulator used for FES range from $40,000 to over $100,000. Such costs will likely be prohibitive to many surgery training programs and simulation centers, therefore regional testing centers are being developed.

The SAGES FES Task Force, in collaboration with SAGES leadership, has opted not to allow practice on the specific FES tasks. Even those centers who own the VR simulator will only be able to access the FES skills for testing. Without access to the FES tasks, or tasks which closely mimic those in FES, learners may be inadequately prepared for taking the high-stakes exam.

We perceived a need for an affordable, non-computer based, assessment tool that can be used for training in basic flexible endoscopy. Our program, termed Simulated Colonoscopy Objective Performance Evaluation (SCOPE), uses a commercially available physical colonoscopy model and a standard colonoscope to perform four specific tasks: scope navigation, tool targeting, loop reduction, and mucosal inspection with retroflexion. The physical model has several distinct advantages over computer based models. Since a genuine colonoscope is used, the learners gain familiarity with the handling of the same instruments used in clinical. The physical model uses a rubber colon designed to mimic the feel of a true colon. The maintenance costs are low since

there are no computerized components of the model. In addition, the acquisition costs are affordable, with an initial investment of less than $10,000 required to begin training.

Our preliminary data using the physical colonoscopy model and our SCOPE program have been encouraging. We have shown that SCOPE, based on the above four tasks, can be administered in less than 50 minutes per learner. We have identified the key metrics for incorporation into a scoring system and have accumulated validity evidence that the SCOPE scoring system objectively assesses the technical skills required to perform standard flexible endoscopy. For each of the four tasks, we have validity evidence that task scores reliably differentiate between novices, intermediates, and experts. Our data indicate that SCOPE is a reliable, simple program for simulating basic flexible endoscopy. SCOPE could be an ideal training platform to prepare for basic clinical endoscopy and FES testing. [7-9]

The goal of this proposal is to develop a proficiency based skills curriculum for FES using SCOPE. We will draw on the success of proficiency based training for FLS and apply the same methodologies to FES. A proficiency based skills curriculum for FES using SCOPE could help prepare learners for the FES examination and could foster the success of the entire FES program.

Hypothesis

Our hypothesis is that training to expert derived performance goals on a non-computer based flexible endoscopy simulator will allow a group of novice endoscopists to acquire a level of skill adequate to achieve a greater than 80% pass rate on the manual skills portion of the Fundamentals of Endoscopic Surgery (FES) assessment. After completing this proficiency based curriculum, these novice endoscopists will also demonstrate performance scores on the Global Assessment of Gastrointestinal Endoscopic Skills for Colonoscopy (GAGES- C) and Simulated Colonoscopy Objective Performance Evaluation (S.C.O.P.E.) assessments equivalent to intermediately experienced endoscopists (50 - 140 endoscopies). Finally, the group of novice endoscopists who complete this proficiency based curriculum will demonstrate significantly higher scores on FES, GAGES-C, and S.C.O.P.E when compared to a control group that simply undergoes repeat assessment without any formalized curriculum (to control for learning effect of repeated assessment).

Methods

Subjects: Two distinct categories of subjects will be needed:

Novice subjects (NS): 45 novice subjects will be recruited.(See power analysis) Inclusion criteria include any healthcare professional adult>18 years of age who has not had significant previous experience with a flexible endoscopic simulator and has performed less than 10 endoscopies (EGD and colonoscopy). Significant endoscopic simulator experienced is defined by self reported time on any endoscopic simulator of greater than 5 hours, or having previously completed a formalized endoscopy training curriculum. Professional backgrounds include but are not limited to medical students and resident physicians. Subjects will be recruited regardless of pregnancy status. Subject data will be identified in databases only by subject number. No identifying data will be recorded and performance will in no way affect any subjects course grading or evaluation on any rotation.

Experienced subjects (ES): 30 experienced subjects will be recruited (see power analysis) Inclusion criteria include any gastrointestinal healthcare professional adult>18 years of age who has performed more than 50 endoscopies. Professional backgrounds include and are limited to General Surgery PGY>=4, Gastroenterology fellows, General, Colorectal, and Minimally Invasive Surgeons, and Gastroenterologists. Subjects will be recruited regardless of pregnancy status. Subject data will be identified in databases only by subject number. No identifying data will be recorded and performance will in no way affect any subjects grading or evaluation on any rotation, or credentialing.

Apparatus and Procedures:

Kyoto Colonoscopy Simulator: A non-computer based physical colonoscopy model manufactured by Kyoto Kagaku Co Ltd, Japan. A plastic external form contains a latex simulated colon that can be configured into different "cases" based on the standard inserts included. This model must be used in conjunction with a colonoscope with capabilities for insuflation, irrigation, and suction, connected to an imaging system and displayed on a 4:3 aspect ratio video monitor.

GAGES-C Assessment: for this assessment, subjects will perform a simulated colonoscopy on the Kyoto simulator. This will involve navigating to the cecum on a standardized case, followed by withdrawal and mucosal inspection to identify 5 numbered targets. For 3 of the targets, subjects will be asked to make contact with them using a standard biopsy forceps. External views of the endoscope and the subjects hands will be video recorded along with the endoscopic view combined into one screen using a video mixer. The recordings will then be scored using GAGES-C scoring system, which assesses scope navigation, use of strategies (loop reduction, positioning, etc), ability to keep a clear field, instrumentation (facility using tools) and quality of exam each on a anchored 5pt likert scale[6]. Evaluators using the scoring system will be blinded to the subjects group and training status.

Simulated Colonoscopy Objective Performance Evaluation (S.C.O.P.E): This is based on the framework of the Kyoto platform described above but has been modified into 4 separate tasks

that include performance metrics and a scoring system. The tasks include *Scope Manipulation*: requires use of torque and tip deflection to move a shape in the colon to the 6 o'clock position and align that shape within an outline of the shape placed upon the monitor screen. Alignment must be held for 5 seconds for each shape before continuing to the next shape. The modified colon contains 10 shapes in various locations. *Tool Targeting*: requires coordination with biopsy forceps to contact a metal target, completing a circuit and sounding a tone. Contact must be maintained for 5 seconds on each target before continuing to the next. The modified colon segment contains 10 targets in various locations. *Loop Management*: perform scope navigation to correctly manage the formation of a standard alpha loop. The task is to insert the scope in the simulated rectum followed by navigation to the cecum through a redundant sigmoid. If a loop is formed, it must first be recognized and then successfully reduced to continue advancing the colonoscope. The task will begin in the left lateral decubitus position but on request, the task can be repositioned in the supine, prone, or right lateral decubitus position. Additionally, abdominal pressure can be provided by the proctor where and when directed by the subject. *Mucosal Inspection*: during withdraw of the colonoscope, identification of polyps placed randomly throughout a length of simulated colon and rectum requiring careful mucosal inspection, including retroflexion.

As an assessment, the tasks are administered sequentially by a proctor using a standard instruction script and standardized scoring metrics. As a training tool, subjects will train on each task until a defined expert performance proficiency level is reached.

Fundamentals of Endoscopic Surgery (FES): The manual skills portion of the FES program is based in virtual reality and delivered by either the GI Mentor II or Bronch Mentor simulators (Simbionix USA, Cleveland OH). It consists of 5 task that assess scope navigation, tool manipulation, loop reduction, retroflexion, and mucosal inspection. The exam is completely computer based and is administered by a proctor. All task instructions and scoring are completed by the computer based simulator and uploaded to a network server. The FES exam can only be given at FES test centers.

Methods:

Phase I: *Establishing performance goals and references*- This phase will involve the ES group to define the task specific training goals for the novice curriculum. Each ES subject will complete a GAGES-C assessment followed by 3 trials of each of the S.C.O.P.E tasks. Three trials are used to help ensure that the simulator specific learning curve has been accounted for. The GAGES-C scores will be used to help calibrate performance of experienced endoscopist on the Kyoto model as the GAGES-C data to date has come from actual colonoscopies. The mean trial 3 performance on each of the S.C.O.P.E. tasks will be used to set the proficiency levels for the training curriculum to be utilized in Phase II.

Phase II: *Assessing the effects of the curriculum*- The NS group will be randomized in a 2:1 ratio between the training group (NST) and the control group (NSC) respectively. Both groups will undergo a pretest consisting of a GAGES-C assessment, a S.C.O.P.E assessment, and an FES assessment. Subjects in the NST group will then train to the proficiency levels established in Phase I for each of the S.C.O.P.E. tasks. The NST group will then undergo a posttest

consisting of a GAGES-C assessment, S.C.O.P.E assessment, and FES assessment within 2 weeks of completion of the curriculum. NSC subjects will receive no training during this phase and will return for the posttest after the same amount of time as it took for the NST group to complete their training. Both groups will be queried as to any additional clinical endoscopic experience that they received between the pretest and the posttest. Once the NSC subjects complete the posttest, they will be allowed to complete the curriculum if they wish, including an additional post curriculum assessment within 2 weeks of curriculum completion.

Phase III: *Long term follow up*- All subjects who complete the curriculum in both the NST and NSC groups will be asked to return for additional assessment at 6 months and 12 months. Subjects will be queried as to any additional clinical endoscopic experience that they received between the assessments. This follow up assessment will consist of 3 trials of each S.C.O.P.E. task to evaluate for rapid spontaneous recovery of skills seen in previous similar studies.[3] They will also undergo an FES assessment.

Data Analysis: For continuous variables, mean performance differences between pretest and posttest assessment within groups will be statistically assessed for significance using paired t-test. Mean performance differences between groups will be statistically assessed for significance with unpaired t-tests. Differences for multiple repeated measures during long term follow up will be assessed with repeated measure ANOVA. For proportions, rates of achieving a passing score on the FES assessment will be statistically assessed for significance using Fishers exact test or chi squared as appropriate.

Sample Size / Power Analysis

Samples size can be estimated using previous data for two of our primary endpoints stated in the hypothesis, GAGES-C and S.C.O.P.E. Previously published GAGES-C scores for novice and intermediate endoscopists[6] showed a difference in means between the two groups of approximately 6, with a standard deviation in the novice group of 3.8 and intermediate group of 1.6. If we use a paired, two tailed t-test (since our subjects undergo a pre-test then a post-test) with alpha set at 0.05, estimated standard deviation of 5.5 and a power of 80%, then we need 9 subject to be able to reject the null hypothesis. Since the exact difference in performance improvement is unknown, Figure 1 shows sample size and power for a difference in means ranging from 3 to 6.

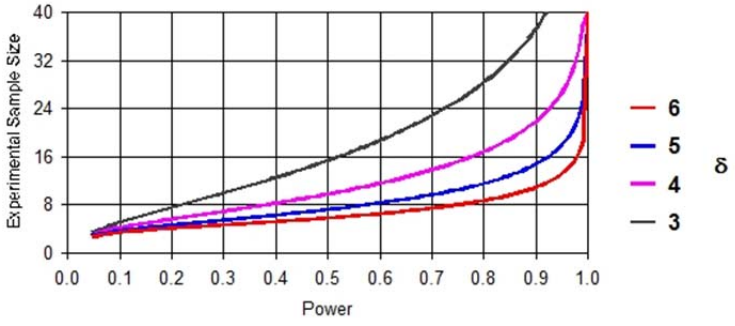

Figure 1:Required sample size as a function of statistical power for differences in means between groups ranging from 3 to 6

Similar calculations can be done using the S.C.O.P.E. score endpoint. Unpublished data currently undergoing peer review showed that for S.C.O.P.E score, novice and intermediate

endoscopists showed a difference in means between the two groups of approximately 115 with a standard deviation in the novice group of 94 and intermediate group of 62.[9] If we apply the same paired, two tailed t-test with alpha set at 0.05, estimated standard deviation of 150 and a power of 80%, then we need 15 subject to be able to reject the null hypothesis. Since the exact difference in performance improvement is unknown, the graph below shows sample size and power for a difference in means ranging from 95 to 125.

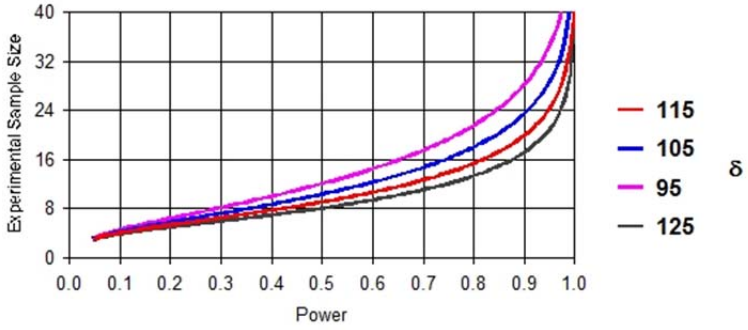

Figure 2: Required sample size as a function of statistical power for differences in means between groups ranging from 95 - 125

Based on these evidence based estimates, a sample size of 24 experimental subjects would allow us to be well powered across a broad range of differences in mean performance. If we allow for a 20% drop out rate, since participation is completely voluntary, that would result in recruiting 30 novice experimental subjects. or 10 subjects / site. In a separate analysis conducted similar to the ones above (not shown), approximately 12 control subjects would be required to reject the null hypothesis between the experimental and control groups with an 80% power. Applying the 20% drop out rate to the control group brings the target subject recruitment to 15, or 5 / site.

Comparison of the ES group with other groups is not part of our hypothesis testing, as this group serves to establish the reference criteria for the GAGES assessment and the proficiency scores for S.C.O.P.E. An estimated recruitment of up to 10 subjects per site should be more than adequate to ensure a broad representation of the desired skill set.

SAGES RESEARCH GRANT APPLICATION
BUDGET SHEET

Detailed budget for 12 month period from __ Jul. 1, 2013 through Jun. 30, 2014.

Dollar amount requested (Omit cents) 30,000

Total for the grant request may not exceed $30,000.

* Salary funds should be used for staff required to execute the study, but should not be used for salary support for the primary investigator. If salary support exceeds 50% of the project budget, then specific justification is required.

**Funds requests for travel for the presentation of a SAGES funded study should be limited to $1,000.

NAME	POSITION TITLE	TIME/EFFORT		SALARY	FRINGE BENEFITS	SUB-TOTALS
		%	Hrs/ Week			
1. E. Matthew Ritter	Principal Investigator*	5	2			
2. James Korndorffer	Assoc. Investigator	4	1.5			0
3. Johnathan Pearl	Assoc. Investigator	4	1.5			0
CONSULTANT COSTS						
EQUIPMENT (List all Items&Total Equipment Cost)	Items					Subtotal
SUPPLIES (List all Items&Total Supplies Cost)	Items Kyoto Colonoscopy SCOPE Models (6 at $2,500 each, total $15,000), Colon Inserts (6 at $1,000 each, total $6,000), MacBook pro computer 13 inch (3 at $1,300 each, total $3,900), Mac Software $660, Misc recording / simulator maintenance supplies $190					25,750
TRAVEL**	PI site visit travel to Tulane and UMD two visits each $3,250, SAGES meeting travel for presentation - $1000					4,250
PATIENT CARE COSTS						
CONSORTIUM/CONTRACTUAL COSTS						
OTHER EXPENSES (List all Items & Total Cost)	Items					Subtotal
TOTAL DIRECT COSTS						30,000

Budget Justification

Personnel

E. Matthew Ritter, MD (5% Effort), Principal Investigator. Dr. Ritter will lead the research effort. He will oversee the resident researchers and Associate-Investigators. He will submit the protocol to and be the lead contact for the IRB, which will allow the residents enrolled in the courses to take a skills test. Finally, he will present his findings at the SAGES meeting. Since his salary is paid for by the US Air Force, no salary support is requested.

James Kornfdorffer, MD (4% Effort), Associate Investigator from Collaborating Organization. Dr. Korndorffer will lead the research effort at Tulane. He will oversee the residents and fellows' work there and report results to the PI, Dr. Ritter. No salary support is requested.

Jonathan Pearl, MD (4% Effort), Associate Investigator from Collaborating Organization. Dr. Pearl will lead the research effort at the University of Maryland, School of Medicine. He will oversee the residents and fellows' work there and report results to the PI, Dr. Ritter. No salary support is requested.

Equipment $0

Supplies $25,750

$15,000 is requested for Kyoto colonoscopy SCOPE models (6 at $2,500 each), which mimic real human tissues, and the residents and fellows will use to practice their techniques on them hands on. $6,000 is requested for colon Inserts (6 at $1,000 each) to be placed inside the Kyoto colonoscopy SCOPE models (above) so that students can practice their techniques on them. $3,900 is requested for MacBook pro computers 13 inch (3 at $1,300 each) so that student scope images and skills test results can be captured at each of the three worksites, maintain and organize data and protocol documents, communicate among the sites, and organize skills test documents and materials. $660 is requested for Mac Software to record images and for basic word processing and spreadsheet applications. $190 is requested for miscellaneous recording / simulator maintenance supplies to maintain the camera equipment and keep the simulator models in good working condition.

Travel $4,250

$1,000 is requested for travel to the SAGES meeting for the PI to present the results of the project. $3,250 is requested for two site trips (each) to the University of Maryland in Baltimore, MD and to Tulane University in New Orleans, Louisiana for the PI to meet with the Associate-Investigators to exchange ideas and discuss the progress of the project.

Other Expenses $0

Indirect Cost $0

There will be no indirect cost requested for this project.

References

1. Vassiliou MC, Dunkin BJ, Marks JM, Fried GM. FLS and FES: comprehensive models of training and assessment. Surg Clin North Am 2010; 90(3):535-58.
2. Ritter EM, Scott DJ. Design of a proficiency-based skills training curriculum for the fundamentals of laparoscopic surgery. Surg Innov 2007; 14(2):107-12.
3. Rosenthal ME, Ritter EM, Goova MT, et al. Proficiency-based Fundamentals of Laparoscopic Surgery skills training results in durable performance improvement and a uniform certification pass rate. Surg Endosc 2010; 24(10):2453-7.
4. Scott DJ, Ritter EM, Tesfay ST, et al. Certification pass rate of 100% for fundamentals of laparoscopic surgery skills after proficiency-based training. Surg Endosc 2008; 22(8):1887-93.
5. Sroka G, Feldman LS, Vassiliou MC, et al. Fundamentals of laparoscopic surgery simulator training to proficiency improves laparoscopic performance in the operating room-a randomized controlled trial. Am J Surg 2010; 199(1):115-20.
6. Vassiliou MC, Kaneva PA, Poulose BK, et al. Global Assessment of Gastrointestinal Endoscopic Skills (GAGES): a valid measurement tool for technical skills in flexible endoscopy. Surg Endosc 2010; 24(8):1834-41.
7. Cox TC, Trinca K, Pearl JP, Ritter EM. Simulated Colonoscopy Objective Performance Evaluation (S.C.O.P.E.) : Identification of Key Metrics for Objective Assessment. Unpublished data. Abstract submitted to 2013 ASE Meeting - included in submission
8. Trinca K, Cox TC, Pearl JP, Ritter EM. Validity Evidence for the Simulated Colonoscopy Objective Performance Evaluation (S.C.O.P.E.) Scoring System. Unpublished data. Abstract submitted to 2013 ASE Meeting. - included in submission
9. Ritter EM, Cox TC, Trinca K, Pearl JP Simulated Colonoscopy Objective Performance Evaluation (S.C.O.P.E.): A non-computer based tool for assessment of endoscopic skills. Unpublished data. Abstract submitted to 2013 SAGES Meeting. - included in submission

Local/Institution Review Board

The IRB submission packet is being assembled as the grant is being prepared and will be submitted concurrently with the grant application. Given that this is standard educational research evaluating a new curriculum, with no procedures being performed on either humans or animals, we do not expect any IRB approval issues.

Available Resources

The Department of Surgery at the Uniformed Services University collaborates frequently with the National Capital Area Medical Simulation Center and the newly opened Walter Reed National Military Medical Center Simulation Center, which is an American College of Surgeon Accredited Education Institute (ACSAEI). Between the two, there's more than 20,000 sq ft of training space with approximately 2000 dedicated to surgical skills in the Procedural Skills Training Lab (PSTL). The PSTL has two endoscopic towers, the S.C.O.P.E prototype, and a newly ordered Bronch Mentor simulator to contribute to this project. Additionally, AV recording equipment along with salaried technician support will be available. The National Capital Consortium General Surgery Residency program supports the educational research effort with a funded research resident in the lab as well. The PI of this, project, Dr. Ritter, serves as the Director of Surgical Simulation at the Walter Reed SimCenter and has been the Assistant Surgical Director at the NCAMSC for the last 8 years.

The Department of Surgery at Tulane works closely with The Tulane Center for Advanced Medical Simulation and Team Training. The center is a 14,000 sq ft facility that is also an ACSAEI. The facility has all of the required tools for flexible endoscopy simulation, including a Simbionix Bronch Mentor. The center also has salaried tech support and AV equipment to contribute to the success of this project. The Tulane AI, Dr. Jim Korndorffer, serves as the Medical Director for the center. A letter of collaboration from Dr. Korndorffer is included below.

The Department of Surgery at the University of Maryland School of Medicine plays an integral role in the Maryland Advanced Simulation, Training, Research, and Innovation (MASTRI) Center. The MASTRI Center's main facilities are located in a 3,600 square foot wing of the University of Maryland Medical Center. The primary simulation areas consist of four converted operating rooms now serving as a configurable part-task training room, variable function room, whole-task trainer room, and cognitive and physical ergonomics research laboratory. The part-task training room serves as the hub for surgical simulation. The space houses 6 FLS box trainers, two VR laparoscopy trainers, and one GI Mentor II endoscopy simulator. There is ample space to house additional training models. The full-time staff members at the MASTRI Center include a director, two training and simulation specialists, and three administrative personnel. Medical and surgical simulation educators come from the various departments within the Medical Center. A letter of collaboration from Dr. Pearl, who is intimately involved in the MASTRI center is included below.

Participation in SAGES

All of the investigators are long time SAGES members and active participants in SAGES. All are fellowship trained in minimally invasive surgery through SAGES approved fellowship programs and have active surgical endoscopy practices. Dr. Pearl has additional expertise in Advanced Flexible GI endoscopy. All investigators serve on the SAGES FES Committee, in addition to multiple other SAGES committees. The PI, Dr. E. Matthew Ritter was the co-author and co-developer of the FLS proficiency based skills training curriculum, and serves as a co-chair of the FLS committee. All three investigators have been faculty and/or course chairs for multiple FLS / Flexible endoscopy courses at SAGES and ACS meetings.

BIOGRAPHICAL SKETCH

NAME Eric Matthew Ritter (Matt)	POSITION TITLE Vice Chairman, Education Norman M. Rich Department of Surgery USUHS, Bethesda MD
eRA COMMONS USER NAME	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
United States Air Force Academy	BS	1993	Chemistry
Uniformed Services University of the Health Sciences	MD	1997	Medicine
David Grant USAF Medical Center	Internship	1997-1998	General Surgery
David Grant USAF Medical Center	Residency	1998-2002	General Surgery
Emory University School of Medicine	Research Fellowship	2002-2003	Simulation, Training and Robotics
Emory University School of Medicine	Clinical Fellowship	2003-2004	Advanced Laparoendoscopic Surgery

A. Personal Statement

The goal of the current proposal is to develop and evaluate the effectiveness of a proficiency based skills training curriculum for the manual skills portion of the Fundamentals of Endoscopic Surgery (FES) program. I am well suited to lead this for three main reasons.

First, clinical expertise. I am a practicing surgical endoscopist, with fellowship training, and 10 years of experience as an endoscopic surgeon. I have a vested interest for both my patients and students to develop solid educational curricula. Reason number two, research experience. As you can see from my references, I was instrumental in the development of a proficiency based curriculum for the Fundamentals of Laparoscopic Surgery (FLS) program. The availability of this curriculum strongly influenced the American Board of Surgery in their decision to mandate FLS certification. I can do the same for FES. Finally, national influence. I am uniquely positioned in both the civilian and military academic communities to ensure wide ranging application and support of a curriculum such as this one. My leadership positions within SAGES as well as the DoD simulation and education communities allow me access to key decision makers that can ensure dissemination of this work at the highest levels.

My assembled research team and I are ready to get to work.

B. Positions and Honors.

Positions and Employment

2012 Aug - present Vice Chairman, Education, Norman M. Rich Department of Surgery, USUHS, Bethesda MD

2012 - present Associate Professor, Norman M. Rich Department of Surgery, USUHS, Bethesda MD

2011 - present Surgical Director, Walter Reed National Military Medical Center Simulation Center, Bethesda MD

2011 Aug - present Attending Surgeon, Walter Reed National Military Medical Center, Bethesda MD

2011 Jun - December Chief of Surgery and Theater Inpatient Trauma Services, 455th Expeditionary Medical Group, Task Force Med East, Craig Joint Theater Hospital, Bagram Air Base, Afghanistan
2010 Jan - July 2012 Chief, Division of Academic Surgery, Norman M. Rich Department of Surgery, USUHS, Bethesda MD
2009 Aug – Nov General/Trauma Surgeon 455th Expeditionary Medical Group, Task Force Med, Craig Joint Theater Hospital, Bagram Air Base, Afghanistan
2009 May – Aug General/Trauma Surgeon, 332nd Expeditionary Medical Group, Joint Base Balad, Iraq
2008 Aug - 2009 Nov Chief, Minimally Invasive Surgery and Emerging Technologies, Norman M. Rich Department of Surgery , USUHS, Bethesda MD
2007 Jan – Jun General Surgeon/ Surgical Services Chief, 379th Expeditionary Medical Group, Al Udeid AB, Qatar
2006-2011 Attending Surgeon, Walter Reed Army Medical Center, Washington, DC
2005 Jan - 2011 Dec Assistant Director, Surgical Simulation, National Capital Area Medical Simulation Center, USUHS, Silver Spring MD
2005-2012 Assistant Professor, Norman M. Rich Department of Surgery, USUHS, Bethesda Maryland.
2004-2005 Attending Surgeon, National Naval Medical Center, Bethesda MD
2003-2004 Attending Surgeon, Emory University Hospital/Emory Clinic Atlanta GA
2003-2004 Attending Surgeon, Crawford Long Hospital, Atlanta GA

Other Experience and Professional Memberships

- Member, Fundamentals of Endoscopic Surgery Committee, Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) July 2012 -present
- Chair, Fundamentals Test Center Sub-Committee, Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) July 2012 -present
- Co-Chair, Fundamentals of Laparoscopic Surgery Committee, Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). April 2009 - present
- Member, Simulation Committee, Association for Surgical Education (ASE) December 2009-present
- Member, Clerkship Directors Committee, Association for Surgical Education (ASE). December 2009-present
- Member, Clinical Guidelines Committee, Society of American Gastrointestinal Endoscopic Surgeons, Sept 2007- 2011
- Site Reviewer, American College of Surgeons Education Institute Committee, October 2005 - present
- Member, Fundamentals of Laparoscopic Surgery Committee, Society of American Gastrointestinal Endoscopic Surgeons. May 2005- April 2009

Selected Honors

2010 American College of Surgeons, Surgeons as Educators Course, Participant
2009 David G. Burris Deployment Award, Uniformed Services University, Norman M. Rich Department of Surgery.
2008 Golden Apple Award for Most Outstanding Surgical Educator. National Naval Medical Center Department of General Surgery.
2006 David C. Wherry Emerging Technologies Award, Uniformed Services University, Norman M. Rich Department of Surgery.
1996 Alpha Omega Alpha, Gamma Chapter of Maryland, Bethesda Maryland.

C. Selected peer-reviewed publications

Most relevant to current application

1. Scott DJ. Pugh CM. **Ritter EM**. Jacobs LM. Pellegrini CA. Sachdeva AK. New directions in simulation-based surgical education and training: validation and transfer of surgical skills, use of nonsurgeons as faculty, use of simulation to screen and select surgery residents, and long-term follow-up of learners. Surgery. 149(6):735-44, 2011 Jun.
2. Rosenthal ME, **Ritter EM**, Goova MT, Castellvi AO, Tesfay ST, Pimentel EA, Hartzler R, Scott DJ. Proficiency-based FLS skills training results in durable performance improvement and uniform certification pass rate. Surgical Endoscopy 2010, 24(10): 2453-7
3. Scott DJ, **Ritter EM**, Tesfay ST, Pimentel EA, Nagji A, Fried GM. Certification Pass Rate of 100% for Fundamentals of Laparoscopic Surgery skills after Proficiency Based Training. Surgical Endoscopy 2008 22(8); 1887-1893
4. **Ritter EM**, Scott DS. Design of a Proficiency-Based Skills Training Curriculum for the Fundamentals of Laparoscopic Surgery. Surgical Innovation 2007 14(2): 107 – 112.
5. Westman B, **Ritter EM**, Kjellin A, Torkvist L, Wredmark T, Fellander-Tsai L, Enochsson L. Visuospatial Abilities Correlate with Performance of Senior Endoscopy Specialists in Simulated Colonoscopy. *Journal of Gastrointestinal Surgery*. 2006 10(4): 593-9
6. Enochsson, L, Westman B, **Ritter EM**, Hedman L, Kjellin A, Wredmark T, Fellander-Tsai L. Objective Assessment of Visuospation, Psychomotor ability and Flow of Residents and Senior Endoscopists in Simulated Gastroscopy. Surgical Endoscopy. 2006, 20(6): 895-9
7. VanSickle KR, **Ritter EM**, Smith CD. The Pretrained Novice: Using Simulation Based Training to Improve Learning in the Operating Room. Surgical Innovation 2006 13(3): 198 – 204
8. **Ritter EM**, McClusky DA, Gallagher AG, Enochsson L, Smith CD. Perceptual, Visuo-spatial, and Psychomotor Ability Correlates with Duration of Training Required on a Virtual Reality Flexible Endoscopy Simulator. American Journal of Surgery. 2006 192(3): 379-84
9. **Ritter EM**, McClusky DA, Lederman AB, Gallagher AG, Smith CD. Objective Psychomotor Skills Assessment of Experienced and Novice Flexible Endoscopists with a Virtual Reality Simulator. Journal of Gastrointestinal Surgery. 2003, 7(7), 871-878
10. Gallagher AG, **Ritter EM**, Satava RM. Fundamental Principles of Experimental Design, Validation, and Reliability: Rigorous Science for the Assessment of Surgical Education and Training. Surgical Endoscopy. 2003, 17, 1525-1529

Other selected peer reviewed publications

11. Van Sickle KR, **Ritter EM**, Baghai M, Goldenberg AE, Huang IP, Gallagher AG, Smith CD. Prospective, Randomized, Double-Blind Trial of Curriculum-Based Training for Intracorporeal Suturing and Knot Tying. Journal of the American College of Surgeons. 2008 207(4); 560 – 568.
12. Van Sickle KR, Baghai M, Huang IP, Goldenberg A, Smith CD, **Ritter EM**. Construct Validity of an Objective Assessment Method for Laparoscopic Intracorporeal Suturing and Knot Tying. *American Journal of Surgery* 2008 196(1); 74-80
13. **Ritter EM**, Kindelan TW, Pimentel EA, Michael C, Bowyer MW. Concurrent Validity of Augmented Reality Metrics Applied to the Fundamentals of Laparoscopic Surgery (FLS). *Surgical Endoscopy* 2007 21 (8);1441 – 5
14. Haluck RS, Satava RM, Fried G, Lake C, **Ritter EM**, Sachdeva AK, Seymour NE, Terry ML, Wilks D. Establishing a Simulation Center for Surgical Skills: What to Do and How to Do It. *Surgical Endoscopy*. 2007 21(7): 1223-32.

15. VanSickle KR, **Ritter EM**, McClusky DA, Baghai M, Smith CD. Attempting to Establish Proficiency Levels for Laparoscopic Performance on a National Scale Using Simulation: The Results from the 2004 SAGES MIST-VR Learning Center Study. Surgical Endoscopy. 2007 21 (1): 5 -10.

16. **Ritter EM**, McClusky DA, Gallagher AG, Smith CD. Real Time Assessment of Knot Quality With a Portable Tensiometer Is Superior to Execution Time for Assessment of Laparoscopic Knot-Tying Performance. Surgical Innovation. 2005 12(3) 233-237.
17. Gallagher AG, **Ritter EM**, Champion H, Fried M, Higgins G, Moses G, Satava R, Smith C. Virtual Reality Simulation for the Operating Room: Proficiency-Based Training as a Paradigm Shift in Surgical Skills Training. Annals of Surgery. 2005 241(2) 364-372.
18. McClusky DA, **Ritter EM**, Gallagher AG, Lederman AB, Smith CD. Correlation between perceptual, visuo-spatial, and psychomotor aptitude to duration of training required to reach performance goals on the MIST-VR surgical simulator. American Surgeon. 2005 71(1) 13-22

C. Research Support.

Ongoing Research Support

90VW-01 USUHS, Office of Program Development Ritter (PI) 10/2012 - 10/2014
Fundamentals of Laparoscopic Skills Training at a Reduced Cost
This project will compare newly developed reduced cost training strategies for the Fundamentals of Laparoscopic Surgery (FLS) with the standard training platforms and strategies.
Funding $28,000
Role: PI.

Tricare Management Agency-Office of Patient Safety (DOD) Ritter (PI) 10/2005-ongoing
Improving Safety of Laparoscopic Surgery Through Implementation of The Fundamentals of Laparoscopic Surgery (FLS) Curriculum.
The goal of the project is to refine the FLS curriculum into a one day didactic course that includes patient safety and deliver the training to all Military hospitals with eventual goal of requiring certification on FLS as a minimum to perform laparoscopic procedures.
Funding: $261,413 total funding
Role: PI

Completed Research Support

Tricare Management Agency-Office of Patient Safety (DOD) Bowyer (PI) 10/2005-9/2007
Development of a Scenario Based, Simulation Enhanced, Team Oriented, Patient Safety Curriculum for Teaching Upper and Lower Endoscopy.
Grant is aimed at the development of a curriculum for improving patient safety during endoscopy
Funding: $183,150
Role: Co-PI

W81XWH-05-1-001 US ARMY (USAMRAA) Bowyer (PI) 10/3/05-10/2/06
Scientific Educational Validation Study of Rapid Fire/Smart Tutor
This study is a designed to validate a novel laparoscopic simulator that adjusts difficulty based on student performance on the simulator.
Funding: $20,000
Role: Co-PI

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Korndorffer Jr., James R	Professor of Surgery
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Tulane University, New Orleans LA	B.S. E.	05/86	Biomedical Engineering
University of South Florida, Tampa, FL	MD	05/90	Medicine
Carolinas Medical Center, Charlotte, NC	Residency	06/95	General Surgery
Tulane University Health Sciences Center	Fellowship	06/05	Minimally Invasive Surgery
University of Illinois, Chicago, Chicago, IL	Masters	05/11	Health Professions Education

A. Personal Statement

The goal of the proposed research is to develop a proficiency-based training program in flexible endoscopy on a physical colonoscopy platform. I am an expert in flexible endoscopy having been trained during residency and routinely performing endoscopy in practice. I serve on the SAGES FES Task Force.

I have vast experience in surgical simulation and am the medical director of the Tulane Center for Advance Medical Simulation. . At the Center train surgery residents through a proficiency-based endoscopy program using virtual reality. Dr E Matthew Ritter and I have collaborated on numerous projects in the past. Developing a proficiency-based training program using this model could provide a cost-effective means of training for FES. This grant would provide be the impetus for developing this valuable, cost-effective training program.

B. Positions and Honors

Positions and Employment

2012 – present Vice-chair, Department of Surgery, Tulane University School of Medicine
2010 – present Professor, Department of Surgery, Tulane University School of Medicine
2005 to 2010 Associate Professor, Department of Surgery Tulane University School of Medicine
2004 to 2005 Instructor of Surgery, Department of Surgery Tulane University School of Medicine, New Orleans, LA
2003 to 2004 Advanced Laparoscopy Research Fellow, Tulane Center for Minimally Invasive Surgery Tulane University, School of Medicine, New Orleans, LA
1997 to 2003 General Surgeon, Active Staff Baptist Medical Center East Montgomery, Alabama
1995 to 1997 General Surgeon, Active Staff, Fayette Medical Center, Fayette, Alabama

Other Experience and Professional Memberships

2012 – present	Society of Gastrointestinal and Endoscopic Surgeons Fundamentals of Endoscopic Surgery Committee
2012 - present	American College of Surgeons Committee on Validation of Surgical Knowledge and Skills
2009 - present	Society of Gastrointestinal and Endoscopic Surgeons Fundamentals of Laparoscopic Surgery Committee
2008 - present	Association for Surgical Education Committee on Graduate Surgical Education Vice Chair 2009-2011, Chair 2011-present
2009 - 2012	Association for Surgical Education Foundation Board
2008 - present	Association for Surgical Education Committee on Simulation
2008 – present	Association of Academic Surgeons Institutional Representative
2008, 2012	American Board of Surgery Associate Examiner
2005 - present	Society of Gastrointestinal and Endoscopic Surgeons (SAGES) Guidelines Committee
2006-2007	NSABP Principal Investigator
2004-2009	SAGES Resident Education Committee

Honors

2009	Minimally Invasive Surgery Leadership Summit Participant
2006	American College of Surgeons, Surgeons as Educators Course Participant
2005	American College of Surgeons, Young Surgeons Representative, Louisiana Chapter
1998	Fellow, American College of Surgeons
1994 - 1995	Best Surgical Resident Teacher, Carolinas Medical Center
1990	University of South Florida COM Student Government Distinguished Service Award
1987 – 1989	Class Vice President University of South Florida COM

C. Selected Peer-reviewed Publications

1. Stefanidis D, Yonce TC, Korndorffer Jr JR, Phillips R, Coker A. Does the Incorporation of Motion Metrics Into the Existing FLS Metrics Lead to Improved Skill Acquisition on Simulators? Does the Incorporation of Motion Metrics Into the Existing FLS Metrics Lead to Improved Skill Acquisition on Simulators? Annals of Surgery (in Press)
2. Slakey DP, Rennie K, Garstka ME, Korndorffer Jr JR. Using Simulation to Improve Root Cause Analysis of Adverse Surgical Outcomes. The Joint Commission Journal on Quality and Patient Safety. In Press
3. Simms ER, Slakey DP , Garstka ME, Tersigni SA, Korndorffer Jr, JR, Can simulation improve upon the traditional method of root cause analysis: A preliminary investigation. Surgery (In Press)
4. Korndorffer Jr JR, Bellows, CF, Harris IB, Tekian A, Downing SM. Effective Home Laparoscopic Simulation Training: An Improved Training Paradigm? American Journal of Surgery. 203 (1); 1 – 7 (2012)
5. Boulet JR, Jeffries PR, Hatala RA, Korndorffer JR Jr, Feinstein DM, Roche JP. "Research regarding methods of assessing learning outcomes." Simulation in Healthcare. 2011 June 23.
6. Korndorffer Jr JR, Slakey DP. Effect of structuring clinical services based on resident educational objectives. J Am Coll Surg 212 (4): 969 – 702. (2011)
7. Davidson IJA, Yoo MC, Biasucci DG, Browne P, Dees C, Dolmatch, B, Gallieni M, La Greca A,

Korndorffer JR, Nolen B, O'Rear S, Peden E, Pittiruti M, Reed G, Scott D, Slakey D. Simulation training for vascular access interventions. J Vasc Access 11: 181 - 190. (2010)
8. Stefanidis D, Hope WW, Korndorffer Jr JR, Markley S, Scott DJ. Initial Laparoscopic Basic Skills Training Shortens the Learning Curve of Laparoscopic Suturing and is Cost-effective. J Am Coll Surg 210 (4):436-40. (2010)
9. Korndorffer Jr JR, Fellinger, E, Reed W. SAGES guideline for laparoscopic appendectomy Surg Endosc 24 (4): 757-761. (2010)
10. Korndorffer Jr JR, Kasten S, Downing S. A call for the utilization of consensus standards in surgical education literature. Am J Surg 199; 99-104. (2010)
11. Stefanidis D, Wang F, Korndorffer JR Jr, Dunne JB, Scott DJ. Robotic assistance improves intracorporeal suturing performanceand safety in the operating room while decreasing operator workload. C:\pubmed\19536599?ordinalpos=1&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DefaultReportPanel.Pubmed_RVDocSum Surg Endosc. 2009 Jun 18. [Epub ahead of print]
12. Stefanidis D, Scott DJ, Korndorffer Jr JR. Do Metrics Matter? Time versus motion tracking for performance assessment of proficiency-based laparoscopic skills training. J Simul Healthcare. 4(2):104-108. (2009)
13. Stefanidis D, Korndorffer Jr JR, Heniford BT, Scott DJ. Limited feedback and video tutorials optimize learning and resource utilization during laparoscopic simulator training. Surgery 142(2):202-6. (2007)
14. Stefanidis D, Korndorffer Jr JR, Heniford BT, Markley S, Sierra R, Scott DJ. Closing the Gap in Operative Performance between Novices and Experts: Does Harder Mean Better for Laparoscopic Simulator Training?, J Am Coll Surg 205 (2):307-13(2007)
15. Stefanidis D, Korndorffer Jr JR, Scott DJ. Re: "Psychomotor testing predicts rate of skill acquisition for proficiency-based laparoscopic skills training". Surgery 141(6):831-2. (2007).
16. Stefanidis D, Haluck R, Pham T, Korndorffer Jr JR, Dunne JB, Reinke T, Markley S, Arellano P, Jones DB, Scott DJ. Construct and face validity and task workload for laparoscopic camera navigation: Virtual reality versus videotrainer systems at the SAGES learning center. Surg Endosc 21(7):1158-64. (2007)
17. Stefanidis D, Scerbo MW, Korndorffer Jr JR, Scott DJ. Redefining Simulator Proficiency Using Automaticity Theory. Am J Surg 193(4): 502-06 (2007)
18. Stefanidis D, Korndorffer Jr JR, Dunne JB, Black FW, Sierra R, Touchard, CL, Rice DA, Markert RJ, Fikre WS, Kastl PR, Scott DJ. Psychomotor Testing Predicts Rate of Skill Acquisition for Proficiency-Based Laparoscopic Skills Training. Surgery 140(2):252-62 (2006)
19. Stefanidis D, Sierra R, Markley S, Korndorffer Jr JR, Touchard CL, Dunne, BJ,Scott DJ. Proficiency Maintenance: Impact of Ongoing Simulator Training on Laparoscopic Skill Retention. J Am Coll Surg 202(4): 599-603. (2006)
20. Stefanidis D, Sierra R, Korndorffer Jr. JR, Dunne JB, Markley S, Touchard CL, Scott DJ. Intensive CME course training on simulators results in proficiency for laparoscopic suturing. Am J Surg 191(1): 23 - 27. (2006)
21. Korndorffer Jr. JR, Stefanidis D, Scott DJ. Laparoscopic skills laboratories: Current assessment and a call for resident training standards. Am J Surg 191(1): 17 - 22. (2006)
22. Maithel SK, Sierra R, Korndorffer Jr. JR, Neumann PF, Dawson SL, Callery MP, Jones DB, Scott DS. Construct and face validity of three laparoscopic simulators: MIST-VR, Endotower, and CELTS. Surg Endosc 20(1): 104-112. (2006)

23. Stefanidis D, Korndorffer Jr. JR, Sierra R, Touchard C, Dunne BJ, Scott DJ. Skill Retention Following Proficiency-Based Laparoscopic Simulator Training. Surgery 138(2): 165-170. (2005)
24. Korndorffer Jr. JR, Sierra R, Stefanidis D, Dunne JB, Scott DS. Simulator Training for Laparoscopic Suturing using Performance Goals Translates to the OR. J Am Coll Surg 210(1): 23 - 29. (2005)
25. Korndorffer Jr. JR, Dunne JB, Clayton JL, Tesfay ST, Brunner WC, Jones DB, Rege RV, Sierra R, Touchard, CL, Scott DJ. Multicenter construct validity for Southwestern videotrainer stations. J Surg Research 128(1): 114-119. (2005)
26. Korndorffer Jr. JR, Hayes DJ, Dunne JB, Sierra R, Touchard CL, Scott DJ. A videotrainer obstacle course for laparoscopic camera navigation translates to the OR. Surg Endosc 19: 161-167. (2005)

D. Research Support

Ongoing Research Support

Board of Regents of the State of Louisiana OPT-IN-11 3/13 - present
Title: Hydra laparoscopic surgical system
Goal is the development and testing of a novel laparoscopic surgical device
Role: Principle Investigator

Doctors Company 5/10-12/12
Simulation analysis of adverse outcomes: Determination of root cause.
Physical disability, depression and substance abuse in the elderly
The goal of this study is to use simulation to identify root casus of adverse events based on closed claims. Modifications will be implemented and repeat simulation perform to determined if correction occurred. Based on results physician training will be developed to minimize further adverse events.
Role: PI

Covidien 7/10 – 12/12
Economic impact of uniformity in energy-based devices.
The goal of this project is to evaluate the impact on work flow and work satisfaction in the operating room after standardization of equipment occurs.
Role: PI

Completed Research Support

Society of American Gastrointestinal and Endoscopic Surgeons 6/10 – 7/11
Do motion metrics lead to improved skill acquisition on simulators.
The goal of this study is to compare the effects of motion metrics and time metrics on training and skill retention..
Role: co-PI

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Jonathan P. Pearl, MD	Assistant Professor of Surgery
eRA COMMONS USER NAME (credential, e.g., agency login) jpearl	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Wayne State University School of Medicine, Detroit, MI	MD	06/99	Medicine
National Naval Medical Center, Bethesda, MD	Residency	06/05	General Surgery
Case Western Reserve University School of Medicine, Cleveland, OH	Fellowship	06/07	Advanced laparoscopy and endoscopy

A. Personal Statement

The goal of the proposed research is to develop a proficiency-based training program in flexible endoscopy on a physical colonoscopy platform. I am an expert in flexible endoscopy having accomplished more than one thousand total endoscopic cases during residency, fellowship, and during 5 years as an attending surgeon. I am a frequent instructor in SAGES and ACS flexible endoscopy courses and have served on the SAGES FES Task Force over most of its existence.

In addition to my expertise in flexible endoscopy, I have vast experience in surgical simulation. At the National Capitol Area Simulation Center I led scores of surgery residents through a proficiency-based FLS training program. I currently hold a leadership position at the Maryland Advanced Simulation Training Research and Innovation (MASTRI) Center.

Dr E Matthew Ritter and I collaborated on the development of the SCOPE model for colonoscopy simulation training. Developing a proficiency-based training program using this model could provide a cost-effective means of training for FES. This grant would provide be the impetus for developing this valuable, cost-effective training program.

B. Positions and Honors

Positions and Employment

1999-2005 Resident, General Surgery, National Naval Medical Center, Bethesda, MD
2005-2006 Ship's Surgeon, USS GEORGE WASHINGTON, Norfolk, VA
2006-2007 Fellow, Advanced Laparoscopy and Endoscopy, Case Western Reserve School of Medicine, Cleveland, OH
2007-2012 Assistant Professor of Surgery, Uniformed Services University, Bethesda, MD
2007-2012 Staff Surgeon, National Naval Medical Center, Bethesda, MD
2012-present Assistant Professor of Surgery, University of Maryland School of Medicine, Baltimore MD
2012-present Chief, Perioperative Services, VA Medical Center, Baltimore, MD

Other Experience and Professional Memberships

2008-2011	Councilor, Washington, DC Chapter, American College of Surgeons
2008-2011	Chair, Young Surgeons Committee, DC Chapter, American College of Surgeons
2008-present	Member, SAGES FES Task Force and SAGES Guidelines Committee
2009-present	*Ad hoc* reviewer, *Surgical Endoscopy*

Honors

1995	Phi Beta Kappa, University of Michigan
2004	First Prize, Surgical Residents Competitive Forum, DC Chapter, ACS
2005	Winner, Harry B Zehner Traveling Fellowship, DC Chapter, ACS

C. **Selected Peer-Reviewed Publications**
Most relevant to the current application

1. **Pearl JP**, Ponsky JL. Natural Orifice Translumenal Endoscopic Surgery: A critical review. J Gastrointest Surg 2007;

2. **Pearl JP**, Marks JM. The future of teaching surgical endoscopy. Surg Innov. 2006; 13(4)

3. Nikfargam M, McGee MF, Trunzo JA, Onders RP, **Pearl JP**, Poulose BK, Chak A, Ponsky JL, MarksJM. Transgastric natural orifice transluminal endoscopic surgery peritoneoscopy in humans: a pilot study in efficacy and gastrotomy site selection by using a hybrid technique. Gastrointest Endoscopy. 2010; 72(2): 279-83.

4. Marks JM, Ponsky JL, **Pearl JP**, McGee MF. PEG Rescue—A practical NOTES technique. Surg Endosc 2007. 21(5): 816-9.

5. Ponsky LE, Poulose BK, **Pearl J**, Ponsky JL. Natural orifice translumenal endoscopic surgery: reality or myth? J Endourol. 2009; 23(5); 733-5.

Selected peer-reviewed publications

1. **Pearl J**, Price R, Richardson W, Fanelli R. Guidelines for diagnosis, treatment, and use of laparoscopy during pregnancy. Surg Endosc. 2011; 25(11): 3479-92.

2. **Pearl JP** and Pennypacker JL. Infarction of a lipoma of the lesser omentum; laparoscopic treatment of a rare condition. Laparosc Endosc Percutan Tech. 2011; 21(4): 197-9.

3. Jin J, Williams CP, Soltanian H, Smith MK, **Pearl J**, Sanabria J, Rosen MJ. Use of abdominal wall allotransplantation as an alternative for the management of end stage abdominal wall failure in a porcine model. J Surg Res. 2010; 162(2): 314-20

4. Cox TC, **Pearl JP**, Ritter EM. Rives-stoppa abdominal hernia repair combined with laparoscopic components separation of abdominal wall components: a novel approach to complex abdominal wall closure. Hernia. 2010; 14(6): 561-7.

5**. Pearl JP**, Rosen MJ. Second-look laparoscopy after laparoscopic relief of strangulated small bowel obstruction. Surg Laparosc Endosc Percutan Tech. 2009 Jun;19(3):241-3.

6. **Pearl JP**, Wind GG, Ritter EM. A meandering external iliac artery: Potential doom outside the triangle. J Am Coll Surg 2009. 208(3): 478-9.

D. Research Support

None

Simulated Colonoscopy Objective Performance Evaluation (S.C.O.P.E.): A non-computer based tool for assessment of endoscopic skills

Ritter EM, Cox TC, Trinca K, Pearl JP

Introduction: Virtual reality(VR) simulators have dominated the assessment of endoscopic skills. While VR simulators have significant benefits, they are frequently limited by high startup and maintenance costs, suboptimal durability with heavy use, and difficulty creating the "real feel" of GI endoscopy. These limitations led us to develop our physical model for endoscopic skills assessment, similar to models seen in other aspects of surgical skills assessment and training. The Simulated Colonoscopy Objective Performance Evaluation (S.C.O.P.E.) was developed to fill the need of a lower cost, non-VR based, valid assessment tool. The purpose of this study was to evaluate the ability of this new tool to objectively assess endoscopic skills.

Methods: Four tasks were created to evaluate the core skills for diagnostic endoscopy using the Kyoto Kagaku colonoscopy model (Kyoto Kagaku Co Ltd, Japan) as a base platform. The four tasks include: **Scope Manipulation** requiring use of torque and tip deflection to align a shape in the colon with a matching shape on the monitor screen. **Tool Targeting** requires coordination with biopsy forceps to contact a metal target. **Loop Management** requires prevention, recognition and reduction of a redundant sigmoid colon with navigation to the cecum. **Mucosal Inspection** requires identification of simulated polyps placed randomly throughout a length of simulated colon and rectum, including retroflexion. Key performance metrics were identified and a scoring system developed based on these parameters. Scores for each task were normalized to allow equal weighting for all four tasks. Thirty-five subjects were recruited for this prospective study and stratified into 3 cohorts based on colonoscopy experience: novice (0-50 colonoscopies)(n=11), intermediate(51-139)(n=13), and experts (>140)(n=11). Subjects performed 2 trials of all 4 of the above tasks. Mean normalized scores were compared between groups for both the individual tasks and the total S.C.O.P.E. score by one way ANOVA. Test-retest reliability was determined using intraclass correlation coefficient.

Results: Across all four tasks, experts (E) consistently outperformed intermediates (I), who, in turn, outperformed novices (N). These differences were statistically significant for all tasks. Mean normalized scores with 95% confidence intervals for each group on each task are as follows: **Scope Manipulation** [N-54 (26-82), I-90 (77-104), E- 106 (93-118) , p=0.0007], **Tool Targeting** [N-40 (24-55), I-79 (65-93), E-88 (72-105) , $p < 0.0001$**], Loop Management** [N-51 (24-79), I-78 (57-99), E- 101(98-105), p=0.003], **Mucosal Inspection** [N-73 (53-92), I-87 (77-96), E-100 (91-108), p= 0.013], and **Total S.C.O.P.E. Score** [N- 218(155-280), I-334 (296-372), E-395 (371-419), $p<0.0001$]. Initial Test - retest reliability for the expert Total S.C.O.P.E. score was respectable at 0.6.

Conclusions: A non-virtual reality, simulation based assessment tool has been created to evaluate the skills required to perform diagnostic endoscopy. Validity evidence shows that scores on these tasks can differentiate between groups expected to have different levels of technical skill. This model shows promise as a low technology tool for objective assessment or training of endoscopic skills. While larger scale validity evidence is needed, the S.C.O.P.E. model shows promise for potential incorporation into programs requiring objective assessment of endoscopic skills, like the Fundamentals of Endoscopic Surgery.

Simulated Colonoscopy Objective Performance Evaluation (S.C.O.P.E.) : Identification of Key Metrics for Objective Assessment

Tiffany C. Cox MD*, Kristen Trinca MD*, Jonathan P. Pearl MD*$, E. Matthew Ritter MD*

*Norman M. Rich Department of Surgery, Uniformed Services University / Walter Reed National Military Medical Center, Bethesda MD

$Department of Surgery, University of Maryland School of Medicine

Background: Objective systems to assess and train flexible endoscopy skills are needed. The purpose of this study was to develop a series of structured tasks to objectively measure endoscopic skills in a non-computer based simulator, and to identify which metrics differentiate different levels of skill.

Methods: Twenty-seven subjects (16 experienced(E) (>140 colonoscopies) , 11 novice (N) (<50 colonoscopies)) were evaluated. Each were read standard instructions for performing the four S.C.O.P.E. tasks (Scope Manipulation(SM), Tool Targeting (TT), Loop Management (LM), and Mucosal Inspection(MI)). All quantifiable variables that could influence performance were recorded including : completion time for each task , number of targets completed (SM and TT), successful loop reduction, maximum insertion length, use of position change and abdominal pressure, unintentional retroflexion (LM), number of polyps missed, incorrectly identified polyps, occurrence of rectal retroflexion, and distance of scope withdrawal during the allotted time (MI).

Results: All subjects performed the tasks using the standard instructions. No tasks were repeated due to device failure. Differences in mean completion times were significant for SM (E= 249 s, N= 422 s, p=0.002), TT (E= 278 s, N= 452 s, p=0.0006), and LM (E= 107 s, N= 493 s, p< 0.0001), but not for MI (E= 487 s, N= 497 s, p= 0.88). Missed polyps were significantly higher for novices (E= 1.4, N= 3.3, p= 0.002) and insertion length was significantly shorter (E= 79 cm, N=66 cm, p= 0.04). Rates of achieving loop reduction (E= 100%, N= 64%, OR= 19, p= 0.02) and correctly performing rectal retroflexion (E= 94%, N= 55%, OR=12.4, p= 0.03) were significantly better for experienced endoscopists. Differences in targets completed, maximum insertion length, incorrectly identified polyps, rates of unintended retroflexion, or use of position change or abdominal pressure were not significant.

Conclusions: It is feasible to administer the S.C.O.P.E. assessment using the standardized script in the allotted amount of time (<50 minutes). Key metrics are completion time for all tasks other than MI, number of missed polyps, achieving loop reduction, and performance of rectal retroflexion. These key metrics will be incorporated into a scoring system for S.C.O.P.E.

Validity Evidence for the Simulated Colonoscopy Objective Performance Evaluation (S.C.O.P.E.) Scoring System

Kristen Trinca MD*, Tiffany C. Cox MD*, Jonathan P. Pearl MD*$, E. Matthew Ritter MD*

*Norman M. Rich Department of Surgery, Uniformed Services University / Walter Reed National Military Medical Center, Bethesda MD

$Department of Surgery, University of Maryland School of Medicine

Background: Objective assessment of technical skills to quantify competency is a growing trend in surgical education. Low cost, objective systems to assess and train flexible endoscopy skills are needed. The purpose of this study was to evaluate the ability of the S.C.O.P.E. system to assess the skills required for diagnostic flexible endoscopy.

Methods: 38 subjects (11 practicing endoscopists, 6 non-endoscopic surgeons, 21 endoscopic trainees) were evaluated. Each subject was read a standard script with instructions for performing each of the four S.C.O.P.E. tasks (Scope Manipulation(SM), Tool Targeting (TT), Loop Management (LM), and Mucosal Inspection(MI)). Performance was measured using a scoring system incorporating previously identified key metrics and designed to reward precision and efficiency. Data were analyzed to assess the relationship between colonoscopy experience and performance on each of the tasks and the overall score. Performance differences between practicing endoscopists, non-endoscopic surgeons, and endoscopic trainees were also assessed for each task and the overall score.

Results: With respect to the total S.C.O.P.E. score, endoscopic trainee performance correlated significantly with total colonoscopy experience. ($r= 0.61$, $p= 0.003$) and colonoscopy experience in the last 12 months ($r=0.63$, $p= 0.002$). Similarly, significant differences were seen between practicing endoscopists, non-endoscopic surgeons and endoscopic trainees ($p< 0.0001$). When the 4 tasks were analyzed individually, each showed significant correlation with colonoscopy experience (SM: $r= 0.44$, $p = 0.044$; TT: $r= 0.45$, $p= 0.04$; LM: $r= 0.47$, $p= 0.032$; MI: $r= 0.65$, $p= 0.001$) and statistically significant differences in performance between the endoscopist groups, with the exception of the Mucosal Inspection task (SM $p < 0.0001$; TT: $p= 0.002$; LM: $p= 0.0008$; MI: $p= 0.27$).

Conclusions: Our study lends validity evidence to the construct that the S.C.O.P.E platform objectively assesses the technical skills required to perform diagnostic flexible endoscopy. Each task and the total score quantified improvement with increased colonoscopy experience and were generally able to differentiate between groups expected to have different endoscopic skills. Though further validity evidence is needed, S.C.O.P.E. shows promise as a tool to objectively assess endoscopic technical skill and as a platform for deliberate, proficiency based skills training.

Tulane University

SCHOOL OF MEDICINE

James R. Korndorffer, Jr. MD, FACS
Professor, Department of Surgery
Program Director, General Surgery Residency
Director, Tulane Center for Advanced Medical Simulation

October 18, 2012

E. Matthew Ritter, MD, FACS
Associate Professor
The Norman M. Rich Department of Surgery
The Uniformed Services University
4301 Jones Bridge Road
Bethesda, MD 20814

Dear Dr. Ritter,

I look forward to the opportunity to serve as an Associate-Investigator on your grant proposal "Development of a Proficiency-Based Skills Training Curriculum for the Fundamentals of Endoscopic Surgery," which you will submit to The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). I believe I can contribute toward the successful completion of your project.

I am currently Vice Chair and Professor of Surgery at Tulane University in New Orleans, LA. I have a Masters in Health Professions Education and my area of research focus is in surgical education and the use of simulation to advance surgical education. In this area of research, I have over 70 publications/presentation, including several from assisting with past SAGES grants. This study is of particular interest to me as my role as Program director of the Surgical Residency because I believe there is a significant need for a non-computer based endoscopy surgical simulator. I would be glad to lend my experience in using simulated gastric models in my lab and could advise you in accomplishing your research objectives. Since I am an employee of the Tulane University, and my effort will be less than 5%, I do not request salary support from this study.

Your proposed study will help us better understand the complex learning processes involved in teaching endoscopic surgery. I believe this research will allow us to better teach our

men and women in the Uniformed Services and in the civilian environment as well. I wish you the best of luck with your proposal.

Sincerely,

James R Korndorffer Jr MD MHPE FACS
Professor and Vice Chair, Tulane Department of Surgery

Tulane University

SCHOOL OF MEDICINE

Douglas P. Slakey, MD, MPH
Robert and Viola Labrano Chair of Surgery
Chairman, Department of Surgery

October 29, 2012

Lisa Straker
Proposal Manager-Team Lead
Office of Sponsored Programs
The Henry M. Jackson Foundation for the Advancement
Of Military Medicine, Inc.
6720-A Rockledge Drive, Suite 100
Bethesda, MD 20817

Dear Ms. Straker,

The Department of General Surgery and the Tulane Center For Advanced Simulation And Team Training (TCASTT), is pleased to support Dr. James R. Korndorffer in his role as Associate-Investigator on your grant proposal "Development of a Proficiency-Based Skills Training Curriculum for the Fundamentals of Endoscopic Surgery," which you will submit to the The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). He will be a valuable investigator for your project.

The proposed research will be performed in the skills lab at TCASTT. There will be no charge for use of the skills lab or administrative space. Two full-time, salaried simulation technicians are available to assist with this project with no additional salary support required. This project is expected to consume less than 5% of Dr. Korndorffer's work week. As such no salary support is required for his time.

I wish you the best of luck with your proposal.

Sincerely,

Douglas P. Slakey, MD, MPH
Robert and Viola Lobrano Chair of Surgery
Chairman, Department of Surgery

1430 Tulane Ave., SL-22, New Orleans, LA 70112–2699 *tel* 504.988.2317 *fax* 504.988.1874 dslakey@tulane.edu

UNIVERSITY of MARYLAND
MEDICAL CENTER

E. Matthew Ritter, MD, FACS
Associate Professor
The Norman M. Rich Department of Surgery
The Uniformed Services University
4301 Jones Bridge Road
Bethesda, MD 20814

October 18, 2012

Dear Dr. Ritter,

I will be glad to serve as an Associate-Investigator on your grant proposal "Development of a Proficiency-Based Skills Training Curriculum for the Fundamentals of Endoscopic Surgery," which you will submit to The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). I would be happy to contribute my expertise toward the successful completion of your project.

I am currently an Assistant Professor of Surgery at the University of Maryland School of Medicine. I have published extensively on endoscopy and currently serve in a leadership position at the Maryland Advanced Simulation, Training, Research, and Innovation (MASTRI) Center. This study is of particular interest to me because of my need for a low-cost and effective method for training students and residents flexible endoscopy. Since I am an employee of the Department of Veterans Affairs and the State of Maryland, and my effort will be less than 5%, I do not request salary support from this study.

Your proposed study will help us better understand the complex learning processes involved in teaching endoscopic surgery. I believe this research will allow us to better teach our men and women in the Uniformed Services and in the civilian environment as well. I wish you the best of luck with your proposal.

Sincerely,

Jonathan P. Pearl, MD
Assistant Professor
Department of Surgery
University of Maryland School of Medicine

UNIVERSITY of MARYLAND
MEDICAL CENTER

Lisa Straker
Proposal Manager-Team Lead
Office of Sponsored Programs
The Henry M. Jackson Foundation for the Advancement
of Military Medicine, Inc.
6720-A Rockledge Drive, Suite 100
Bethesda, MD 20817

October 26, 2012

Dear Ms Straker,

The Division of General and Oncologic Surgery and the Maryland Advanced Simulation, Training, Research, and Innovation (MASTRI) Center at the University of Maryland School of Medicine is pleased to support Dr. Jonathan Pearl in his role as Associate-Investigator on your grant proposal "Development of a Proficiency-Based Skills Training Curriculum for the Fundamentals of Endoscopic Surgery," which you will submit to The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). He will be a valuable investigator for your project.

The proposed research will be performed in the skills lab at the MASTRI Center. There will be no charge for use of the skills lab or administrative space. Two full-time, salaried simulation technicians are available to assist with this project with no additional salary support required. This project is expected to consume less than 5% of Dr. Pearl's work week. As such no salary support is required for his time.

I wish you the best of luck with your proposal.

Sincerely,

John A. Olson, Jr., MD, PhD
Campbell and Jeanette Plugge
Professor of Surgery
Vice Chair, Department of Surgery
Chief, Division of General and
Oncologic Surgery
University of Maryland
School of Medicine