STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Official title: Development and Validation of Virtual Laparoscopic Hiatal Hernia Simulator (VLaHHS)

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Development and Validation of Virtual Laparoscopic Hiatal Hernia Simulator (VLaHHS)

1. Research Question:

The goal of this study is to establish the face, content, discriminant and predictive validity of the Virtual Laparoscopic Hiatal Hernia Simulator (VLaHHS)

2. Principal Investigator:

a. Dr. Ganesh Sankaranarayanan, PhD – PI
b. Dr. Daniel Scott MD
c. Dr. Carla Holcomb MD

3. Funding

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4. Background:

Gastroesophageal Reflux Disease (GERD) affects nearly 20% of population of USA leading to significant decrease in quality of life[1]. GERD is abnormal distal esophageal acid exposure that results in typical symptoms, such as heartburn and regurgitation. If left untreated, GERD can lead to more serious complications such as esophagitis, Barrett's esophagus and esophageal adenocarcinoma. This type of esophageal cancer is the fastest growing cause of cancer mortality[2]. GERD is caused by the failure of the natural reflux barrier, which includes the lower esophageal sphincter (LES)[3]. The most common symptom of GERD is heartburn, and is thought to be due to the stimulation and activation of mucosal chemoreceptors in the distal esophagus. **Though the pathogenesis of GERD is multifactorial, a strong link to hiatal hernias has been well established[4–6].** Similarly, the presence of a hiatal hernia has been found to be an important factor in patients with esophagitis[6–10]. In a study with 293 patients having upper gastrointestinal endoscopy, 84% of patients with esophagitis had a concomitant hiatal hernia. It has also been shown that the presence of a hiatal hernia is linked to Barrett's esophagus[11–13] and doubled the risk of esophageal adenocarcinoma[14].

A hiatal hernia is a condition involving herniation of the contents of the peritoneal cavity, most commonly the stomach, through the esophageal hiatus of the diaphragm, and into the mediastinum[15]. **Age**[16–18] and **obesity**[7,19,20] are the **major risk factors** for the development of hiatal hernia.

Surgery at the hiatus and its Challenges: Hiatal hernia surgery is a complex and advanced laparoscopic procedure. For cases of paraesophageal hernia, the distortions in the anatomy can be extreme, making the repair very challenging. The anatomical location of the esophagus and the esophageal hiatus make up this procedure's advanced nature. The esophagus is intimately associated with the aorta in position and its attachments. Additionally, the inferior vena cava is immediately adjacent to the hiatus. Moreover, the dissection in the mediastinum close to pleural cavity and the pericardium makes this procedure much more advanced when compared to other

laparoscopic procedures. The laparoscopic repair of hiatal hernia consists of three main steps (1) **Dissection and reduction of hernia sac with its contents and assessement of intraabdominal esophageal length**, (2) **Crural repair to restore the appropriate sized hiatus** and (3) **Fundoplication to reestablish the reflux barrier**.

The laparoscopic hiatal hernia surgery requires expertise that is achieved with a substantial amount of procedures to master. Recurrence rate for paraesophageal hernia repair can range up to greater than 50% at five years. Lacking the proper skill level can make a patient prone to complications, such as early recurrence of the hiatal hernia, a slipped fundoplication, adjacent organ injury, esophageal or stomach perforation, or worsened dysphagia. Failure for the proper learning curve to be achieved can have disastrous outcomes in low volume centers. However, there have been limited studies on the assessment of the learning curve to do this procedure. One study with a single surgeon took 26 cases before the recurrence rate fell below the acceptance rate[21]. Learning curve assessment for laparoscopic Nissen fundoplication has shown to be in the range of 50 to 300 cases[22–24]. In a study of 1710 patients, the procedure varied significantly despite the recommendation for the first 20 cases to be under expert supervision. [25]. **This emphasizes the need for improved training in this procedure before a surgeon can be performing it on their own.**

In order to address this gap, we will develop a Virtual Laparoscopic Hiatal Hernia Simulator (VLaHHS). The goal of this study is to develop scenarios for the simulator and the assessment of the face, content, discriminant and predictive validity of the VLaHHS.

5. Experiment Design:

The goal of developing scenarios for the simulator will be accomplished first and establishing the validity of the VLaHHS will be conducted in three phases after that:

1) 1) Needs assessment survey of current practices in laparoscopic hiatal hernia repair

(2)
a. Development of scenarios and metrics for the VLaHHS
b. Assessment of validity of metrics developed for VLaHHS

(3) Assessment of validity of VLaHHS
1. Phase I – Face and content Validity Assessment of VLaHHS
2. Phase II – Discriminant Validity Assessment of VLaHHS
3. Phase III – Learning Curve, Retention and Transfer Assessment (predictive validity) of VLaHHS

Each phase of the study will hypothesize an aim specific to the validity type. The experimental design for each of the three validity assessments is described in Part2.

Development and Validation of Virtual Laparoscopic Hiatal Hernia Simulator (VLaHHS)

Part 1 : Needs Assessment Survey for the VLaHHS

Aim: To understand current surgical practices in laparoscopic hiatal hernia repair in order to design a virtual reality hiatal hernia simulator to enhance surgical training

Hypothesis: Not applicable

Eligibility: Any community or academic surgeon who performs laparoscopic hiatal hernia repair and is willing to participate in the survey.

Method: The survey link will be sent either individually to surgeons across the nation as well as through the Society for American Gastrointestinal and Endoscopic Surgeons (SAGES) to increase participation (See recruitment email message – form I). The survey will comprise multiple choice questions on demographics, training, procedure, and virtual simulator with some free text answer options. The survey will be designed and distributed via RedCap (Survey document attached). It is entirely voluntary and anonymous. The responders IP addresses will not be recorded nor stored. The approximate time to complete the survey is 10-15 minutes. There is no compensation for those who choose to participate. Survey responses will be recorded on RedCap and answers will serve as a needs assessment for this project and can be used to better design the proposed virtual simulator for laparoscopic hiatal hernia repair. Since participants will be de-identified, we seek an exemption for written consent.

Part 2a : Development of Scenarios and Metrics for the VLaHHS

The laparoscopic hiatal hernia surgery is a complex procedure that is performed under anesthesia and consists of various phases, tasks and subtasks each requiring different levels of cognitive skill (decision making, judgment, assessment etc.) and motor skill demands.

Aim: To identify various, phases, tasks, subtasks, complications and cognitive skills of the laparoscopic hiatal hernia procedure and develop metrics for assessment.

Hypothesis: Not applicable

Eligibility: Foregut surgery attending with three or more years of post-fellowship experience at The University of Texas Southwestern Medical Center and nationally.

Method: In order to identify the above details of the procedure, we will perform a cognitive task analysis (CTA) of the laparoscopic hiatal hernia procedure to characterize the various tasks and subtasks and critical decision-making steps. We will begin by creating a hierarchical task analysis (HTA) of the procedure. HTA is a well-known method that breaks down any given surgical procedure into tasks, sub tasks, and motion end effectors and has been successfully used to classify various minimally invasive procedures[26–32]. We will then perform unstructured interviews with expert foregut surgeons (at least 3 years of post-fellowship experience). During the session we will ask them to describe the procedure as they do it right from patient positioning and port placement until the end of the procedure. They will be asked to break each of the phases into tasks and subtasks. We will also ask experts to identify the cognitive demands on each of these steps to identify key decision-making, judgment and problem solving skills needed to complete each of the tasks. We will take detailed notes and conduct a *knowledge audit* to identify the most important aspects of their expertise[33]. We will use this information to develop a set of metrics for assessment in laparoscopic hiatal hernia procedure.
The interview session will be conducted either in person, by phone or by video conferencing facility provided by The University of Texas Southwestern Medical Center. The session can last up to an hour. The PI's Dr. Sankaranarayanan, Dr. Scott and Dr. Holcomb know a lot of foregut surgeons throughout USA as they are members of the Society for American Gastrointestinal and Endoscopic Surgeons (SAGES) in which the PI's are active members. We will reach out these expert surgeons individually.
Since this expert interview session doesn't constitute a Human Subject Study, we seek an IRB exception.

Part 2b: Assessment of Validty of Metrics Developed for VLaHHS

Aim: To assess the validity of the metrics developed for VLaHHS from expert interviews

Hypothesis: We hypothesize that the metrics developed for the VLaHHS will be capable of distinguishing the skill levels of novice (general surgery (GS) residents, Year 1 - 2), intermediate (general surgery (GS) residents, Year 3-5, fellows and attending with 1- 20 independent laparoscopic hiatal hernia cases)and experts (Surgery fellow and attendings with mode than 20 independent laparoscopic cases).

Eligibility:
Inclusion Criteria:

1. Novice Group - General surgery residents in years 1 – 2.
2. Intermediate Group – General surgery residents in years 3-5, surgery fellows attending with 1-20 independent hiatal hernia cases.
3. Expert Group – Surgery fellows and attendings with more than 20 independent ;laparoscopic hiatal hernia cases.

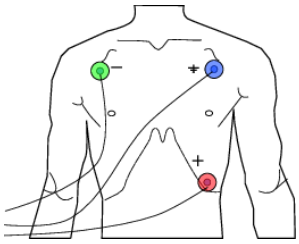
Exclusion Criteria: None

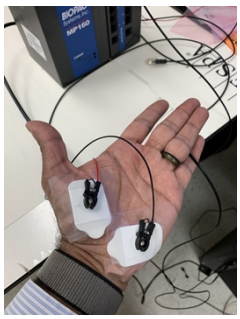
Method:

a) **VLaHHS – Crural Closure Task:** The experimental design is a between-subjects design with three groups: (1) Novice: GS residents recruited from PGY 1-2 residents at UTSW and at the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) annual meeting (2) Intermediate: GS residents

recruited from PGY 3-5 at UTSW and the SAGES annual meeting (2) Expert: GS fellows and attendings recruited at UTSW and at the SAGES annual meeting. At the beginning of the study, subjects will complete a short questionnaire detailing demographic information (including gender, age, handedness, etc.), previous clinical experience, simulator experience, and video game experience (see Appendix A II). After filling the demographics information, subjects will be provided details about the task they would be performing and after that, they will be asked to perform the task up to two times on the silicone crura model (see section 6 Apparatus for details about the model). At the conclusion of the trials, subjects will be asked to fill in a post questionnaire that assessed the quality of the simulator and the NASA TLX questionnaire that assessed their mental workload (See Appendix B II and CII). The sessions should last less than an hour.

Subjects' performance (laparoscopic camera view of the task) will be recorded for assessment and will not capture any identifying information such as subjects face. The laparoscopic tool motions (left and the righ hand tools) will be captured using a magnetic position tracking system (3D Guidance (3DG) trakSTAR System, Model 180 (2 mm OD) Sensors and Mid-Range Transmitter). We may also capture the heart rate variability and skin conductance to assess the stress levels of the participants using the Biopac MP-160 (Biopac systems Inc.). The systems uses electrodes placed on the skin after applying a small amount of conductive gel for measuring hear rate (ECG -3 electrodes (positive, negative and ground placed on a triangle –as shown in the figure) and skin conductance (EDA -2 electrodes placed on the palm of the hand- as shown in the figure)





b) VLaHHS – Fundoplication Task: The experimental design is a between-subjects design with three groups: (1) Novice: GS residents recruited from PGY 1-2 residents at UTSW (2) Intermediate: GS residents recruited from PGY 3-5 at UTSW (2) Expert: GS fellows and attendings recruited at UTSW. At the beginning of the study, subjects will complete a short questionnaire detailing demographic information (including gender, age, handedness, etc.), previous clinical experience, simulator experience, and video game experience (see Appendix A II). After filling the demographics information, subjects will be provided details about the task they would be performing and after that, they will be asked to perform the task up to two times on an explanted porcine silicone stomach with

esophagus model (see section 6 Apparatus for details about the model). At the conclusion of the trials, subjects will be asked to fill in a post questionnaire that assessed the quality of the simulator and the NASA TLX questionnaire that assessed their mental workload (See Appendix B II and CII). The sessions should last less than an hour. Subjects' performance (laparoscopic camera view of the task) will be recorded for assessment and will not capture any identifying information such as subjects face. The laparoscopic tool motions (left and the righ hand tools) will be captured using a magnetic position tracking system (3D Guidance (3DG) trakSTAR System, Model 180 (2 mm OD) Sensors and Mid-Range Transmitter). We may also capture the heart rate variability and skin conductance to assess the stress levels of the participants using the Biopac MP-160 (Biopac systems Inc.). The systems uses electrodes placed on the skin after applying a small amount of conductive gel for measuring hear rate (ECG -3 electrodes (positive, negative and ground placed on a triangle –as shown in the figure) and skin conductance (EDA -2 electrodes placed on the palm of the hand- as shown in the figure).

Part 3 : Assessment of validity of VLaHHS Part

A. Phase I- Face and Content Validity Assessment of VLaHHS

Aim: The goal of this phase of the study is to establish the face validity of the VLaHHS.

Hypothesis: No hypothesis is being tested in this phase.

Eligibility:

Surgery Attendings at The University of Texas Southwestern Medical Center (UTSW) will be recruited for this phase of the study.

Attendings with less than 2 years of foregut surgery practice will be excluded from the study.

Method:

The **face validity** (degree of graphical and haptic realism of the simulator) and **content validity** (how detailed it is) for the VLaHHS simulator will be established using expert review sessions.

There will be several development cycles for VLaHHS. During each development cycle, a minimum of five expert surgeons at UTSW will be asked to perform the tasks on the simulator and provide feedback on a 5-point Likert scale questionnaire (Appendix A-I) that assesses the degree of realism of the task, quality of visual realism, instrument handling, haptic feedback and the detail of the surgical task. Based on the feedback, VLaHHS will then be refined and reassessed by the same experts. As the end of the development cycle of the VLaHHS task, two independent experts who were not part of the original expert

group will assess the face validity using the same questionnaire to establish expert consensus.

B. Phase II- Discriminant Validity Assessment of VLaHHS

Aim: The goal of this phase of the study is to establish discriminant validity (the ability to distinguish the performance of subjects with varying experience) of the VLaHHS.

Hypothesis: We hypothesize that the performance of subjects with less or no experience in laparoscopic hiatal hernia will be lower compared to performance of subjects with more experience

Eligibility:

Inclusion Criteria:

4. General surgery residents in years 1-2 with no experience in independent laparoscopic hiatal hernia cases
5. General surgery residents 3-5 and attendings with experience of 1 -20 independent laparoscopic hiatal hernia cases
6. General surgery attendings with experience of more than 20 independent laparoscopic hiatal hernia cases.

Exclusion Criteria:

none

Method:

The discriminant validity, which is the degree to which the simulator can differentiate between two groups of different skill levels, will be established by conducting this study for two separate tasks in VLaHSS, namely, (1) Hiatal hernia dissection and crural closure and (2) Fundoplication.

The experimental design is a between-subjects repeated measures design with two groups: (1) Group 1: GS residents recruited from PGY 1-2 residents at UTSW with no independent laparoscopic hiatal hernia cases and at the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) annual meeting (2) Group 2: GS residents recruited from PGY 3-5 at UTSW and attendings with 1-20 independent laparoscopic hiatal hernia cases at UTSW and at the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) annual meeting (3) Group 3: General surgery attending with experience of more than 20 independent laparoscopic hiatal hernia cases at UTSW and at the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) annual meeting. At the beginning of the study, subjects will complete a short questionnaire detailing demographic information (including gender, age, handedness, etc.), previous clinical experience, simulator experience, and video game experience (see Appendix A II). After filling the demographics information, subjects will perform two practice trials to familiarize themselves with the simulator and its interface. Subjects will then perform three trials of either of the two tasks on the VLaHHS. At the conclusion of the trials, subjects will be asked to fill in a post questionnaire that assessed the quality of the simulator and the NASA TLX questionnaire that assessed their mental workload (See Appendix B II and CII). The sessions should last less than an hour.

The dependent measures for assessing performance will be a computed score based on completion and errors. Subjects' performance will also be videotaped. The videotaping will

focus only on subjects hand and the VR display, and any identifying information such as subjects face will not be captured.

C. Phase III – Learning Curve, Retention and Transfer Assessment (Predictive Validity) of VLaHHS

Aim: The goal of this phase of the study is to establish the learning curve and predictive validity of the VLaHHS

Hypothesis: We hypothesize that the subject trained in VLaHHS will improve their skills compared to control with no training and show better transfer of skills on to an actual procedure

Eligibility:

Inclusion Criteria:

General Surgery residents PGY 1-5.

Exclusion Criteria:

None

Method:

The learning curve of VLaHHS will be established by training subjects in the task over extended period until they reach a plateau. The predictive validity will be established by comparing the training group with a control group with no training by testing their skills on a simulated surgical task using a crural repair silicone model and porcine fundoplication model as described in the apparatus section .

The experimental design is a between-subjects design with two groups to which participants will be randomly assigned: (1) Group 1 (Simulation Group): training with VLaHHS, (2) Group 2 (Control Group): no training. Two separate tasks ((1) Crural closure and (2) Fundoplication) of VLaHHS will be tested separately (10 subjects per task). Before the testing session begins, all participants will receive a guided, hands-on orientation to the task that is being tested. They will then take a pre-test in which they will be asked to perform the task once to mark their baseline performance (i.e. initialize their learner profile). For the training phase, participants in Group 1 will perform the tasks on VLaHHS for an hour a day for a maximum of no more than three weeks (3 weeks' x 5 days = 15 sessions). In each session of no more than an hour, subjects will repeat the task five times.

Participants in Group 2 will continue with their normal residency training but will not participate in VLaHHS training at all.

Two aspects of learning will then be assessed post-training: skill learning and transfer-of-training. For the Simulation Group, skill learning will be measured immediately following training (post-test) and again after two weeks to measure retention. For the Control Group, skill learning will be measured four weeks after orientation and again two weeks later to measure retention. Finally, immediately after post-test, transfer-of-training will be assessed using simulated crural repair or fundoplication model. The transfer study will be conducted either at the UTSW Simulation Center or at the Artificial Intelligence and Medical Simulation (AIMS) Lab in campussouth.

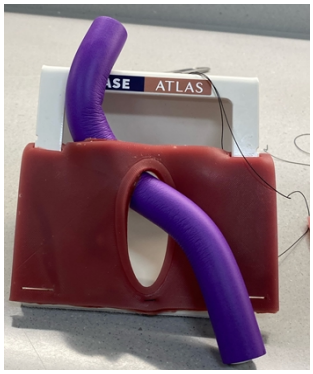
Dependent measures for learning curve and retention will be the score computed from completion time and errors on the VLaHHS and the workload assessment measured using the NASA-TLX questionnaire after each session. For the transfer task, Subjects performance on the crural repair and fundoplication task will be video recorded and evaluated by a minimum of three experts using Global Assessment Tools for Intraoperative Laparoscopic Skills (GOALS) subjective evaluation method (See Appendix AIII)[34].

The videotaping will focus only on subjects hand and any Identifying information such as subjects face will not be captured.

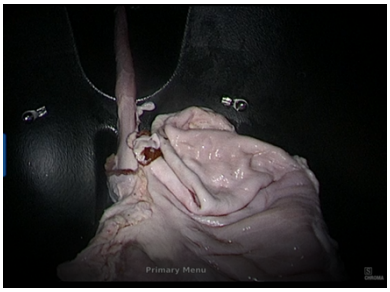
6. Apparatus:

a. Validation of Metrics (2b)
For the validation of the metrics, we will be using either a silicone or an explanted porcine organ model as described below.

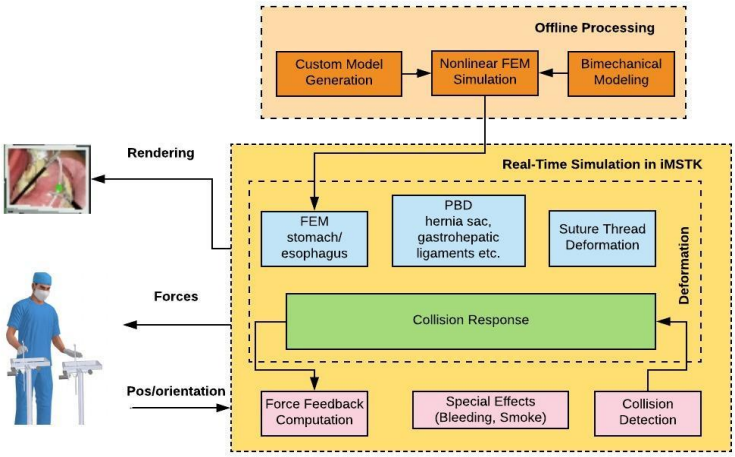
(i) Crural Repair Task: For this study, we will be using a custom silicone model of the crura that is molded at the simulation center and a rubber model of the esophagus (see figure). The crural model will be mounted on a platform and placed inside a rectangular box , secured with velcro to the base of the box. The box will have holes on the top to insert laparoscopic tools. A small camera placed on a tripod within the box will capture the task for performance which will be displayed on a monitor.



(ii) Fundoplication Task: For this study, we will be using an explanted porcine stomach with esophagus placed and secured inside a special container (Lap Easier-R from EndosimInc.) as shown in the figure with the laparosopic view from the inside. The porcine stomach with esophagus will be purchased from Animal Technologies inc. as frozen specimens and will be thawed before using it in the study.



b. Assessment Validity of VLaHHS (part 3) In VLaHHS the user will perform the procedure using laparoscopic surgical tools connected through a novel haptic (touch) interface. The simulator will present a realistic scenario of anatomy that



includes stomach, liver and other ligaments. Both position based dynamics (PBD) and Finite Element Simulation (FEM) models will be used for simulating the organs and tissues. The VLaHHS will also be capable of simulating suturing. The users motion, completion time and errors will be captured by VLaHHS to calculate the score automatically.

7. Feasibility:

A) Subject Population

Study Phase	Subject Population
Part 1	Foregut and General surgeons at UTSW and non-UTSW surgeons who could be reached by email either individually or through the Society of American Gastointestinal and Endoscopic Surgeons (SAGES)
Part 2a	Foregut surgeons at UTSW and non-UTSW surgeons on north America
Part 2b	General surgery residents at UTSW, general surgery attending at UTSW and at the annual SAGES meeting.
Part 3 Phase I	General Surgery Attendings at UTSW
Part 3 Phase II	GS residents at UTSW and General surgery residents/attendings at UTSW and at the annual SAGES meeting
Part 3 Phase III	GS residents at UTSW

B) Subject Number

Study Phase	Power Analysis	Target subject accrual
Part 1	Not required. We will try to collect survey response from as many participants as possible	N/A
Part 2a	Not required. We will try to interview as many surgeons as possible	N/A
Part 2b	A power analysis with α=0.5 , effect size f = 0.5 and power β=0.8 using the G*software indicated a minimum of 10 subjects per group. We will recruit a total of 90 (15 sub/group x 3 Groups = 45 subjects * 2 tasks = 90 subjects)	90
Part 3 Phase I	Not required for face and content validity study. We will recruit ten attendings, 5 during development and 5 after completion, to a total of 10	10
Part 3Phase II	A power analysis with α =0.5 , effect size f=0.5 and power β=0.8 using the G*software indicated a minimum of 10 subjects per group. We will recruit a total of 90 (15 sub/group x 3 Groups = 45 subjects * 2 tasks = 90 subjects)	90
Part 3 Phase III	A power analysis with α=0.05, effect size f=0.5 and power β= 0.8 using G* software indicated that a minimum of 5 subject per group. We will recruit 10 subjects per task (5 per group) for a total of 20 subjects for the two tasks over a course of one year.	20

C) Consenting Procedure

Study Phase	Consenting Procedure
Part 1	Since this will be survey feedback, we request waiver for consent for this study. An IRB approved cover letter will be used to inform participants about the study. This cover letter will be sent to potential participants via e-mail with a link to survey embedded in it.
Part 2a	Since this is not a human subjects study, we request a waiver
Part 2b	Subjects will be assured that their participation in the study is entirely voluntary. The study will be presented to residents and fellows during one of their regularly scheduled conference times. Only those interested will be asked to sign the IRB approved consent form.
Phase I	Since it will be an expert feedback study, we will request waiver of consent for this study. An IRB approved cover letter will be used to inform participants about the study. This cover letter will be shared with potential participants at a regularly scheduled research meeting.

Phase II	Subjects will be assured that their participation in the study is entirely voluntary. The study will be presented to residents, fellows and attendings during one of their regularly scheduled conference times. Only those interested will be asked to sign the IRB approved consent form. Additionally other attendings may be recruited via annual SAGES meeting.
Phase III	Subjects will be assured that their participation in the study is entirely voluntary. The study will be presented to residents during one of their regularly scheduled conference times. Only those interested will be asked to sign the IRB approved consent form

8. Statistical Plan:

Part 1:
Assessment of response will be grouped into categories (numerical values and 5-point Liker scale) and descriptive statistics will be used to present the data. Based on the number of years of experience, the responses will be further divided into groups and difference in responses will be computed either using a Mann-Whitney (2 groups) or Krsukal-Wallis (more than 2 groups) tests.

Part 2a: Not required

Part 2b: The data will be first analyzed to remove any outliers and tested for normality using Shapiro-Wilk test. If the data is normal, a mixed repeated measures ANOVA will be performed. A post hoc analysis between groups will be performed using Tukey's HSD method. If normality condition is violated, then a non-parametric equivalents Kruskal-Wallis and Mann-Whitney U test will be used.

Part 3 Phase I:
Assessment on a 5-point Likert scale will be used to capture the subject's feedback. Median scores will be calculated to assess the quality of the simulator.

Part 3 Phase II:
The data will be first analyzed to remove any outliers and tested for normality using Shapiro-Wilk test. If the data is normal, a mixed repeated measures ANOVA will be performed. A post hoc analysis between groups will be performed using Tukey's HSD method. If normality condition is violated, then a non-parametric equivalents Kruskal-Wallis and Mann-Whitney U test will be used.

Part 3 Phase III
After testing for normality, pre-, post- and retention data for both groups will be analyzed using a mixed ANOVA analysis. Post hoc analysis will be performed using Tukey HSD test. If the normality condition is violated, then non-parametric equivalents Kruskal-Wallis and Mann-Whitney U test will be used. Cumulative Summation Analysis (CUSUM) will be used to track subjects' improvement for every trial. For the transfer test, interrater reliability will be assessed using Cronbach's α. The GOALS scores of both the groups will be compared using an independent samples t-test. In case the data violates the normality condition, we will use the non-parametric equivalent Mann-Whitney u test.

9. Timeline

The anticipated timeline for completion of individual study phases is as follows:
Part 1: 3 months
Part 2a: 3 months
Part 2b: 6 months
Phase I: 2 years.
Phase II: Immediately following completion of Phase I (1 year).
Phase III: Immediately following completion of Phase II (1 year).

10. Risk and Benefits Assessment

This is an educational study involving training and simulation and is entirely voluntary. All data will be kept anonymous. Subject's performance will have no impact on their status with the department or administration. Participants may experience time away from work while they are undergoing practice and test sessions. However, scheduling of these sessions will be as per ease of the participants. Subjects in Phase II and Phase III may experience minor muscle fatigue due to standing for a period of up to an hour. The level of physical effort is similar to that experienced in performing an actual colorectal procedure or training sessions in the simulation lab.

A potential benefit could be acquisition of skills as they are being repeatedly performed during the training sessions on the simulator. We hope through this study we can help create a simulator that would assist in training in laparoscopic hiatal hernia surgery for surgeons in future.

11. Subject Privacy and Confidentiality

All subject files will be stored in a locked office with limited access. All electronic files will be saved in password protected computer in a locked office. Additionally all study staff is HIPAA trained. The results from this study will be used to perfect the quality and accuracy of tasks in the simulator. When results are disseminated individual identity is not disclosed. The research staff will collect the questionnaire data and the PI will be responsible for ensuring data security.
The study records will be retained for 2 years after IRB acknowledgement of formal study closure. These documents will be stored in PI's office and computer. After this time period all paper files will be securely shredded and electronic files will be permanently deleted.

12. Compensation to Subjects

Phase II and Phase III participants will be offered a stipend as delineated below. The amount offered is neither considered unreasonable nor coercive.

- Part 1: No compensation

- Part 2a: No compensation
- Part 2b Subjects at UTSW: $20 per task, $40 total; Part 2b Subjects at the annual SAGES meeting will not be compensated.
- Part 3 Phase I : No compensation
- Part 3 Phase II Subjects at UTSW: $50 per task, $100 total; Part 3 Phase II Subjects at the annual SAGES meeting will not be compensated.
- Part 3 Phase III Subjects:
  a. Group1: pre-test- $20, post-test- $20, retention-test $20, training $20/each session for a maximum of 15 sessions, transfer test $20 – Total of $360/subject

  b. Group 2: pre-test- $20, post-test- $20, retention-test $20, transfer test $20 – Total $80/subject

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