

# MITIE

Methodist Institute for Technology, Innovation & Education Houston, Texas 2013 Research Report



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## Preface

We hope you will enjoy this annual report on the research activities of the investigators at work in the Methodist Institute for Technology, Innovation and



Education (MITIE). MITIE is a multidisciplinary education and research institute of the Houston Methodist Hospital System and Research Institute in Houston, Texas. The educational mission of MITIE is to provide efficient, simulation based training to health care providers in practice in the fields of procedural and complex team performance with the goal of improving patient care and safety. The research mission of MITIE is to develop innovative technologies and procedures, to expand the understanding of surgical disease, and create novel educational platforms resulting in advances in surgical and procedural care while improving the operating room functionality and safety.

This report presents the wide spectrum of clinical and translational research underway in MITIE. Offering a unique platform incorporating sophisticated technologies and simulated environments, investigators from the Methodist Houston Hospital, University of Houston and other partner institutions have come together to perform innovative research with the specific goal of improving the practice of procedural medicine. From improving the process of surgical training and assessment, to multiscale modeling the biology of surgical disease and the impact of procedural interventions, the unique MITIE platform gathers scientists from many disciplines and institutions to preform exciting work. For more details on MITIE and the wide scope of educational and scientific initiatives, visit the publications line at the MITIE website: <u>www.mitietexas.com</u>

Barbara Lee Bass, MD Executive Director Brian Dunkin, MD Medical Director Marc Garbey, PhD Director, Research Integration Program

# 1. Research in Training & Assessment

The practice of state of the art surgery demands that surgeons and others who perform invasive procedures have access to ongoing training throughout their long careers. Given the extraordinary pace of technical advances in surgery – from the introduction of new devices, instruments, and procedures, to the introduction of transformative technologies such as hybrid imaging - procedural suites and robotic devices, the need for non-patient based hands on training has never been greater or more challenging.

At MITIE, we combine research with our educational programs. MITIE investigators are working on projects

to improve the efficiency of procedural skill acquisition using hands-on training in simulated environments. Others are creating curricula to define the components of skill proficiency, while some are developing novel assessment tools to determine if the educational programs have been successful. The goal is to improve the educational and training program to ensure that practicing surgeons can efficiently and safely acquire new skills to incorporate into their practices for the benefit of their patients. MITIE enables the medical professional throughout the nation and the world to realize the mission of the Houston Methodist Hospital System – delivery leading medicine to patients safely and effectively.



## The Role of Stress Responses in the Acquisition of Laparoscopic Skill

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#### **Challenges and Clinical Impact**

Laparoscopic methods have found broad applications in surgery because they are minimally invasive. This is of obvious benefit to the patient, but it comes at some `cost' to the surgeon. Specifically, in laparoscopy: (a) depth perception is impaired; (b) there is dissociation of visual and motor axis, rendering hand-eye coordination difficult; (c) motion is limited to 4 degrees of freedom; (d) tactile sensing is reduced; and (e) hand tremors effects are magnified. All these translate into partial loss of proprioception, rendering training harder and lengthier. The question is what can be done to shorten training time and at the same time render laparoscopic skill acquisition easier.



#### Rationale for approach

To answer the research question we need to identify the role of stress responses during laparoscopic skill acquisition. Surgical training is challenging and thus, it excites the sympathetic system. The loss of proprioception in laparoscopic training interferes with the sensorimotor feedback loop, further exacerbating the surgeon's stress responses.

We can unobtrusively quantify neurophysiological responses via thermal facial imaging.

#### Methods

Subject grouping was consistent with the standard categorization of surgical skill level (n=7 novices and n=10 experienced).

The surgeons trained on laparoscopic skills of varying difficulty, in 5 sessions separated 2 weeks from each other. In every session they practiced each skill 5 times, while they were imaged.

Algorithmic processing of the thermal imagery yielded a signal that quantified perinasal perspiration. The algorithm included a virtual tissue tracker that kept track of the region of interest, despite the subject's small motions. This ensured that the physiological signal extractor operated on consistent and valid sets of data over the clip's timeline. The tracker estimated the best matching block in every next frame of the thermal clip via spatio-temporal smoothing. A morphology-based algorithm was applied on the evolving region of interest to compute the perspiration signal.



The perinasal perspiration signal served as the primary indicator of stress. In facial thermal imagery, activated perspiration pores appear as small 'cold' (dark) spots, amidst substantial background clutter. The latter is the thermophysiological manifestation of the metabolic processes in the surrounding tissue.

We applied a contour-based black top-hat transformation in every frame of the thermal clip to capture the evolution of the perspiration spots. Then, we used this to compute the instantaneous energy in the perinasal region, producing a signal which is representative of stress responses.



We validated the perinasal perspiration method against Galvanic Skin Response (GSR) sensing, which is the current standard in real-time measurement of peripheral sympathetic responses, indicative of stress state.

#### **Product / Results**

Novice surgeons exhibited significantly higher levels of stress with respect to experienced surgeons, while performing the laparoscopic drills. This elevated arousal state in novice surgeons was accompanied by a significantly higher level of distressed expressions.



Due to loss of proprioception laparoscopic techniques present a significant challenge to the uninitiated, maximizing stress responses and thus, minimizing reactivity time. Novice surgeons perform at maximum speed, which is mismatching to their skill level, exacerbating error rates, which in turn amplifies stress. This sustains a vicious cycle that we call sympathetic looping. The key to break sympathetic looping and facilitate skill acquisition is to reduce stress, possibly by eliminating time performance considerations in the early stages of laparoscopic training.



#### Thanks

This material is based upon work supported by the National Science Foundation award IIS-0812526 entitled 'Do Nintendo Surgeons Defy Stress?' It was also supported in part by a grant from the Methodist Hospital entitled 'Co-Design and Testing of Stress Quantification Experiments.'

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A. Wesley, P. Lindner, and I. Pavlidis. Eustressed or distressed? Combining physiology with observation in user studies. *Proceedings of the 2012 ACM Conference on Human Factors in Computing Systems (CHI)*, Austin, Texas, May 5-10, 2012.

## A Proficiency-based Da Vinci® Skills Simulator<sup>™</sup> Training Curriculum

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#### **Challenges and Clinical Impact:**

Nearly 400 da Vinci® Skills Simulators (dVSS) (Fig. 1) were sold in 2011. Despite this unprecedented availability of a sophisticated surgical simulator, a validated curriculum has not been developed to guide users on what tasks to rehearse and to what level of performance. This study defined a proficiency based skills training curriculum for the dVSS that fosters goal-directed independent practice and that can be incorporated into a comprehensive robotic training curriculum. This will provide goals for surgeons in training as well as objective measurements to indicate when a surgeon is proficient in robotic surgery.



Figure 1 -- Da Vinci® Robotic Console with dVSS

#### Rationale for approach:

The Fundamentals of Laparoscopic Surgery is the gold standard for training residents to proficiency in basic laparoscopic skills needed to perform laparoscopic surgery and measuring their performance to determine if they have reached basic proficiency. They used expert performance to determine proficiency goals for trainees that showed strong predictive validity.

With the rapid growth of robotic surgery (see Fig. 2), there is clearly a need for a similar program to train residents in basic robotic surgery. We sought to use performance data from our cohort of expert robotic surgeons to develop a training curriculum for residents on the dVSS which is very often supplied with robotic consoles and thus broadly available for training purposes.



International United States

Figure 2 – The Rapid Rise in Robotic Surgical Procedures

#### Methods:

Choosing tasks and metrics: Expert robotic surgeons deconstructed robotic surgery into 8 essential elements (Table 1) and then evaluated each of the dVSS tasks to determine which elements they contain. Of the 33 DVSS tasks, only 8 were determined to be unique and these were chosen for validation testing. The 85 metrics provided by the simulator were also studied, and the 11 found to be unique were used to measure expert proficiency. Prior work by our group established construct validity for 7 of the 8 tasks (Energy Switcher was not valid)<sup>1</sup>.

Table 1	Task	Description
1	Pick and place	Pick up an object and set it down in a specific location
2	2-handed transfer	Transfer an object from one hand to another in space
3	Wrist manipulation	Use wristed instruments to advantage
4	Camera control	Manipulate camera for optimal view
5	Clutching	Use clutch control to optimize position of hands at surgeons console and minimize working space
6	3 <sup>rd</sup> - arm	Use of 3 <sup>rd</sup> arm for retraction and manipulation
7	Suturing	Suturing efficiently and accurately
8	Energy	Use of energy – monopolar and bipolar

Table 1: The 8 essential elements of robotic surgery deconstructed from robotic surgery by expert robotic surgeons.

Determining expert proficiency: After an initial "warm-up," 18 expert robotic surgeons performed each of the 7 tasks while recording 11 metrics. A mean and standard deviation were calculated and proficiency set at two standard deviations below the mean to capture a 95% confidence interval level (see Table 2).

Table 2	Overall Score	Time to Complete Exercise (sec)	Economy of Motion (cm)	Instrument Collisions	Master Werkspace Range (cm)	Critical Error	Instruments Out of View	Excessive Force Applied (sec)	Missed Targets	Drops
Peg Board Level I	81	80	180	0	10.0					
Peg Board Level 2	89	113	278	0	11.1	0				
Match Board Level 3	43	349	676		15.3	3		102.0		0
Ring and Rail Level 2	63	223	415	4	10.7	1	5.0	8.5		
Ring Walk Level 3	56	162	310	3		1				
Suture Sponge Level 3	59	326	443	1	8.0	0		0	13	
Tubes	63	244		5	8.8	1			9	

Table 2: Selected, proficiency based performance metrics for each exercise based on achievement at 2 standard deviations away from mean expert performance. Omitted metrics did not demonstrate a statistically significant difference between expert and novice performance or were not applicable.

#### Product / Results:

The proficiency goals for novice robotic surgeons based on the performance of 18 experts is listed in Table 2. It is suggested that these scores be achieved on two consecutive repetitions. Listed metrics are those found to be relevant from prior construct validity testing.

#### Conclusion

This study defines expert performance for 7 tasks and 11 metrics on the dVSS that can be used for proficiency based robotic skills training. Future work will determine the learning curve to achieve proficiency and evaluate translation of simulator skills to clinical practice using a validated clinical assessment tool for robotic surgery.

This curriculum can be implemented by training directors to provide target performance metrics validated by the panel of expert robotic surgeons.

#### Thanks:

We would like to acknowledge Intuitive Surgical Incorporated for providing the robotic simulator on which to conduct this study.

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## Which skills really matter? Proving face, content, and construct validity for a commercial robotic simulator

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#### **Challenges and Clinical Impact:**

A novel computer simulator is now commercially available for robotic surgery using the Intuitive da Vinci system (Fig. 1). Initial investigations into its utility have been limited due to a lack of understanding of which of the many provided skills modules and metrics are useful for evaluation. In addition, construct validity testing has been done using medical students as a "novice" group - a clinically irrelevant cohort given the complexity of robotic surgery. This study systematically evaluated the simulator's skills tasks and metrics and investigated its face, content and construct validity using a relevant novice group



Figure 1 – The da Vinci Skills Simulator (dVSS)

#### Rationale for approach:

We sought to establish validated proficiency metrics for the da Vinci "backpack" simulator. To guarantee relevant construct validity, we used residents for our novice group, a more advanced group of intermediate surgeons, and a group of experts. Using professional surgeons allows us to show which tasks on the simulator can show clinically relevant differences in skill levels.

#### Methods:

Expert surgeons deconstructed the task of performing robotic surgery into eight separate skills. The content of the 33 modules provided by the da Vinci Skills Simulator (Intuitive Surgical, Sunnyvale, CA) were then evaluated for these eight skills and eight of the 33 determined to be unique. These eight tasks were used for evaluating the performance of 46 surgeons and trainees on the simulator (25 novices, 8 intermediates, and 13



Figure 2 - Basic Object Manipulation

experts). Novice surgeons were general surgery and urology residents or practicing surgeons with clinical experience in open and laparoscopic surgery, but limited exposure to robotics (less than 10 cases). Intermediate surgeons were those with between 11 and 50 cases. The expert cohort had more than 50 cases. Performance was measured using 85 metrics across all eight tasks.

#### Product / Results:

#### Face and content validity

Figures 3 and 4 demonstrate the results from the questionnaires regarding face and content validity. 81% of novices and 92% of experts "agreed" or "strongly agreed" that the technical skills required to complete the simulated tasks reflect those necessary to complete actual robotic surgery. 89% of novices and 77% of experts "agreed" or "strongly agreed" that the simulator tasks encompass skill sets that experienced robotic surgeon should have. When further queried, expert robotic surgeons most commonly listed the absence of a skills task to rehearse knot tying as the most significant missing element.



Figure 2 - Face Validity Results



Figure 3 - Content Validity Results

#### Product / Results: (continued)

#### Construct validity

An exhaustive analysis of each of the 85 metrics of performance supplied for each of the eight skills sets revealed that 10 of the 85 were unique and performed well in separating the performance of novices versus experts. The additional metric of "Missapplied Energy Time" was left in the analysis even though it did not perform well because it is the only simulator measure of energy application. A description of these 11 metrics and what they measure is provided in Table 1. The metrics that performed best across all the skills tasks were "overall score", "time", and "economy of motion". "Instrument collision", "master workspace" and "critical errors" were also strong metrics across most tasks. Tables 5-12 show the results for each individual task. Overall, the simulator is able to differentiate between the performance of experts and novices across all eight tasks particularly using the metrics of "overall score", "time", and "economy of motion". The more difficult tasks of "Ring rail 2", "Suture sponge", and "Tubes" were also able to discern between the performance of intermediates and novices using these same metrics. "Suture sponge" was the strongest single skills task demonstrating statistically different performances between novice and experts and novice and intermediates across all metrics.

		Modians (N) (95% Cilj		Comparisons Between Groups Mann-Whitney-U [Z], effect size (/), pivalue			
Metric: Exercise	Novice	Intermediate	Expert	Novice vs. Intermediate	Novice vs. Expert	Intermediate va. Expert	
Overall Score							
Energy Switching - Level 1	68.52 (23) [63.38 · 74.01]	79.13 (6) [70.20 - 91.30]	82.85 (13) [76.04 - 86.22]	32.00 [Z = -1.992] r = -0.37 p = 0.046	61.00 [Z = -2.915] r = -0.49 p = 0.004	35.00 [Z = - 0.351] r = -0.08 p = 0.726	
Match Board - Level 3	34.01 (24) [29.37 - 42.36]	41.30 (8) [34.15 - 44.19]	55.76 (13) [42.57 - 59.51]	62.00 [Z = -1.481] r = -0.23 p = 0.139	67.00 [Z = -2.833] r = -0.47 p = 0.005	34.00 [2 = - 1.304] r = 0.28 p = 0.192	
Peg Board - Level 1	78.00 (25) [65.62 - 78.75]	83.78 (8) [75.01 - 92.96]	87.32 (13)  80.87 - 91.56]	59.00 [Z = -1.722] r = -0.30 p = 0.085	74.00 [Z = -2.723] r = -0.45 p = 0.006	45.00 (Z = - 0.057) r = -0.01 p = 0.612	
Peg Board - Level 2	82.3 (24) [66.42 - 83.62]	94.12 (8) [87.7 - 97.78]	92.76 (88.65 - 95.78)	33.00 [Z = -2.742] r = -0.48 p = 0.006	52.00 [Z = -3.309] r = -0.54 p = 0.001	50.00 [Z = - 0.145] r = -0.03 p = 0.885	
Ring Walk - Level 3	44.11 (22) [28.90 - 48.52]	59.09 (8) 38.40 – 69.58]	63.49 (12) [56.43 - 70.09]	46.00 [Z = -1.970] r = -0.36 p = 0.049	35.00 [Z = -3.490] r = -0.60 p = 0.00	31.00 [Z = - 1.310] r = -0.29 p = 0.190	
Ring & Rail - Level 2	42.62 (24) [33.8- 49.95]	79.34 (8) [65.94 - 86.32]	74.83 (12) [62.62 - 79.96]	11.00[Z = -3.699] r = -0.65 p < 0.001	29.00 [Z = -3.859] t = -0.64 p < 0.001	37.00 (Z = - 0.850) r = -0.19 p = 0.096	
Suture Sponge - Level 3	40.20 (23) [34.90 - 51.04]	65.93 (8) [55.23 - 86.17]	67.98 (10) [59.28 - 78.02]	26.00 [Z = -2.960] r = -0.54 p = 0.003	31.00 [Z = -3.29] r = -0.57 p = 0.001	39.00 [Z = - 0.089] r = -0.02 p = 0.929	
Tubes	50.00 (23) [44.50 - 56.44]	73.08 (7) [54.44 - 79.75]	70.86 (12) (63.22 - 78.49)	31.00 [Z = -2.43] r =044 p = .015	36.00 [Z = -3.55] r = -0.60 p < 0.001	33.00 [Z = - 0.761] t = -0.17 p = 0.447	

Table I – Performance of Three Groups on the Selected Simulator Tasks

Interestingly, "Energy switching 1" showed significant differences in performance between novice and experts for "overall score", "time", "economy of motion", and "master workspace", but not for "misapplied energy" suggesting that it is not specific for measuring skill in energy use. In fact, the "misapplied energy" metric was not significantly different in any group. Finally, the simulator could not discern the performance difference between intermediate and expert groups across all skills tests.

#### Conclusion

This study systematically determined the important modules and metrics on the da Vinci Skills Simulator and used them to demonstrate face, content, and construct validity with clinically relevant novice, intermediate, and expert groups. This data will be used to develop proficiency-based training programs on the simulator and to investigate predictive validity.

#### Thanks:

We would like to acknowledge Intuitive Surgical Incorporated for providing the robotic simulator on which to conduct this study.

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## A Proficiency Based Skills Training Curriculum for the Fundamentals of Endoscopic Surgery

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#### **Challenges and Clinical Impact:**

The American Board of Surgery is enhancing its commitment to flexible endoscopy in the surgical resident curriculum including mandatory completion of a Fundamentals of Endoscopic Surgery (FES) curriculum and skills testing prior to being allowed to sit for board certification. There is a clear need for additional training resources for surgical residents. There is also a need for a proficiency based training curriculum.

#### Rationale for approach:

We sought to provide easily reproducible, inexpensive training models for practicing endoscopic surgery along with a proficiency based curriculum for skills training on those modules. This will provide a valuable training option for surgical residency programs with limited budgets. Additionally, unlike the test for Fundamentals of Laparoscopic Surgery, residents are not allowed to practice on the actual test platform prior to sitting for the official skills test. We sought to provide models that would allow them to practice the basic and intermediate psychomotor skills sets they will need when facing the test.

By providing proficiency metrics and scores based on expert performance, we also sought to provide training goals for residents to allow for self-guided practice.

#### Methods:

We developed a novel upper endoscopy model (Fig. 1) out of a shoe box, pipe insulator, packing material, a plastic liner, and some stickers. This model allows trainees to learn the basic psychomotor skills of working the gastroscope. The metric for this model was the time required to correctly identify all six targets.

For lower endoscopy training, we purchased a colon model from



Figure 1 – Trus Model for Upper Endoscopy

Olympus of Japan (Fig. 2). This model provides a lifelike latex colon that can be configured to vary the difficulty of the model. It offers simple configurations as well as advanced, difficult configurations requiring reduction of sigmoid alpha loops and redundant transverse colon. The metric for the model is the time it takes to achieve cecal intubation.



Figure 2 – Olympus of Japan Lower Endoscopy Training Model

For endoscopic targeting, we developed a novel model using an operation game (Fig. 3) and a wired biopsy forceps that activates the operation noise. It requires two hand technique, torque, tip deflection, and targeting. Metrics included time to successfully target each of 6 targets and errors.



Figure 3 – The MITIE Flexible Endoscopy Targeting Model

12 expert endoscopists used the three models to determine proficiency metrics then filled out surveys to measure face and content validity.

#### Product / Results:

Based on the performances of our 12 expert surgeons, proficiency metrics were determined for each of the three models (Table I).

Suggested STEP Proficiency Metrics							
Model	Time	Errors	Repetitions				
Trus Upper Endoscopy Model	133 s	N/A	2 Consecutive				
CM-15 Colonoscopy Model	325 s	N/A	2 Consecutive				
MITIE Flex Endo Targeting Model	273 s	≤3	2 Consecutive				

Table I - Recommended Proficiency Metrics for Trainees

Exit survey results are listed below showing strong face and content validity as well as an appropriate level of difficulty and usefulness for training.

As the Fundamentals of Endoscopic Surgery is a standardized skills test administered on the GI Mentor system (Fig. 4), it is important that residents be able to train the skillsets needed to perform well on that test. Table 2 shows that the combination of the three models allows for practice with each of the skillsets tested.

These inexpensive models will be incorporated into an FES curriculum for surgical residents.



Figure 4 -- The GI Mentor II Endoscopic Training Platform

	Trus	CM-45	Targeting Game	FES I	FES II	FES	FES IV	FES V
Tip Deflection	•	•	0	•	•	•	•	•
ScopeTraversal	•			٠	٠	0	•	•
Torque	•	•	•	•	•	•	0	•
2-Hand Technique	•	•		•	•	•	•	•
Loop Reduction					•			
Retroflex	•					•		
Traverse Sphincter								
Mgmt. of Insufflation		0						
Targeting			0			0		•

Table 2 – The list of skills trained by the models with their correlating task in the Fundamentals of Endoscopic Surgery Skills Test

#### Thanks:

We would like to acknowledge Olympus of Japan for generously providing the CM-15 Colon Model

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## A Porcine Model To Simulate Colonic Stenting

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#### Challenges and Clinical Impact:

As surgical and clinical techniques evolve, there is a need for models and simulators that allow physicians to practice them prior to implementation in the clinical setting.

Even with current technology, Inanimate and non-tissue models do not fully replicate the behavior and response of real tissue.

A model that uses explanted porcine tissue is inexpensive and easily obtainable, but there are limitations to the models when insufflation and endoscopic procedures are attempted.



By novel usage of a baby bottle to close one end of an explanted porcine colon, we are able to create a reliable, accurate and inexpensive colonic model. This model not only uses natural tissues, but may be insufflated, cannulated with an endoscope. It is also the ideal model for colonic stenting.

#### Methods:

To create the colonic model, a baby bottle with nipple intact is used. The assembly of the model begins by cutting the baby bottle in half as well as cutting the tip of the nipple. The open end of the porcine colon is then placed around the open proximal end of the baby bottle.

The bottle top is secured in place and the colonoscope can then be inserted into the lumen of the bowel.

The insufflation is maintained as the nipple prevents air escaping from the bowel lumen.



A baby bottle nipple is ideal because it can be used to provide a proximal seal for the endoscope. The tip of the nipple is atraumatic and can be cut in a way that the inner diameter closely matched with that of the endoscope to maintain insufflation and to limit the potential of entrapment or pinching of mucosa between the two devices during insertion and exchange.

To simulate a colonic stricture, umbilical tape can be loosely tied circumferentially around the colon.

The view from within the insufflated lumen will then show a "stricture" that the endoscope can not pass.



The endoscopist then can deploy a stent across the "stricture" allowing visualization of the previously obscured distal colon. This simulates successful stenting of the stricture.



38 participants with a range of case experiences from 0 to over 500 agreed to participate in a study approved by the institutional review board to evaluate the model; they provided demographic data and filled out surveys after training on the model.

The post-procedure questionnaire was based on a 5 point Likert scale and given to all participants.

#### Product / Results:

Of the 38 participants, 87% felt the difficulty was appropriately challenging. 95% felt the model was useful to evaluate lower GI stenting skill proficiency, 92% felt the model was suitable for initial training in flexible endoscopy, and 97% felt the model was suitable for advanced training in flexible endoscopy as well as training of lower GI stenting.



Lower GI stenting is a challenging procedure that trainees need a reliable training model to practice. Our porcine model is a novel, inexpensive, easily reproducible model that was well received by fellows using it to train.

It is easily adapted to be used in basic stent placement training as well as advanced placement through strictures. It will be incorporated into a lower GI endoscopy training curriculum and soon to be implemented on a national level.

#### Thanks:

We would like to thank the Houston Methodist Department of Surgery as well as the staff at MITIE..

#### References:

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## The MITIE Computerized Laparoscopic and Surgical Skills (CLASS) Trainer A Novel Platform to Provide Virtual Mentoring and Track Learning Progress

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#### Challenges and Clinical Impact:

There are significant resources provided to residents that allow for skills training outside of the operating room. Unfortunately, these resources are underutilized. The independent skills lab allows for 24 hour skills practice, but acquisition of new skills is difficult without a mentor. Record keeping consists of log books residents are encouraged to fill out, but compliance is variable.

Without an accurate electronic record of activity, it is difficult to hold trainees accountable. Diligent trainees are also less likely to feel that hard work in the skills lab will be appreciated.

Trainees working alone must also manipulate a timing device to measure their performance. The MITIE Computerized Laparoscopic and Surgical Skills (CLASS) Trainer will revolutionize skills training. Trainees log into a skills training session using a login and password or by scanning a fingerprint. This allows for rapid access to the system with electronic record keeping of all training activity including video capture of performances and automatic timing. Trainees have access to instructional videos for each skills task. Users self report errors and adjust the start and end times based on the rules for each task. Trainees and mentors can review performances and video replays. An electronic high score board in the skills lab will show top performers and play videos of their top performances.



Figure 1 – The MITIE CLASS Trainer



Figure 2 - The MITIE CLASS Trainer Skills Menu



#### Methods:

The simulator is being developed to run on Windows PC's using the latest state of the art technologies including Direct X and Media processing libraries to leverage the power of a modern PC to provide a smooth, elegant experience for trainees.

Additionally, the back end utilizes a powerful database and streaming technology to allow for review of performances.

An administrator page is provided through a web interface that allows for managing and monitoring training.

A high score viewer can run 24 hours a day in a prominent location in the skills lab helping foster a spirit of competition among residents.

0:34.95



The Skills Selection Menu



Instructional Video for Trainees



**Time Skills Task in Progress** 

Virtue Success Williams All

Stop Tria

Session Summary Page





Task Performance History

**Robotic Skills Training Menu** 

#### Planned Investigational Study:

We hypothesize that resident participation in the skills lab will increase with the availability of CLASS Trainers in the skills lab. The combination of easy access, accountability, and availability of online tutorials and training goals is expected to not only increase use in the lab but also lead to better skills performances by surgical trainees in the operating room. We will compare the participation and performance between groups of trainees with and without the CLASS Trainer to confirm this hypothesis.



#### The Future:

The MITIE CLASS Trainer will be refined and incorporated in a comprehensive skills curriculum residents. Studies will validate advantage in skills proficiency for residents utilizing the system. The training content will be expanded and refined.

# 2. Clinical Research & Quantitative Modeling

A review of history shows that the discipline of surgery goes far beyond the technical performance of a procedure in the operating room suite. Examination of key milestones in the birth of the surgical discipline reveals that knowledge of human anatomy and physiology was essential to the creation of a surgical procedure. Similarly, understanding the biological basis of disease allows for identification of opportunities

to intervene and cure. Today's newest "surgical" tools are based in the computational sciences. Facilitated by advances in computer based technologies to model surgical disease, computational models allow assessment of the impact of interventions on human anatomy and disease progression. Using individualized patient data and exquisite digitized



imaging technologies, precision surgery to deliver a personalized procedure is an opportunity on the horizon. This exciting new field is the focus of several research teams using the MITIE platform.

## Validation of an In-Patient Systemic Inflammatory Response Syndrome (SIRS) Screening Tool For the General Surgical Ward

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#### **Challenges and Clinical Impact:**

Sepsis is as an overwhelming inflammatory reaction by the body in response to an infection. The end result is often deadly. Despite tremendous research efforts, death rates from septic shock remains unchanged at > 50% [Dombrovsky, et. al.] Septic shock is the leading cause of death in non-cardiac units. [Sands, et. al.] There are 751,000 cases of sepsis per year in the U.S. with an annual cost of US\$17 billion. [Angus, et. al.] By 2010, it is estimated that there will be 934,000 cases per year. [Halpern, et. al.] The economic impact of sepsis ranges from US\$15-55 billion accounting for about 0.5% of GDP and about 13% of national health care expenditures. [Halpern, et. al.]

#### Rationale for approach:

Physicians and scientists have focused their efforts to identify ways to treat sepsis and save lives. One of the best ways to prevent death and associated costs from sepsis is to identify sepsis early in its onset. By identifying sepsis early, physicians and other health care providers can intervene early, treat the inciting infection, and prevent progression of the inflammatory response to the more deadly and morbid severe sepsis and septic shock stages. [Rivers, et. al.]

#### Methods:

**Data Sources and Procedures:** The data analyzed was part of an IRB approved prospectively collected data set. The data was collected over a six month period spanning April, 6th, 2009 through October 6th, 2009 on patients admitted to one 30 bed general surgical ward. We collected four physiologic parameters: Current heart rate (HR), current respiratory rate (RR), maximum temperature (T<sub>max</sub>) from the prior 12 hours, and minimum temperature (Tmin) from the prior 12 hours. We also collected one laboratory value, the white blood cell count (WBC) from the previous 24 hour period. The data was collected twice each day, once at 12 noon and then again at 12 midnight. All screens were completed within 2 hours of these times.

**Subjects:** 959 unique hospitalized patients located on a surgical ward at a major academic tertiary care referral center within the Texas Medical Center.

**Instrument:** The four physiologic values and the most recent WBC were recorded by the nursing staff via an online SIRS screening tool. Each member of the nursing staff team received an in-service from the research staff and demonstrated comprehension and competence with using the tool prior to study initiation and data collection. (See Figure 1 below). The scoring of each of the individual subcomponents and the composite SIRS score were all automatically calculated by rules and logic embedded within the online tool. The scoring algorithm followed criteria specified in Table 1. The composite SIRS Score is derived by adding each of the four subcomponent scores together. A composite SIRS score  $\geq$  4 is categorized as a positive screen.



pints	0	1	2	3	4
heart rate (bpm)	70 - 109		55-69	40 - 54	≤ 39
			110-139	140 - 179	≥ 180
Temperature (ºC)		34 - 35.9	32 - 33.9	30-31.9	≤ 29.9
min					
max	36-38.4	38.5 - 38.9		39-40.9	≥41
resp rate (br / min)	12 - 24	10-11	6 - 9	35-49	≤ 5
		25 - 34			≥ 50
latest WBC (kcell /	3-14.9	15 - 19.9	1-2.9		< 1
mm³)			20-39.9		≥ 40

The degree of physiological derangement for each of the parameters was scaled from 0 to 4 on a scoring matrix (see table above). The scoring system was based on the work by Knaus, et. al. which resulted in the APACHE-II scoring system. This scaling technique effectively straightens the U-shaped curve observed when using measures of variance, such as the standard deviation, to plot physiological data with deviation magnitude on the Y-axis and the discrete parameter value on the X-axis. Most biological systems exhibit behaviors often observed with mathematical models of dynamic systems that constantly strive to remain in a critical state. See the figure below for an illustration of the curve straightening effect.



Results:

The prevalence of sepsis in the screened population was 0.02 (1.67%). The area under the curve was 0.978. The sensitivity of the instrument was > 0.9999, the specificity was 0.96 (95.9%). The positive predictive value (PPV) of the instrument was 0.29 (29.1%) and the negative predictive value (NPV) of the tool was > 0.9999 (99.9%).



#### Conclusion:

The SIRS Screening tool, with a positive screen (+) threshold set to  $\geq$  4 is a valid instrument for the detection of patients at risk for developing sepsis in the general surgical in-patient population at large academic tertiary care referral centers. This screening tool has improved the early recognition of sepsis in our in-patient general surgical ward, enabling early therapeutic intervention. Preliminary results on whether or not the early detection and early intervention enabled by this tool has a positive impact on outcomes are very encouraging. Further research in this field is on-going.

#### Table 2:

Omnibus Test		× <sup>2</sup>			dſ		Nagelkerke R <sup>2</sup>	
Statistic		7.920		1		0.005		0.522
			Logistic Reg	ression H	Equation Stat	tistics		
							OR 95% CI	
Source	В	SE	Wald	df	р	OR	Lower	Upper
T Score	1.394	0.298	21.968	1	≤ 0.001	4.033	2.251	7.225
RR Score	1.570	0.594	9.990	1	0.008	4.806	1.501	15.390
WBC Score	2.043	0.370	30.475	1	≤ 0.001	7.712	3.734	15.928
HR Score	1.021	0.412	6.138	1	0.013	2.776	1.238	6.227
Constant	-7.599	1.086	48.948	1	≤ 0.000	0.001		

Thanks:

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## Quantitative image analysis of CT scans to track the plasticity of arterial anatomy pre- and post-operatively after Endovascular Aneurysm Repair

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#### Challenges and Clinical Impact:

Secondary interventions after Endovascular Aneurysm Repair (EVAR) remain the standard for repair of abdominal aortic aneurysms despite significant improvement of endografts multiple generations. over Understanding the interactions between aortic anatomy, aortic wall the characteristics and the endograft may predict poor outcomes and timing of secondary interventions.



#### Rational for Approach:

Our hypothesis is that a systematic analysis of patients' 3D aorta reconstruction with time points separated by up to a year in interval may give us some quantitative indicator of risk of failures, and perhaps a better understanding of the path to failure. The objective is to develop a simple image analysis tool that extracts the most relevant information in the long-term follow up of patients after EVAR, which can be indicators of potential failure.

#### Methods:

We have retrospectively identified 5 patients who have had an EVAR and preoperative imaging available. All images were CTA of the abdomen and pelvis using standard protocols. This protocol was approved by the IRB.

We followed a three-step method:

1. A 3D reconstruction of the anatomy of the AAA-Stent complex including the lumen and sac was created. The region of interest was usually immediately above the bifurcation up to the level of renal arteries and two centimeters below the bifurcation towards the iliac arteries.

2. We did a co-registration of this 3D reconstruction to monitor the time evolution of the EVAR repair. We assumed that the spine could be used at least partially to establish a fixed reference framework.



Red : before surgery Blue : after surgery

3. We extracted geometric indicators of the 4D reconstruction: The computation of the skeleton of the arterial system was pivotal to the analysis. It was used to measure curvatures along the descending aorta and angles at the iliac. We also extracted a longitudinal descending profile of the lumen and sac volume above the bifurcation to monitor the AAA repair.



#### Product:

The long term evolution of EVAR repair for five patients with our image analysis method:

Patient	1	2	3	4	5
Year follow up	0.5	2	5	5	5
# Exam	1+1	1+2	0+3	1+5	1+4
Stent vertical	?	Weak	s	s	s
Aneurisme vertical	s	$\downarrow$	$\downarrow$	5	$\downarrow$
angle	7	Z	5	$\checkmark$	~
angle	167	170 S	162 🧷	176	167
✓ curvature	s			_>	_/>
Lumen inlet	s	5	7	7	7
Lumen near outlet	1	s	s	7	7
Volume sac	7	7	7	7	7
Volume lumen	X	$\rightarrow$	s		$\searrow$

Table 1. (S stands for stable i.e. no change over time Arrows give the direction of variation of the quantity of interest) While our data set was rather small and has limited statistical value, we observed that

- There is significant plasticity of the geometry of the lumen/stent/aneurysm system for all the patient data we have. All measurements we obtained from our image analysis such as lumen volume, sac volume, neck angle, angle formed by the iliac may evolve significantly over time. That is, we observe variation of these quantities that are much larger than the noise level of the measure itself.
- These variations can be non-monotonic in time and non-uniform in space. For example, the volume of a specific section of the lumen or sac may grow while another section decays, and vice versa. All potential combinations seem possible.
- All of the above is true for what one would consider a rather successful EVAR, i.e. the sac has a volume that is stable, or decreasing, and the lumen does not show any significant enlargement or stenosis (see patient 2).

We clearly need to expand this image analysis with Computational Fluid Dynamics (CFD) as a next step to provide a quantity of numerical indicators extracted from 4D image reconstruction as well as flow pattern that can eventually be helpful to better understand the biological consequences of EVAR. The idea is to provide a number of standardized indicators to address the long term follow up of EVAR that can be quickly computed on a large enough database of clinical cases. The construction of this data base with several hundred patients is under way.

#### Thanks:

The Methodist Debakey Heart and Vascular Center and the Vietnamese Educational Fund for the partial funding of the project.

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## CFD Challenge: Predicting Patient-Specific Hemodynamics at Rest and Stress through an Aortic Coarctation

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#### **Challenges and Clinical Impact:**

Narrowing of the aorta (coarctation) accounts for approximately 10 % of congenital heart defects in the western world. A consequence of this narrowing is the existence of high pressure gradients increasing cardiac workload. Consequent flow changes during stress may result in a several-fold increase in the pressure drop compared to rest. To replicate physiological stress conditions during exercise, a pharmacological stress-test is sometimes performed, which are not ideal for the patient as often unwanted side-effects

Fig. 1: Aortic coarctation model Provided by the organizers



Rationale for approach:

An alternative may be assessing changes in the pressure gradient during stress using computational simulations utilizing patientspecific information. In this approach, it has not yet been established, how to 'adequately' modify the boundary conditions for the stress case. A wide variety of simulation techniques utilizing different concepts of boundary conditions exist, which have yet to be thoroughly assessed towards their applicability for the described medical problem. The here reported study was previously presented at MICCAI 2013 as part of a CFD (computational fluid dynamics challenge) on a model of an aortic coarctation (figure 1) [1].

#### Methods:

Fig.2: Computational mesh used in the simulations



An implicit unsteady 3D model of the patient-specific aorta was coupled to a three element Windkessel model (RCR) for a more accurate treatment of the outlet boundary conditions.

 <u>1. Geometry</u>: The geometry was originally extracted from a 3D contrastenhanced magnetic resonance angiography (MRA) dataset. This STL file was imported into STAR-CCM+ 8.04.

<u>2. Computational Mesh:</u> The final computational mesh constructed based on the provided STL file contained 2,946,175 polyhedral elements with 5 prism layers in the near wall region. A local refinement was used in the region of the coarctation to improve the resolution of the flow structures as the blood accelerates through the constriction (figure 2).

<u>3. Solver and Physics:</u> The simulation was run in STAR-CCM+ 8.04. An implicit unsteady model using a segregated approach was used to solve the time-accurate Navier-Stokes equations. A second order backward Euler scheme was used to advance through time. Second order upwind schemes were used for convection. Time-step size was 0.001 seconds, fluid density was 1000 kg/m<sup>3</sup> and fluid viscosity was 0.004 Pa.

4. Boundary Conditions: Blood flow information was acquired using phase contrast magnetic resonance imaging (2D, cardiac-gated, respiratory-compensated with through-plane velocity encoding). Cardiac output was 3.71 l/min, heart rate was 47 beats per minute with a duration of the cardiac cycle of 1.277 seconds. The organizers of the CFD challenge provided a 15-term Fourier reconstruction of the inflow waveform. Bases on these Fourier coefficients. A flat velocity profile was defined at the inlet. This was chosen over a fully developed profile since the distance from heart is not sufficient to produce fully developed flow. Ideally, the velocity profile (potentially containing swirl) may be extracted from phase contrast magnetic resonance imaging.

A three element Windkessel model (ZCR) [2] was coupled to the outlet boundaries via a java macro (freely available on Macrohut <u>http://macrohut.cd-adapco.com/phpBB3/viewtopic.php?f=4&t=321</u>). The Windkessels were solved using a first order, backward Euler implementation and are coupled to STAR-CCM+ in an explicit manner. The Windkessel parameters are taken from Brown et. Al [3], where the values were tuned to match the clinical flow and pressure waves for this case.

#### Product / Results:

<u>1. Rest Case</u>: Good agreement between the clinically measured pressure at the inlet and flow at outlet 1 (descending aorta) was obtained at end systole, peak flow and end diastole (figure 3).



Fig. 3. Left: Average pressure at inlet (ascending aorta). Red: simulation results, green: clinically measured values provided by the organizers of the CFD challenge. Right: flow at outlet 1 (descending aorta).

The peak to peak pressure drop was predicted as being 22.6 mmHg while the cycle averaged and maximum point to point pressure drops were predicted to be 2.5 mmHg and 27.8 mmHg respectively. Wall shear stress values varied from maximum 110 Pa at peak flow to 1.8 Pa during end diastole (figure 4). Pressures varied from a maximum of 95 mmHg at peak flow to 50 mmHg at end diastole (figure 4).



Fig. 4. Left: Wall shear stress at time points noted. Right: pressures. A large increase of pressure values proximal to the coarctation during peak flow can be appreciated (pressure scale from 0 to 95 mmHg)

<u>2. Stress Case:</u> For the stress case, inflow boundary conditions were adjusted as indicated by the data available at the CFD challenge website. The pressure obtained from the simulations at the ascending aorta and the flow rate at the descending aorta were overestimated (figure 5). Pressure values deviated by as much as a factor of approximately 3 which was largely due to an overestimation of the baseline pressure (figure 5) combined with the fact that the assumption of a rigid wall will produce a more pronounced effect at higher flow rates. Better agreement between the simulated and the clinically measured flow rates was achieved (figure 5). The peak to peak pressure drop was predicted as being 203.7 mmHg while the cycle averaged and maximum point to point pressure drops were predicted to be 23.5 mmHg and 176.3 mmHg respectively.



Fig. 5. Left: Average pressure at inlet (ascending aorta). Red: simulation results, green: clinically measured values provided by the organizers of the CFD challenge. Right: flow at outlet 1 (descending aorta). Colors as in previous plot on top.

#### Thanks:

Support from cd-adapco for performing the computational simulations is gratefully acknowledged.

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# 3. Smart Hospital Operating Room& New Procedures

A core research theme for MITIE based investigators is to design an "intelligent" operating room , a room that will automatically collect and disseminate OR data – technology in use , operative steps, patient physiology, team function - to understand the ongoing tasks and sequences of an operation. The goal of this research is to better inform the multidisciplinary operating room team of the activities in this sophisticated and high risk environment. The research will improve operating room efficiency, minimize the risk of error, and determine optimal human performance and functions to deliver surgical care efficiently and safely.

The NSF funded Industry/University collaborative research center entitled "Cybhor – CYBer-physical systems for the Hospital Operating Room" gathers university based investigators at the University of Houston, the University of Florida, Gainesville and MITIE based scientists together with industry partners to identify new technologies, procedures, and engineering methods to create a smart operating room. The research will define new opportunities to create safer and more efficient operating theatres to improve patient care.



## ORAware: Video Analytics for OR Awareness

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#### **Challenges and Clinical Impact:**

The Operating Room (OR) is by far the most complex and expensive environment within any hospital. With the advent of technology and increase in the number of minimally invasive surgeries, electronic signals in the OR are on the rise. Nonetheless, their effective utilization for tasks outside those of providing relevant information to the surgical team during a surgery have not been fully realized [1]. We propose to leverage and use existing electronic signals coupled with video cameras within the OR for the design of a system that is aware of the surgical context for understanding OR usage, staging, and scheduling.

#### Rationale for approach:

Surgeries are complex operations, but surgeries of the same kind tend to have similar and reproducible workflows. This is especially the case for many minimally invasive procedures. Hence, the proposed contextaware monitoring system will be trained from surgeries of the same kind for the purpose of workflow standardization. Such a system will be capable of on-line monitoring of the overall surgical process and best practices [2]. In addition, it could be used to automatically write reports at the end of a surgery or trigger simple events like calling the next patient. Such mundane tasks could easily improve the overall workflow of a busy OR.





#### Methods:

In this project, we will initially focus on laparoscopic procedures. These surgeries are primarily performed by use of tools that are inserted in the patient's body through small incisions. Generally, one incision is used to insert the laparoscope while another incision is used to place a camera observing the operating field. Since several electronic systems are already used in laparoscopic procedures, this will facilitate the integration of signals for the design of the proposed system. In addition, we will place video cameras that can monitor the OR, the area surrounding the operating table, and the surgical tools. Tools will be tagged using 2D barcodes or disposable RFID tags for localization. In developing the envisioned system, the project objectives will include: 1) development of automatic activity recognition methods to identify key surgical steps; 2) construction of a model describing the overall surgical workflow, relating the low-level activities recognized to surgery-specific semantic knowledge; 3) development of performance measures across all surgical steps; 4) development of methods for automatic triggering of events; and 5) evaluation and validation of developed methods and models. Initial efforts will focus on simplified activity recognition models involving independent signals of human activity (cleaning, suturing, etc.), instrument selection (scissors, trocar, etc.), and operating field (insertion, retraction, etc.). Complex interactions will be modeled after initial performance evaluation of the system [3-5].



Calibrated Camera showing ground plane (floor)

We are initially focusing on analysis directly from video placed in the OR for room observation. We are developing an intelligent, non-obtrusive, real-time, continuous monitoring system for assessing human activity. This system consists of two main modules, namely: 1) A non-obtrusive tracking system that continuously: i) tracks all subjects in the OR, ii) analyzes the spatio-temporal movement pattern of each subject, and iii) detects and measures descriptive information continuously of each tracked subject; and 2) A decision system that: i) correlates each subject's spatio-temporal patterns with others; and ii) correlates those to OR usage and stages.

In achieving our initial objectives, the camera is calibrated so that localization of the subjects can be performed with respect to the planar ground plane (floor). Each video frame is subject to detection of observed humans and their position is mapped to the ground plane. Each detected subject is tracked and their trajectory (spatio-temporal position on the ground plane) is clustered. Clusters are modeled with respect to each other to recognize a group behavior in the OR, which is than subject to classification to recognize a semantic label representing the usage or staging of the OR.



Modeling for human motion clustering and group association

#### Results:

Having detected human subjects in each video frame, their positions were clustered. Shown below are detections as well as the clusters observed under two different stages of OR usage. Further analysis will lead to improved understanding of motion behaviors and automatic identification of different stages of OR usage.



Automatic detection of human subjects and clustering of their positions during two different stages of OR usage

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## Smart Trocar and Advanced OR Awareness

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#### Challenges and Clinical Impact:

Laparoscopic surgery is a popular alternative to open surgery due to the considerable reduction of recovery time, pain and complications. However, limited access to the operating field, indirect vision, and ORs originally built for open surgery may make the surgeon's work more difficult and inefficient. Currently, OR managers are interested in tools that create OR awareness, a collection of data that assists the surgeon during the procedure. Tool identification and location is component of OR awareness that has historically been accomplished by the naked eye.



#### Rationale for approach:

Some automated systems exist (e.g. mainly system based on laparoscope images, see picture above, or RFA tags); however, the accuracy of these systems is compromised by the presence of metals and fluids in the operating field and the reliance on a constantlychanging point of reference for the tracking device. We propose a minimally intrusive, yet robust, surgical tool recognition system that start from the trocar "point of view" equipped with a wireless camera and communicating with a computer system. This modified trocar can recognize the laparoscopic tools coming in and out without interfering with the procedure in anyways.

#### Methods:

We developed a simple solution to identify each tool. Our approach is based on digital identification of colored. The scheme below illustrates the principle of our system.



With our approach, the wireless camera is able to detect the identification marker placed around each instrument shaft. Accurate even in dim lighting, subsequent Hough transform and color analysis provides us the code corresponding to the marker.



If a color is detected it is set to 1 else it is set to 0 (as shown in the example below).

pink	yellow	green	blue	brown		
0	1	0	0	1	=	9

#### Product:

The current laparoscopic tool recognition system is shown beside. It takes advantage of the camera to identify a colored marker placed around the shaft of each tool. For each tool of the same type, the color code is identical, what gives us the possibility to design an infinite amount of markers that will be accurately recognized.



First results demonstrate that our system for tools recognition is effective and highly robust. Indeed, the current system reaches an instrument identification accuracy of more than 95%. The diagram below shows that the closer the marker is to the trocar, the higher the rate of correct identifications.



Percentage of correct identifications

The designed system should be able to reach an even greater accuracy with later work on the color analysis in the Hue Saturation Value space.

#### **Results:**

By combining a wireless camera with trocars and adding simple landmarks on laparoscopic tools, we designed a simple and inexpensive system to improve OR awareness in an accurate way. The idea of the smart trocar is to make an automated recognition of the tools in the field of minimally invasive surgery in order to improve patient safety and upgrade surgeons' efficiency. This product will lead to more evolved systems able to guide surgeons during laparoscopic procedures and even to realize simple surgical tasks.



#### Thanks:

This work was partially supported by the Bookout Chair of Professor Barbara Bass, the Atlantis Program and Karl Storz.

#### **References:**

Smart trocar and surgical procedure management system: UH ID # 2013-006; USPTO Provisional Patent Application # 61/734,506; USPTO Non Provisional Patent Application # 14/099,430; PCT Patent Filing # PCT/US2013/073592. Inventor-ship: Garbey, Toti, Bass, Dunkin, Sherman.

Barbara L. Bass and Marc Garbey, A Road Map for Computational Surgery: Challenges and Opportunities, to appear in the Journal of Computational Surgery.

### Smart Trocar: Towards a New Type of Laparoscopic Surgery

Barbara L. Bass<sup>1,2</sup>, Brian Dunkin<sup>1,2</sup>, Marc Garbey<sup>3</sup>, Albert Huang<sup>1</sup>, Lucie Thiébaut<sup>3,4</sup>

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#### Challenges and Clinical Impact:

Laparoscopic surgery is a constant challenge even for experienced surgeons mostly because of the indirect vision. How can we help them and make their work easier? This is the question we are trying to answer with the smart trocar project. During a laparoscopy, the surgeon must rely on 2D visual cues to interpret depth. By providing more information in regards to the location of the instruments, accuracy, efficiency and safety may be increased.



#### Rationale For Approach:

In the first steps of our project, our information will only concern the global position of the tool, the type and its relative movement during the surgery. The position relative to the intraabdominal space will not be given by our work at this point. Our final goal consists in improving the laparoscopic surgeon's experience by providing him a new information channel: a surgical procedure guide.

#### Methods:

In order to solve the localization problem we exposed previously, we designed a system based on computer vision. Using specific markers painted on the ceiling of the operating room and a small camera attached to the trocar, we are able to estimate the absolute position of this trocar within the OR with triangulation. Our approach consists first in simulating the position of feature points of the markers for specific sets of location parameters (3 rotations R and 3 translations T), then in extracting the observed feature points from the camera's images and finally in comparing observed data to simulated ones to get the set of parameters corresponding to the trocar's motion.



#### Product:

Based on these results we are currently developing prototypes of smart trocars. The whole system is based on two main functionalities: the tool's GPS and the instruments' identification system. Both of those systems use the same device: a modified trocar that includes a small wireless camera on its upper edge.



Our system is successful even with partial occlusions of camera's field of view and to changes in illumination conditions. It should provide an accuracy of 1mm on the translation parameters and 0.5 degrees on the rotation ones. The first results obtained only for a height shift or a roll angle show a high potential with below 0.4 degrees and around 1mm accuracy. Moreover, even if not fully optimized yet, our system is able to accurately extract feature points from an image in less than 15 seconds.



This image show how the feature points are detected with adding to them the information about their locations in the space (North, South, East, West). We have these locations thanks to our knowledge of the position of the cross between each other. Furthermore, identification of those points reaches a high success rate as can be seen on the following diagram.



Programming in C/C++ and working in a dynamic way (e.g. by adding a tracking algorithm for the cross patterns) will speed our system up to give us a real time position feedback.

#### Results:

This technology developed in the framework of the smart trocar project is an inexpensive one that gives a simple solution for real issues in the field of laparoscopic surgery. Our system improves the surgeon's efficiency while increasing the patient safety through OR awareness in a reliable way.

#### Thanks:

We are especially thankful to the department of surgery of Houston Methodist for supporting the development of our project.

#### References:

Barbara L. Bass and Marc Garbey, A Road Map for Computational Surgery: Challenges and Opportunities, to appear in the Journal of Computational Surgery

Global Laparoscopy Positioning System with Smart Trocars: UH ID # 2014-019; USPTO Provisional Patent Application # 61/734,506. Inventor-ship: Garbey, Bass, Dunkin.

## Endoscopic Suture Fixation of Gastroesophageal Stents With and Without Submucosal Injection in a Porcine Model

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#### **Challenges and Clinical Impact:**

Self expanding metal stents (SEMS) are useful for treating leaks after bariatric or upper gastrointestinal (GI) surgery. Stent migration is common, however, occurring in 12 to 40% of patients and can lead to additional costs, repeat procedures, and potential morbidity. Methods utilized to reduce migration include clip fixation and "sleeving" a second stent within the first to increase the proximal "landing zone". Recently, suturing the stent into place endoscopically has been shown to increase pullout forces in a porcine model, but raises concern about full thickness suture penetration into adjacent organs.



Figure 1 - Self Expanding Metal Stents (SEMS)

#### Rationale for approach:

We hypothesized that submucosal injection prior to suture fixation would decrease the likelihood of full thickness suture penetration while still providing significantly greater pull-out forces than no sutures or endoscopic clipping.

#### Methods:

155mm SEMS were placed into the esophagus of porcine explant models with 75mm of the stent within the esophagus and beyond 80mm extending the gastroesophageal junction distally so as to mimic stent placement for leaks after upper GI and bariatric surgery. A force meter was used to measure the pullout force required to dislodge the stent in Newtons (N). In each explant, the stent was first deployed without fixation and the pullout force measured to act as a control. The stent was then replaced and the explant randomized to one of three groups (n=5 per group): fixation with two clips, two endoscopic sutures without submucosal elevation, or two endoscopic sutures with submucosal elevation. The pullout forces were again measured and the ratio of the experimental pullout force to the control calculated as a measure of the efficacy of the fixation. After each trial, the specimens were examined for signs of transmural penetration. Suture fixation was accomplished using the OverStitch™ Endoscopic Suturing Device (Apollo Endosurgery, Austin, TX). Paired-samples ttest and Fischer's exact two tailed test was used to compare study groups to controls and one-way ANOVA for comparison among groups.



Figure 2 - a) The Apollo Overstitch Affixed to the handle of the gastroscope. b) The Apollo Overstitch Affixed to the working end of the gastroscope.

#### Product / Results: (continued)

The control pullout force was  $3.27 \pm 0.67N$  (n=15). Endoscopic suture fixation without submucosal injection resulted in a statistically significant increase in stent pullout force (23.01 ± 5.05N; mean force ratio 765%; 95% confidence interval [CI]: 362-1167%; p < 0.01). Endoscopic suture fixation with submucosal injection also resulted in a statistically significant increase in pullout force (14.26 ± 4.51N; mean force ratio 462%; 95% confidence interval [CI]: 281-643%; p < 0.01) while fixation with clips did not increase the pull out force (3.40 ± 0.59N; mean force ratio 108%; 95% confidence interval [CI]: 56%-159%; p = 0.988). Suture fixation without submucosal elevation was also statistically stronger than with elevation, but 7 of 10 sutures placed without submucosal elevation (p = 0.003).

Study Group	Stent Pullout Force	Force Ratio (95% CI)	p-Value
Control (n=15)	3.27 ± 0.67N	1.00	
Clip Fixation	3.40 ± 0.59N	1.08 (0.56-1.59)	0.988
Endoscopic Suture Fixation with Submucosal Injection	14.26 ± 4.51N	4.62 (2.81-6.43)	< 0.01
Endoscopic Suture Fixation without Submucosal Injection	23.01 ± 5.05N	7.65 (3.62-11.67)	<0.01

Table I - Pullout forces measured for each of the study groups



Figure 3 - a SEMS in place in an esophagus

#### Conclusion:

Endoscopic suture fixation of SEMS with or without submucosal elevation results in a statistically significant increase in pullout force compared to clip or no fixation. However, suture fixation with submucosal injection avoids transmural suture penetration and may prevent injury to nearby organs and structures.



Figure 4 - A force meter being used to measure peak forces required to dislodge a stent

#### Thanks:

We would like to acknowledge Apollo Endosurgery for generously providing Apollo Overstitch devices, sutures supplies, and tissue explants to make this study possible.

We would also like to thank Boston Scientific for their generous donation of Self Expanding Metal Stents used in this study.

Finally, we would acknowledge the generous gift of endoscopy equipment and clips used in performing this study.

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# 4. Multiscale Modeling of ComplexBiological System

Basic medical discovery has long moved from the Petri dish to the animal model to clinical applications. Similarly, in reverse, clinical observations often lead to hypotheses for testing in vitro or in vivo models. This process of translation from bench to bedside is often hampered by differences in scale related

to species differences, imprecise biological assessment tools, or Inadequate molecular, cellular, or animal models. The application of computational methods for multiscale modeling, integrating models of molecular and cellular activity, tissue mechanic and physics, provides alternative tools to investigate the impact of disease or a surgical procedure on patients. This research in multiscale modeling of complex biological systems, as applied to breast cancer and atherosclerotic vascular disease, is an active program in the National Institutes of Health multiscale modeling consortium.

## Events in Vascular Remodeling



## Computational Modeling for Breast Conservative Therapy

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#### Challenges and Clinical Impact:

Breast Conservative Therapy allows for the effective treatment of breast cancer with reduced surgical morbidity coupled to radiotherapy, as opposed to a total mastectomy. Breast Conservative Therapy, while maintaining high survival rates for the patients, largely improve the cosmetic outcome of the surgery and its impact on the patient's quality of life. This operation however still presents a significant physiological and psychological impact on the patient.

#### Rationale for approach:

Our goal is to propose a complete and realistic model of the breast after surgery, in order to offer relevant insights as to the cosmetic outcome of the surgery and to facilitate the communication between the surgeon and the patient.

A complete understanding of the physics of the breast and the biology of wound healing are needed to propose a model that is relevant to the use of the surgeon. Our model also requires an extensive validation with clinical data and has to be adaptable to the variations observed during the healing process.

#### Methods:

A set of MRI images was acquired before the operation and served as a reference data to create a virtual model of the patient's breast. Using simple and partially-supervised image segmentation techniques the MRI dataset was segmented in order to retrieve the 3D shape of the breast as well as the distribution of the internal fat and glandular tissues.



The virtual reconstruction functioned as a reference model. This virtual model was considered free of mechanical constraints, and could be altered with the inclusion of a virtual lumpectomy cavity in order to model the outcome of the surgery. This virtual model could then be translated into a finite elements model. The finite element model of the breast takes into account the mechanical properties of the breast tissues and was used to compute the shape of the virtual breast under gravity using a finite element solver.



In parallel, we developed a healing model that models the closing of the wound in regards to the lumpectomy cavity. This agent-based model projected the growth of the tissues at the cellular level, which was dependent from the local mechanical stress. This allowed for precise tuning of its interactions with the mechanical model. In combination, those two models provided a modular multi-scale model that could describe the healing process at the cellular and tissue level.

In order to achieve the validation of our model, we needed to perform a comparison between the output of the simulations and clinical data. This allowed us to evaluate the range of the various parameters involved in the model. For this purpose, a clinical study was set-up involving the long-term monitoring of 15 patients diagnosed with breast cancer and who would undergo breast conservative therapy at Houston Methodist.





At each meeting with the patient during the clinical study, various data acquisitions were performed.

First, ultrasound images were acquired at the site of the lumpectomy in order to asses the changes in the cavity shape, followed by a FLIR thermal imagery of the surface of both breasts to evaluate the degree of inflammation of the operated breast.

Finally a stereoscopic system was used to compute a 3D surface reconstruction of the breast in order to monitor the changes in the breast shape between each meeting with the patient.

#### Product:

The aim here was to provide a "Virtual Surgery Toolbox" that could be easily used by the surgeon and that will provide relevant insights for the patient. This tool will help the surgeon in the decision process that is taken along with the patient by visualizing a virtual outcome of the surgery.

The outcome of the surgery can be display graphically using the 3D finite element model of the breast of the patient that has been previously processed or by using a set of relevant indicator of the

cosmetic defect of the breast.

The Virtual Surgery Toolbox aims to be simple enough while maintaining a reasonable degree of accuracy in the result it delivers. The tools were developed and tested using clinical data from patients of Houston Methodist. At the same time, the number of parameters that can be tuned by the surgeons are kept minimal:



We define first surgery-specific parameters such as the size of the lumpectomy cavity, that can be modeled as an ellipsoid, and its position in the breast.

Then, patient-specific parameters are involved in order to characterize the mechanical properties of the fat, glandular and skin tissues the patient's breast.



Finally, additional parameters can be used to take into account the radiotherapy and inflammation phases of the healing.

#### Thanks:

This work was supported by the John F. and Carolyn Bookout Distinguished Endowed Chair of the Department of Surgery at Houston Methodist, the Atlantis Exchange Program and the Partner University Fund.

We also thank the Research Computing Center at the University of Houston.

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### A Multi-scale Computational Framework to understand Vascular Adaptation

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#### Challenges and Clinical Impact:

In 2004, cardiovascular disease was the underlying cause of death; accounting for 36.3% (871,517) of all 2,398,000 deaths in 2004 (1 of every 2.8) in the United States. Over the last two decades, researchers have been trying to characterize vascular adaptation in the form of intimal hyperplasia and outward remodeling. However, the links between hemodynamic factors, inflammatory biochemical mediators, cellular effectors, and vascular occlusive phenotype remain lacking.

The modeling and prediction of vascular adaptation following local injury (through a combination of intimal hyperplasia and wall remodeling) has great importance in biomedical research. There is great potential in identifying treatment targets, creating diagnostic models, and other opportunities with this information.

#### Rationale for Approach:

We propose a multi-scale computational framework of vascular adaptation to systematically test our hypothesis using clinical and experimental data. We hypothesize that a specific gene regulatory network, modulated by defined blood shearing forces, determines the global adaptive response of the vein graft wall following acute injury. Our implementation is (i) modular, (ii) uses a heterogeneous network of computer architecture adapted to each component of the model, and (iii) facilitates the agile development of the model.

#### Methods:

The predictive model of vascular adaptation was composed of a series of modules, each integrated with in vivo validation experiments. Three modules comprised the multi-scale modeling of the vascular adaptation. The first was the agent-based model (ABM) which is a mathematical approach for analysis of dynamic systems in which elements, after being placed within a grid of specified shape, evolve through a number of discrete time steps governed by a set of rules based on the states of the neighboring cells. Rather than attempting to define the behavior of a complex system at the level of the continuum, via a system of coupled differential equations, the agent-based model breaks the complex system into discrete components (Smooth Muscle Cells. Extra Cellular Matrix, and macrophage) that are governed by a set of simple rules. The complex behavior of the system emerges then from the local interaction of the elements expanded over a very large grid.





The cell dynamic, for example Smooth Muscle Cells (SMC) apoptosis/mitosis, or Extra Cellular Matrix deposition/degeneration inside the ABM is governed by some probabilistic rules associated with shear stress and tension generated at the wall.

The vein graft was considered as a straight duct where Poiseuille flows were generated by a constant pressure gradient. We used a finite volume scheme to compute velocity (v) at the wall on a regular spatial grid and an immersed boundary implementation of the no slip wall condition v = 0 on  $\delta\Omega$ . We used a level set technique to compute the normal component gradient of the velocity at the wall with the standard formula: **Vu. VS** where S was a regularization of the step function.

The Blood Flow Module (BFM) was where we did all of the calculations regarding shear stress. This potential flow was computed taking into account in the irregular geometry of the vein section that was deformed by the transmural pressure (i.e. the difference of pressure inside the lumen and the outward wall). Transmural pressure causing tissue deformation was another key factor involved in vascular adaptation. The module involved with the calculation of tissue deformation was the **Tissue Mechanic Module (TMM)**.



This module used Neo-Hookean hyperelastic model to simulate the tissue deformation of the vein wall generated by the transmural pressure.

Finally these three modules were coupled to transfer required information to investigate the effect of key parameters of the model involved in vascular adaptation.



#### Product:

We envision this model to have substantial impact on the identification of novel therapeutic targets that control the remodeling response following vascular injury, and ultimately predict the success or failure of the intervention. Through linkage of hemodynamics with tissue deformation and cell dynamics, we anticipate the following applications:

 Streamlined screening of biologic compounds that are likely to yield a successful outcome following vascular intervention. Coupled with high throughput genomics, this model will provide the ability to select promising agents that should move forward into clinical investigation.

 In silico experimentation using the biology network model to identify previously unidentified targets for treatment.



 Monitor Phase I/II clinical trials to evaluate the impact of the treatment on the network "state", recognizing those compounds most appropriate for transition into large human testing

#### Thanks:

This work is being supported by the National Institutes of Health (NIH) under the NIH, R01, HL095 508-01 and U01HL119178-01.

We would like to thank the Research Computing Center at the University of Houston.

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## Facts and Milestones

- State of the art 34,000 square foot facility opened in 2011.
- Accredited as an American College of Surgeons Comprehensive Educational Institute.
- Accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC).
- Research performed in MITIE has been supported by the National Science Foundation (NSF); The Centers form Medicare and Medicaid Services (CMS) Innovation award program (CMS), the Department of Defense (DOD), the Houston Endowment, the Hearst Foundation and numerous other agencies and foundations.
  MITIE is a co-partner with the University of Houston, and the University of Florida -Gainesville in the NSF sponsored Industry/University Collaborative Research Center "Cybhor CYBer-physical systems for the Hospital Operating Room".
- MITIE serves as the home of the Computational Surgery Laboratory led by Professor Marc Garbey.

# MITIE by the Numbers

- More than 23,000 learners, from eight nations, have trained at MITIE since 2007

- Training has been offered in more than 25 different clinical and procedural disciplines from ophthalmology to heart surgery.
- MITIE has served as a training and assessment platform for the introduction of novel procedures now included in the practice of surgeons at the Houston Methodist Hospital.



- (1) Administration (2) Brief/Debrief Rooms (3) Principal Investigator Offices (4) Reception (5) Break-out Area
- (6) Coffee Bar
- (7) MedPresence Room
- (8) Locker Rooms
- (9) Teleconference Suite

- 30 MRI-guided Operating Suite (1) Fifteen Procedural Training Stations
- 12 Collaboration Area
- 3 Graduate Student Office
- 4 CT Scan-guided Operating Room
- (15) Confidential Research Suite
- 6 Surgical Robotic Suite
- (17) Simulation Suites
- 18 Partial Task Training Suites

· Inanimate skills lab

#### 2 Research Gore

- · Research operating rooms
- · Two robotic training labs
- One proprietary-technology development room

#### 1 Procedural Skills Lab

- · 15 small-scale operating rooms
- · MedPresence room