

New GERD Therapies and the Challenge of Lifelong Learning

L. Michael Brunt MD

Department of Surgery

Section of Minimally Invasive Surgery Washington University

School of Medicine

St. Louis, Missouri



Washington University in St. Louis

SCHOOL OF MEDICINE



L. Michael Brunt, MD

Disclosures

- None

New GERD Therapy Challenges

- Lessons from history
- Process/guidelines for learning new procedures
- Opportunities to do better
- Importance of outcomes assessment
- Ethical considerations/informed consent

Cutting Edge

A Tiny TV Camera Is Fast Transforming Gallbladder Surgery

The Keyhole Technique Uses
Tiny Incision, May Work
For Other Operations Too

Doctors Scramble to Learn It

Wall Street Journal
Dec. 10, 1990

MEDICINE NEWSWEEK, February 12, 1990

Hanging Up the Knife

A novel surgical technique promises to save patients time, money and blood



One Tool, Many Uses

- Appendicitis
- Bowel tumors and adhesions
- Gallstones
- Gynecological problems: fibroid tumors, endometriosis, ectopic pregnancies
- Lung lesions

'In 20 years, major abdominal surgery will be nearly extinct': Nezhat

table, but no one is wielding a knife. In place of the usual seven-inch incision, Dr. Camran Nezhat makes a small puncture in her navel and inserts a baton-size scope equipped with a tiny video camera and a laser. Then, after easing irrigation and grasping instruments through even smaller openings just above her pubic bone, he turns on the camera and sets about his work. Eyes fixed on one of four TV screens, he moves deftly through her abdominal cavity, searing through the webs of scar tissue that have once again mummified several organs and attached her bowel to her abdominal wall. Within about 90 minutes, Martha B. is out of the operating room, having lost teaspoons instead of cups of blood. She'll leave the hospital within

Newsweek
February 12, 1990

AN ANALYSIS OF THE PROBLEM OF BILIARY INJURY
DURING LAPAROSCOPIC CHOLECYSTECTOMY

Steven M. Strasberg, M.D., F.R.C.S.(C), F.A.C.S., Martin Hertl, M.D., *and*
Nathaniel J. Soper, M.D., F.A.C.S.

**Intraoperative Cholangiography and
Risk of Common Bile Duct Injury
During Cholecystectomy**

David R. Flum, MD, MPH

E. Patchen Dellinger, MD

Allen Cheadle, PhD

Leighton Chan, MD, MPH

Thomas Koepsell, MD, MPH

ORIGINAL ARTICLE

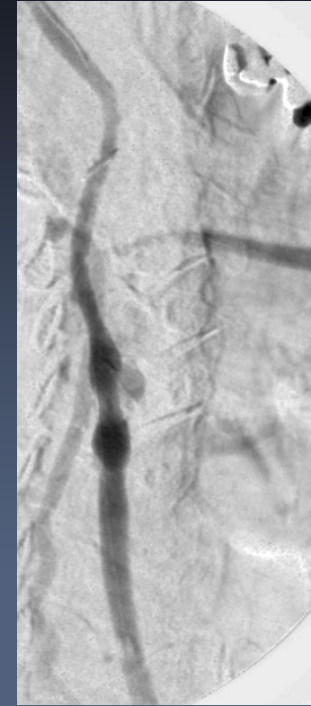
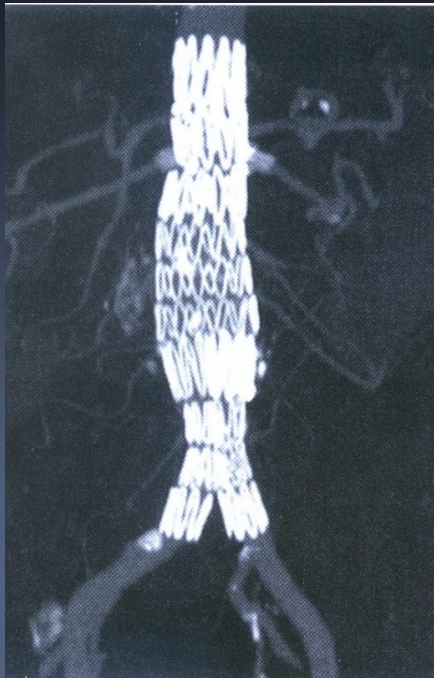
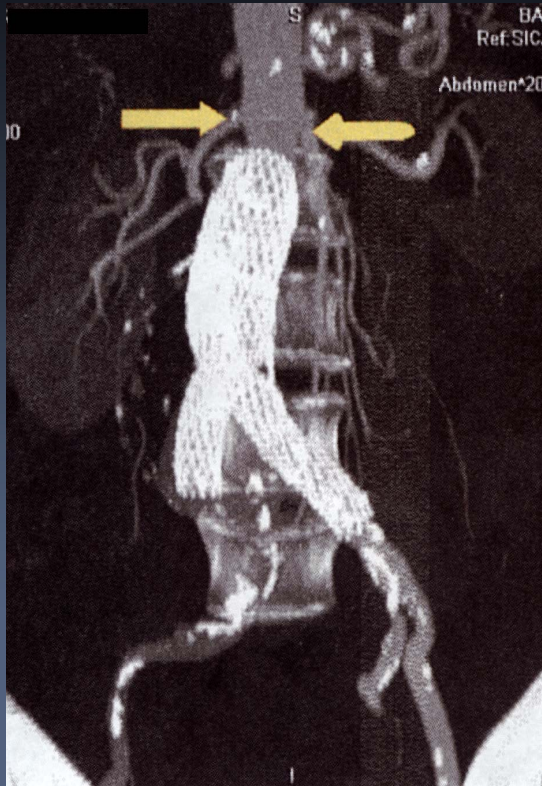
**Common Bile Duct Injury
During Laparoscopic Cholecystectomy
and the Use of Intraoperative Cholangiography**

Adverse Outcome or Preventable Error?

David R. Flum, MD; Thomas Koepsell, MD; Patrick Heagerty, PhD; Mika Sinanan, MD; E. Patchen Dellinger, MD

Endovascular Surgery Procedures

Carotid Artery Stenting

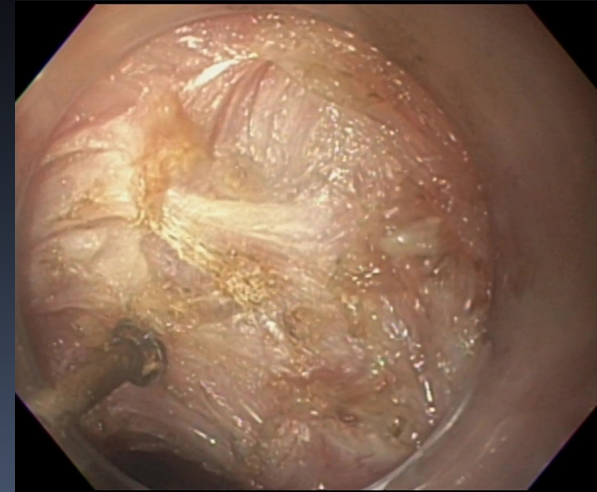


Pre Stent

Post Stent

21st Century New GERD Therapies

- Endoluminal therapies for GERD
- Endoscopic RF Ablation techniques
- Magnetic sphincter augmentation (Linx)
- Robotic foregut surgery
- Per oral endoscopic techniques (POEM, POP)
- EndoFLIP



Drivers of New Technology Implementation into Practice

Positive

- Improve patient care and outcomes
- Enhance efficiency or performance of procedures
- Add precision to interventions or diagnostics
- Achieve less invasiveness (MIS revolution, endoluminal therapies)

Drivers of New Technology Implementation into Practice

Positive

- Improve patient care and outcomes
- Enhance efficiency or performance of procedures
- Add precision to interventions or diagnostics
- Achieve less invasiveness (MIS revolution, endoluminal therapies)

Potential Undue Influences

- Financial incentives
- Lure of the technology or procedure
- Desire to remain competitive, increase market share
- Lay public impressions (eg laser CCX)

Drivers of New Technology Implementation into Practice

Positive

- Improve patient care and outcomes
- Enhance efficiency or performance of procedures
- Add precision to interventions or diagnostics
- Achieve less invasiveness (MIS revolution, endoluminal therapies)

Potential Undue Influences

- Financial incentives
- Desire to remain competitive, increase market share
- Lure of the technology or procedure
- Lay public impressions (eg laser CCX)

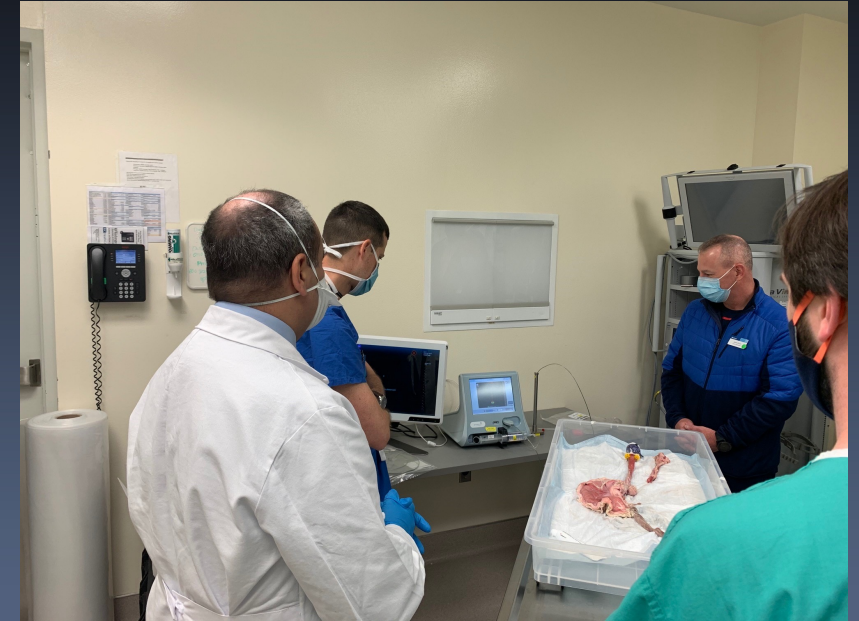
GENERAL GYNECOLOGY

The commercialization of robotic surgery: unsubstantiated marketing of gynecologic surgery by hospitals

Maria B. Schiavone, MD; Eugenia C. Kuo, MD; R. Wendel Naumann, MD; William M. Burke, MD; Sharyn N. Lewin, MD; Alfred I. Neugut, MD, PhD; Dawn L. Hershman, MD; Thomas J. Herzog, MD; Jason D. Wright, MD

Process

- Literature review/assessment and understanding of technical aspects and risks and results
- Lab training (equipment, settings, usage, interpretation)
- Collaboration with current high level practitioners and industry
- Case observation/proctoring
- Assessment of outcomes



SAGES Guideline for Introduction of New Technology/Techniques: Principles

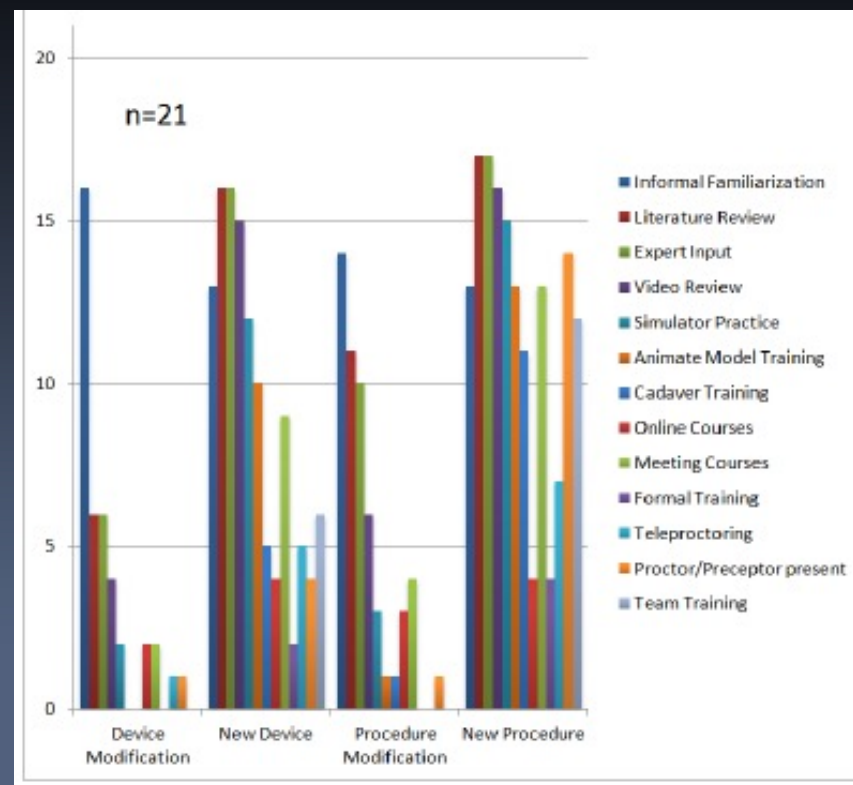
- Establishment of efficacy and effectiveness of a new procedure
- Importance of training prior to implementation in patients
 - Learning curves vary based on skill and task complexity
 - Steep learning curve early in experience
 - Coincides with highest risk of harm to the patient
 - Consideration of collaborative/team training
- Experienced centers, specialty societies, and industry all have a role
 - Industry role should be limited to new and modified devices

Stefanidis D et al Surg Endosc 2014;28: 2257-2271

What Elements Should be a Part of Training in New Technology?

SAGES Guideline

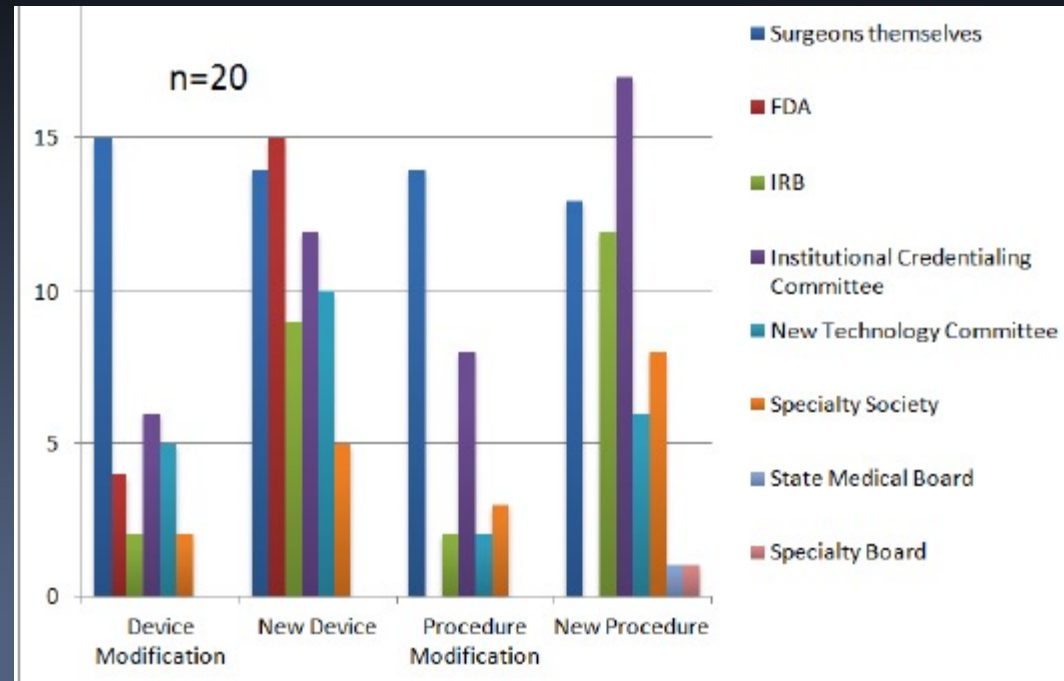
- Device or Procedure specific training
- Steps depend on the novelty/change
 - Device familiarization
 - Literature review
 - Expert input
 - Video review of device/procedure
 - Practice on appropriate models (simulated, animate, cadaveric)
 - Formal course training
 - Proctoring or tele-proctoring
 - Team training



Stefanidis D et al Surg Endosc 2014;28: 2257-2271

Who Should Monitor the Introduction of New Technology?

- Modified devices- surgeons only (Hernia mesh recalls)
- New procedures-
 - Surgeons
 - FDA
 - Credentialing committee
 - IRB



Stefanidis D et al Surg Endosc 2014;28: 2257-2271

Outcomes Assessment

Safety analysis of first 1000 patients treated with magnetic sphincter augmentation for gastroesophageal reflux disease


J. C. Lipham,¹ P. A. Taiganides,² B. E. Louie,³ R. A. Ganz,⁴ T. R. DeMeester¹

Per-Oral Endoscopic Myotomy: A Series of 500 Patients



Hanuhiro Inoue, MD, PhD, Hiroki Sato, MD, PhD, Haruo Ikeda, MD, Manabu Onimaru, MD, PhD, Chiaki Sato, MD, PhD, Hitomi Minami, MD, PhD, Hiroshi Yokomichi, BMath, MD, MPH, DPH, PhD, Yasutoshi Kobayashi, MD, MPH, Kevin L. Grimes, MD, Shin-ei Kudo, MD, PhD

Experience-based expert consensus on the intra-operative usage of the Endoflip impedance planimetry system

Bailey Su^{1,2}  · Christy Dunst³ · Jon Gould⁴ · Blair Jobe⁵ · Paul Severson⁶ · Kirsten Newhams⁵ · Aaron Sachs⁶ · Michael Ujiki¹

Technology Review Resources



American Foregut Society Statement on Appropriate Patient Selection and Use of Magnetic Sphincter Augmentation (LINX).

Click [here](#) to read more about patient selection for LINX patients.

AFS position paper on CLE


Esophageal & Gastric Disorders Guidelines

Practice update: EndoFLIP in esophageal disorder management

Practice update: POEM in Achalasia

Wide Area Transepithelial Sampling with Computer Assisted 3D Analysis (WATS3D)

Technology Review Resources



MEMBERSHIP EDUCATION RESOURCES FOR PATIENTS PRACTICE SUPPORT ASGE GUIDELINES

ASGE Guidelines >

Tech Assessments > **Technology Status Evaluation Reports**

📄 **Devices and techniques for flexible endoscopic management of Zenker's diverticulum (with videos) 2021**

Gastrointest Endosc 2021; Volume 94, Issue 1; P3-13 / DOI: <https://doi.org/10.1016/j.gie.2021.02.020>

📄 **Endoscopic polypectomy devices 2021**

Gastrointest Endosc 2021; Volume 94, Issue 1; P1-2 / DOI: <https://doi.org/10.1016/j.gie.2021.02.005>

📄 **Single-use duodenoscopes and duodenoscopes with disposable end caps**

Gastrointest Endosc 2021; Volume 93, Issue 5; P997-1005 / DOI: <https://doi.org/10.1016/j.gie.2020.12.033>

📄 **Video capsule endoscopy 2021**

Gastrointest Endosc 2021; Volume 93, Issue 4; P784-796 / DOI: <https://doi.org/10.1016/j.gie.2020.12.001>

📄 **Enhanced EUS imaging (with videos) 2021**

Gastrointest Endosc 2021; Volume 93, Issue 2; P323-333 / DOI: <https://doi.org/10.1016/j.gie.2020.06.075>

📄 **Artificial intelligence in gastrointestinal endoscopy 2020**

Video GIE 2020; Volume 5, Issue 12; P598-613 / DOI: <https://doi.org/10.1016/j.vgie.2020.08.013>

📄 **Techniques and devices for the endoscopic management of gastroparesis (with video) 2020**

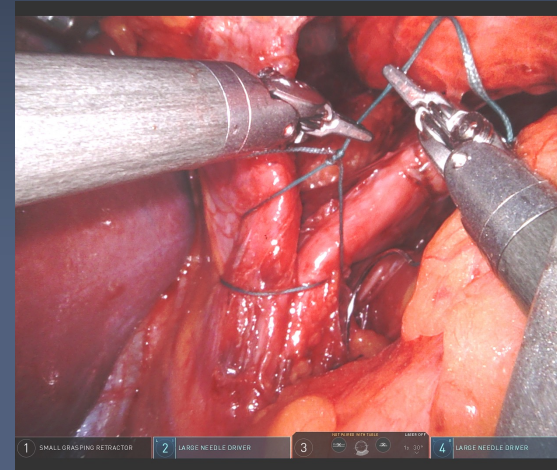
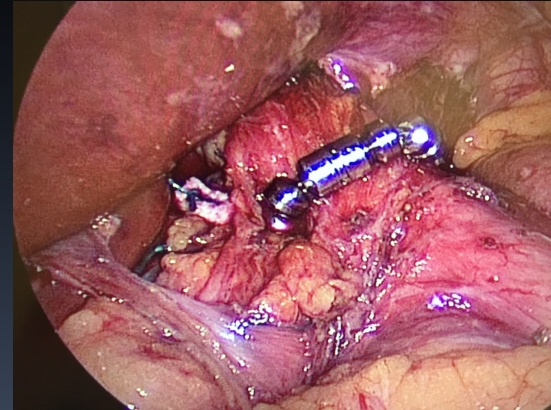
Technology Assessment/Principles

SAGES Technology and Value Assessment Committee (TAVAC) Safety and Effectiveness Analysis

- Peer reviewed publications
- Technology alerts (review of recent FDA approved devices)
- Safety and efficacy reviews (should be free of bias, COI)
 - Technology overview
 - FDA instructions for use
 - Current clinical practice and alternatives
 - Clinical evidence summary
 - Safety and efficacy data
 - Publication review/limitations of published data
 - Panel recommendations re safety and efficacy

What about Hands-on Training?

- Video review of device/procedure
- Practice on appropriate models (simulated, animate, cadaveric)
- Partner with experienced colleague (even if new to technique)
- In-person case observation
- Proctoring or tele-proctoring
- Team training



Lower Photo Courtesy M. Awad

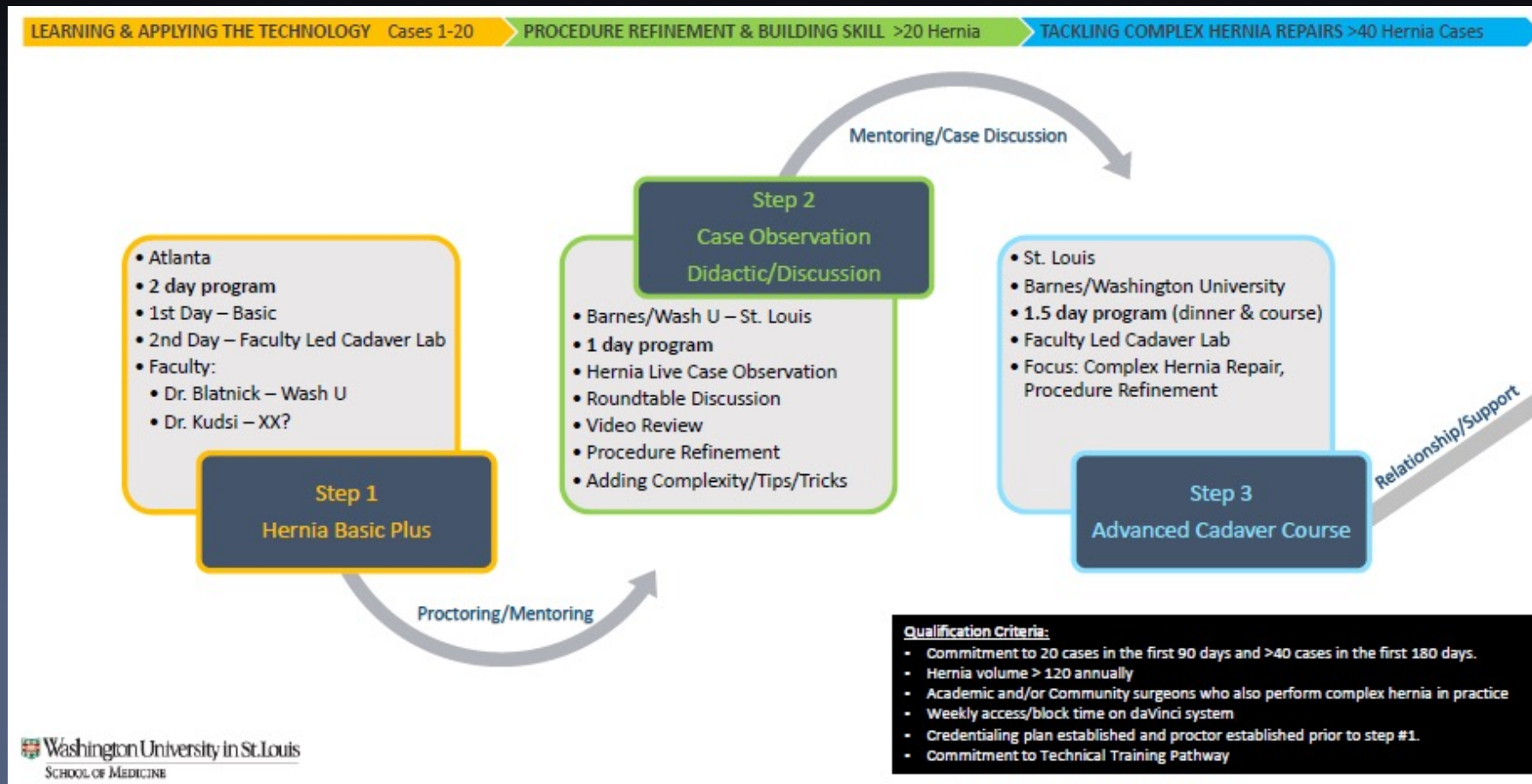
Postgraduate Robotic Surgery Training

- Phase IV – Beyond Residency, Clinical Partnership
- Case Observation (Foregut, Hernia @ WUSM/BJH)
- Proctoring
 - Development in one's own local environment
- “Telepresence” - Remote mentoring / proctoring / observation
- Continued collaboration/mentorship



Michael Awad, MD, PhD,
Robotic Foregut Surgery

Robotic Surgery Pathway to Hernia Repair



Slide Courtesy Jeff Blatnik, MD

Barnes-Jewish Hospital/Wash U Compass Program

- Longitudinal training and mentorship pathway
- 25 surgeons trained in robotic inguinal and ventral hernia repair
- Over 2200 procedures performed
- Surgeons present their own recorded cases for review and feedback

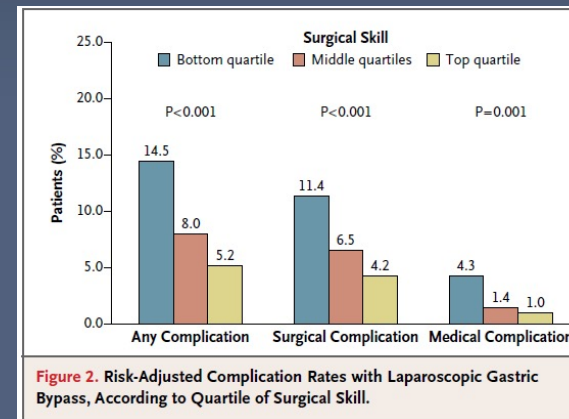
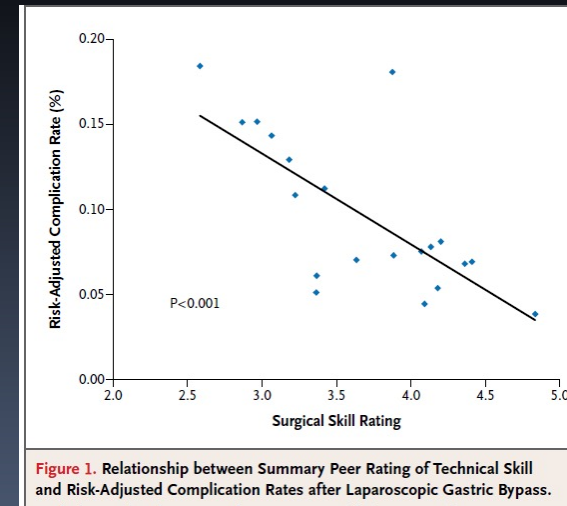


Robotic Hernia Course 2018,
Jeff Blatnik, MD Course Director

Surgical Skill and Complication Rates after Bariatric Surgery

- Video case review of 20 bariatric surgeons
- Technical skill varied widely
- Greater skill assoc with fewer complications, lower rate of reoperations and readmissions

Birkmeyer JD et al NEJM 2013; 369: 1434-42



Video-Based Surgical Coaching An Emerging Approach to Performance Improvement

Caprice C. Greenberg, MD, MPH; Janet Dombrowski, BSN, MHSA; Justin B. Dimick, MD, MPH

- Current approach to educating practicing surgeons inconsistent with adult learning principles
- Conferences and PG courses don't often use individualized goal-directed learning
- Such activities are removed from the point of care
- Mastery as a state of continual learning rather than simply high level performance
 - Senge P. In: The Fifth Discipline: The Art and Practice of Learning Organization
- Focus should be on formative evaluations rather than summative

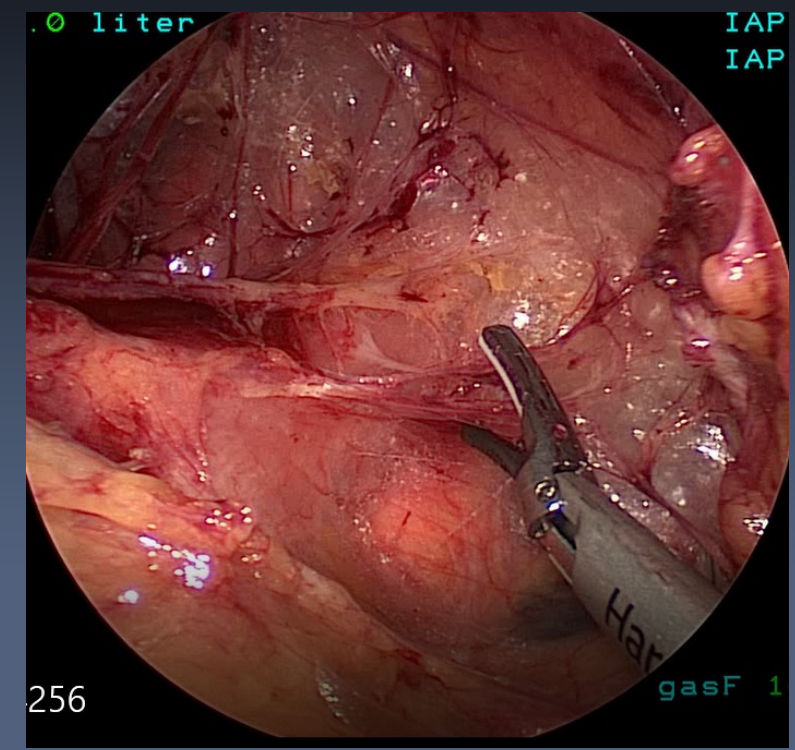
Greenberg CC et al JAMA Surg 2-16; 151: 282-83.

Video-based assessment for laparoscopic fundoplication: initial development of a robust tool for operative performance assessment

E. Matthew Ritter¹ · Almee K. Gardner² · Brian J. Dunkin³ · Linda Schultz⁴ · Aurora D. Pryor⁵ · Llane Feldman⁶

Table 1 Importance and difficulty means for all sub steps of the procedure

Step	SubStep	Criticality Mean ± SD	Absolutely essential (%)	Difficulty Mean ± SD	Difficult (%)
Visualization of the operative field	Ensure safe & effective liver retraction	4.18 ± 0.91	49	2.20 ± 1.06	2
	Put pars flaccida in view	3.99 ± 1.04	42	1.93 ± 1.02	3
Hiatal dissection ^a	Ensure diaphragmatic hiatus is in frame	4.50 ± 0.78	66	2.28 ± 1.13	4
	Open gastrohepatic ligament	4.32 ± 0.96	60	1.86 ± 0.95	2
	Open/release the phrenoesophageal ligament ^a	4.60 ± 0.76	72	3.02 ± 0.87	3
	Create adequate retroesophageal window ^a	4.78 ± 0.54	82	3.79 ± 0.86	19
	Safely manipulate esophagus (with or without penrose) ^a	4.74 ± 0.58	80	3.48 ± 0.97	12
Fundus mobilization ^a	Mobilize fundus for wrap creation (with or without division of short gastrics) ^a	4.59 ± 0.74	71	3.25 ± 0.89	7
	Divide retrogastric attachments	4.29 ± 0.84	48	3.46 ± 0.88	10
Esophageal mobilization ^a	Complete visualization of base of left crus ^a	4.53 ± 0.68	61	3.73 ± 0.77	12
	Retract esophagus to optimize mediastinal dissection	4.30 ± 0.82	52	3.58 ± 0.90	14
	Safely divide tissues surrounding the esophagus ^a	4.53 ± 0.69	65	3.91 ± 0.86	26
Hiatal repair ^a	Expose posterior junction of right and left crus	4.49 ± 0.70	60	3.56 ± 0.89	12
	Close crura with sutures ^a	4.69 ± 0.59	76	3.54 ± 0.85	12
	Reinforce closure with pledgets	2.08 ± 1.24	5	3.15 ± 1.05	10
Wrap creation ^a	Reinforce closure with mesh	1.95 ± 1.12	4	3.40 ± 0.98	13
	Pass the fundus posteriorly ^a	4.60 ± 0.72	72	3.32 ± 0.97	11
	Position the wrap around esophagus (assess geometry/twist) ^a	4.76 ± 0.49	79	3.74 ± 0.93	21
	Ensure wrap positioned around esophagus (not stomach) ^a	4.81 ± 0.45	84	3.58 ± 0.97	18
	Assess wrap tension (with or without bougie) ^a	4.46 ± 0.81	62	3.62 ± 0.94	17
	Secure wrap with suture ^a	4.65 ± 0.68	75	3.50 ± 1.02	17



Ritter M et al Surg Endosc 2020; 34: 3176-83

Leverage Communication Technology for Training

- Lab training (equipment, settings, usage, interpretation)
- Industry support
- Collaboration with current high level practitioners
- Case observation



Ethical Considerations/Informed Consent: What is the Current State?

- Most patients undergoing innovative surgery do so outside the protection of a clinical trial (outside of IRB)
- Absence of legal requirement to inform patients of the innovative nature of a procedure
- Guidelines for introducing new technology and practice are published but do not often specify what actually should be discussed with patients during the informed consent process

Mastroianni AC Health Matrix Cleve 2006; 16: 351-442.
Lee Char SJ et al Surgery 2013; 153: 473-480

Informed consent for innovative surgery: A survey of patients and surgeons

- Survey of surgery clinic patients and faculty at university medical center and affiliated hospitals
- 85/113 attending surgeons and 383/541 adult postop pts completed survey

Lee Char SJ et al
Surgery 2013; 153: 473-480

Informed consent for innovative surgery: A survey of patients and surgeons

- Survey of surgery clinic patients and faculty at university medical center and affiliated hospitals
- Patients placed more emphasis on:
 - Whether surgeon was performing for first time or not
 - *80% could not decide* without this information
 - Discussion of risks and benefits
 - Known risks, known benefits, potentially unknown risks
 - Surgeon's special training for the procedure
- Least important information:
 - Surgeon's potential conflict of interests

Lee Char SJ et al
Surgery 2013; 153: 473-480

Summary

- Introduction of new technology important to advancing clinical care in GI surgery and endoscopy
- Structured process critical for introducing new technology to ensure safe and effective use
- Leverage of modern communication technology and use of adult learning principles should be employed
- Transparency in the informed consent process and consideration of patient values are paramount

