

Adoption of New Technology: A View from Multiple Sides

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Disclosure

- Dual employment
 - University of Southern California
 - Intuitive Surgical: Medical Affairs



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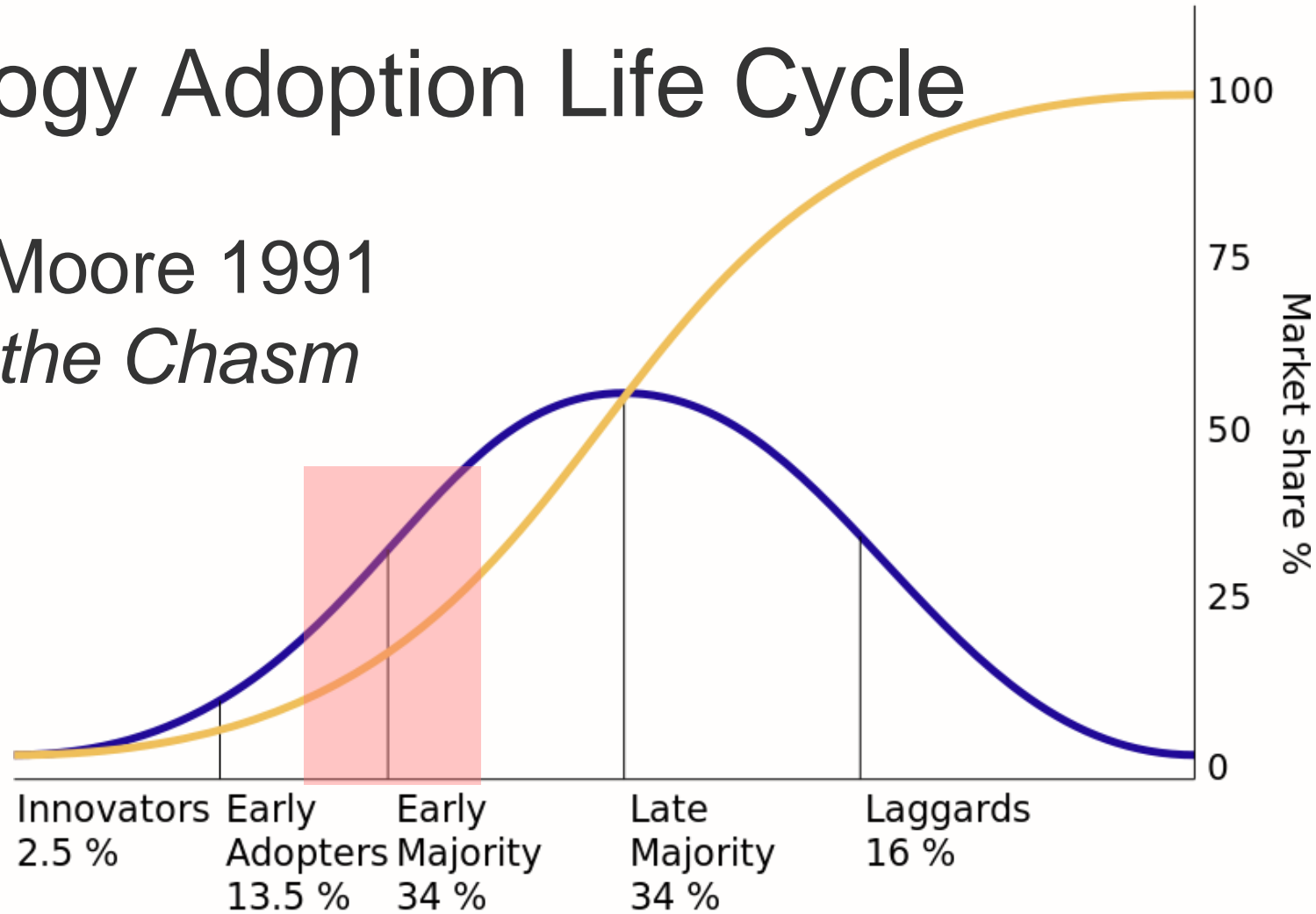
Objectives of this Talk

Different perspectives

- FDA
- Industry
- Surgeon
- Hospital
- Academia
- Patient

Technology Adoption Life Cycle

Geoffrey Moore 1991
Crossing the Chasm



The Problem: Surgery is Ubiquitous...

- 40-50 million procedures in U.S. every year¹
- 313 million procedures globally every year²
- In contrast, 16.4 million flights handled by FAA in U.S. every year³

And Post-Op Mortality is High

	Deaths per year	Year	Percent Total Deaths	Reference
Total All-Aged Deaths	2,839,205	2018		9
Cardiovascular and Stroke	793,840	2017	28%	CDC
Cancer	599,108	2017	21%	CDC
Injury	169,936	2017	6%	CDC
Major Surgery (inpatient) (1.32% of 50M)	660,000	2006	23%	4, 8

Data from Centers for Disease Control (CDC) website.

*vs. 2 fatalities from US air carriers in past 10 years

Surgeons are Frequently Sued

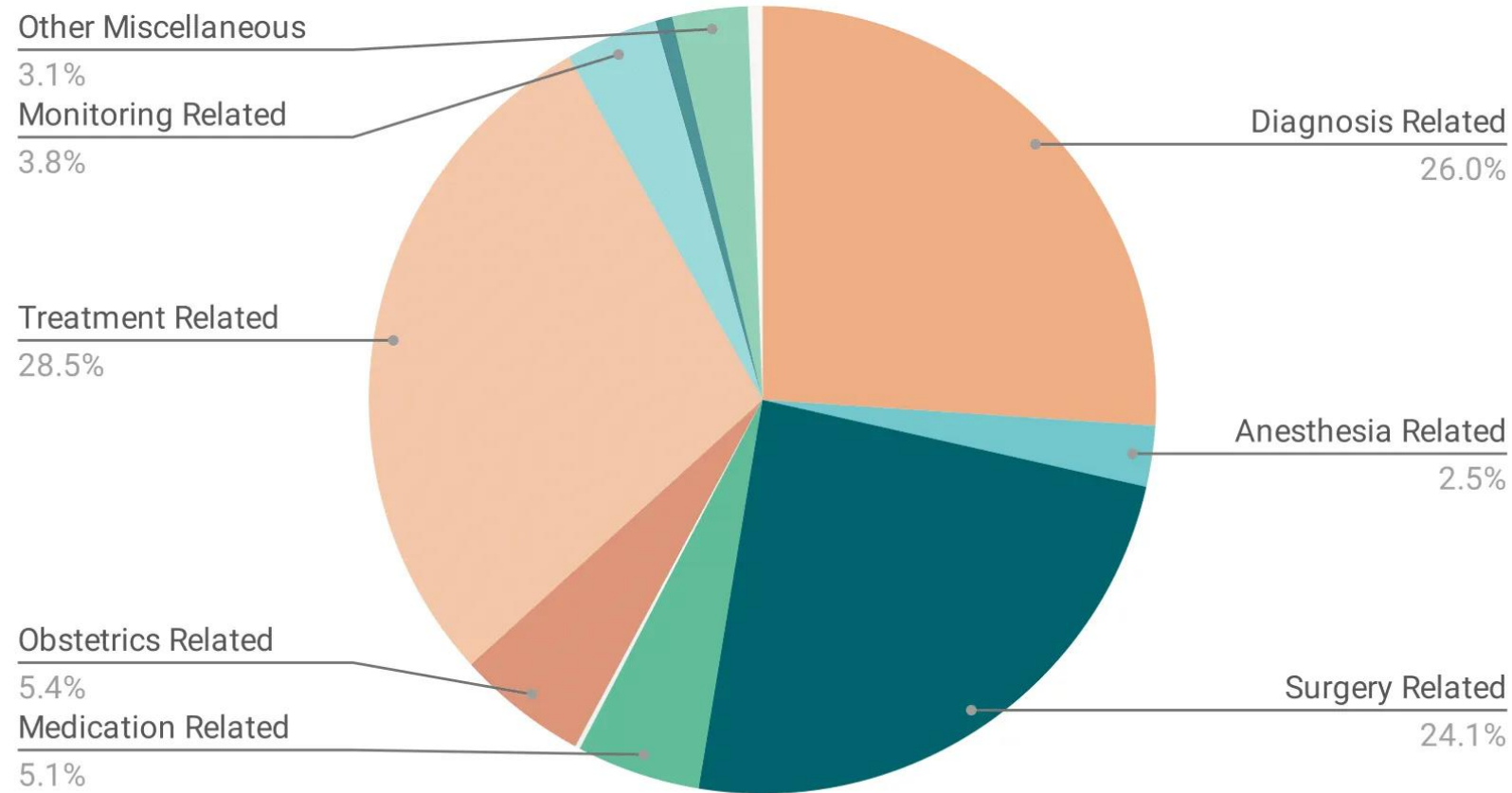
Medical Liability Claim Frequency, 2016

Specialty	Percentage of Physicians			Number of Claims per 100 Physicians
	Ever Sued	Sued 2+ Times	Sued in Last 12 Months	
	(1)	(2)	(3)	(4)
Anesthesiology	36.3%	17.9%	1.3%	64
Emergency medicine	51.7%	25.7%	3.0%	108
Family practice	33.4%	13.8%	1.1%	55
General surgery	63.2%	50.1%	8.0%	205
Internal medicine	31.7%	14.8%	3.1%	57
Internal medicine sub-specialties	25.5%	11.0%	1.0%	44
Obstetrics/Gynecology	63.6%	44.1%	6.7%	162
Pediatrics	17.8%	6.0%	1.0%	28
Psychiatry	16.1%	5.9%	1.9%	25
Radiology	37.6%	21.4%	0.4%	82
Surgical sub-specialties	47.4%	25.0%	3.3%	110
Other specialties	19.5%	5.8%	2.5%	29
Observations	3211	3145	3147	3145

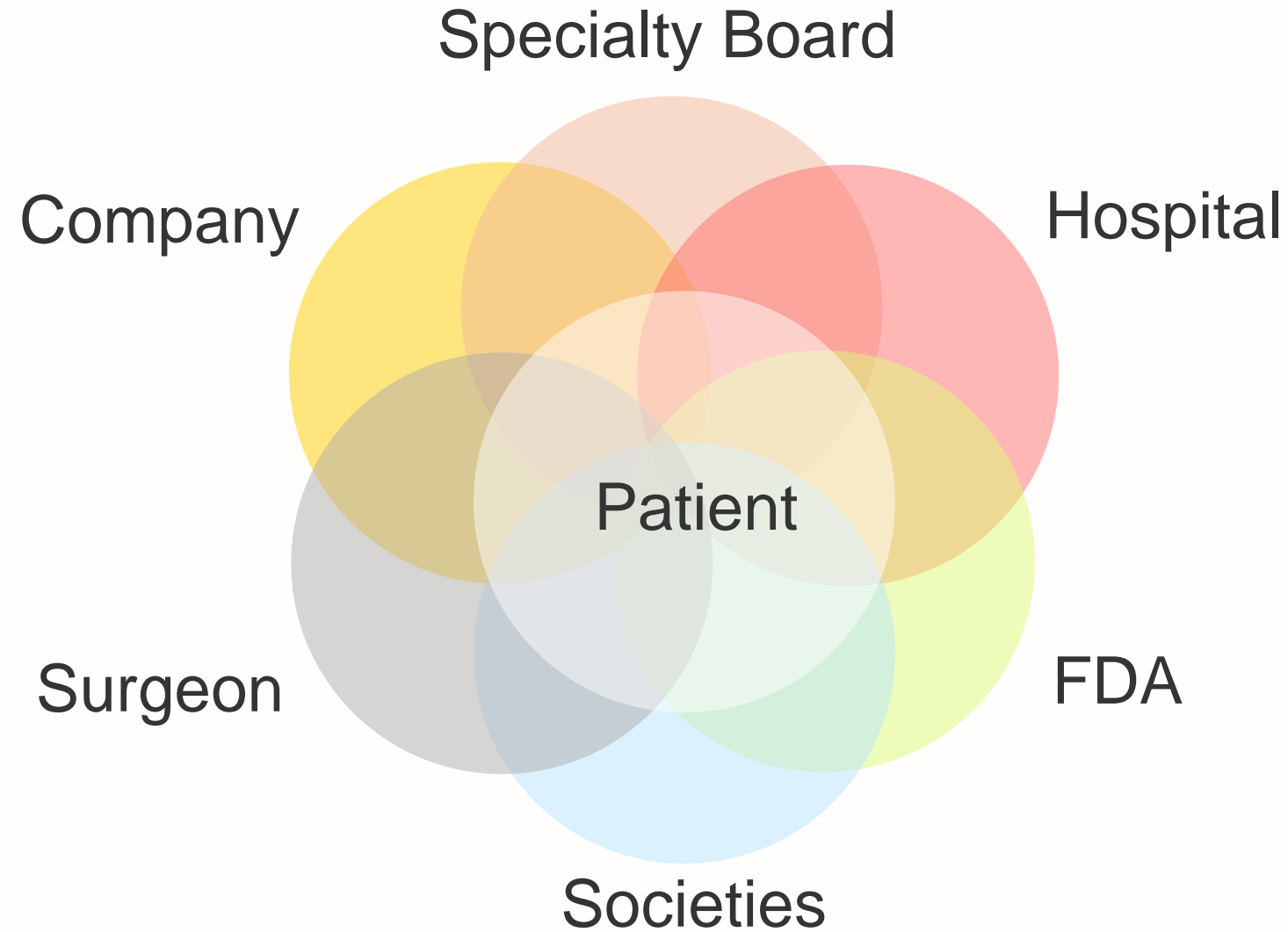
Source: Author's tabulation of data from the AMA's 2016 Benchmark Survey.

80,000 U.S. Medical Malpractice Suits Per Year

Causes of medical malpractice claims (2017-2021)



Patient Safety First



FDA Perspective

FDA

- Center for Devices and Radiological Health (CDRH)
- FDA approval is necessary to market and sell a medical device in the U.S.
- Company must provide evidence the device is **safe** and **effective**
- FDA does not regulate the practice of medicine

Step 1: Classify the Medical Device

Medical Device Amendments of 1976

- **Class I:** Minimum potential harm (47%)
 - Elastic bandage
- **Class II:** Moderate potential harm (43%)
 - Robotic surgical system
- **Class III:** Sustain or support life, are implanted, or present potential unreasonable risk (10%)
 - Implantable pacemaker

Step 2: Choose the Premarket Submission Pathway

Section 510(k) Food, Drug, and Cosmetic Act

- **Premarket Notification (PMN) or 510(k):** demonstrate the device is substantially equivalent (as safe and effective) to a device already on the market
 - Class II
- **Premarket Approval (PMA):** a new product containing new materials or differ in design to other products on the market
 - Class III

Step 3: Prepare Appropriate Information for the Premarket Submission

- Evidence and data compiled by the company
- Can request feedback for potential application
 - **Q-Submission Program (Q-Sub)**
 - System to track interactions
 - **Pre-Sub:** formal written request for feedback based on specific questions, including evidence requirements
- Decision within 60 days of submission

Investigational Device Exemption (IDE)

- Clinical study approved by FDA to collect safety and effectiveness data
- Data is used to support either PMA or 510(k)
- Investigator-led or industry-sponsored
- Use of device is limited to sites and time period described in the IDE study
- Requires IRB and often CMS approval

Step 4: Comply with Applicable Regulatory Controls

- Register device with FDA
- FDA approval with labeling for intended use and IFU (instructions for use)
- Special Controls – class II devices
 - Performance standards
 - Post-market surveillance
 - Patient registries
 - Special labeling requirements

Industry Perspective

Industry Responsibilities

- Need FDA approval of the device for its specific indication. Otherwise, a company cannot market, sell, train, or support use of the device
- Technical & human factors data
- Safety and efficacy data
- IFU (instructions for use) delineate proper way to set up and use device

How Does a Company Prove the Device is Safe and Effective?

- Bench research
- Cadaver and animal studies
- Technical validation and verification
- Human factors
- Clinical study or clinical data
 - Confirmatory study
 - Real world evidence
 - RCT

Example of Robotic-Assisted Surgical System

- Generally 510(k) but may be PMA
- Labeling approval for “general thoracoscopic surgical procedures”
- Demonstrate it has significant equivalence to the predicate device (thoracoscopic/VATS)
- For each specific indication must be cleared as a separate 510(k) labeling modification (lobectomy, thymectomy)
- Umbrella vs. covered procedures

Training Responsibilities

- A device company cannot teach the practice of medicine, i.e. how to operate
- Technology training is led by company (non-surgeons)
 - Designed by engineers, human factors, surgeons, and educators
 - How to use the device: controls, buttons, etc.
- Clinical application training (use of the device in a specific procedure) is led by surgeons

Example of Training Breakdown

Industry-Led

- On-line learning
- Hands-on in service
- Simulation
- Dry lab model training
- Wet lab model training

Surgeon-Led

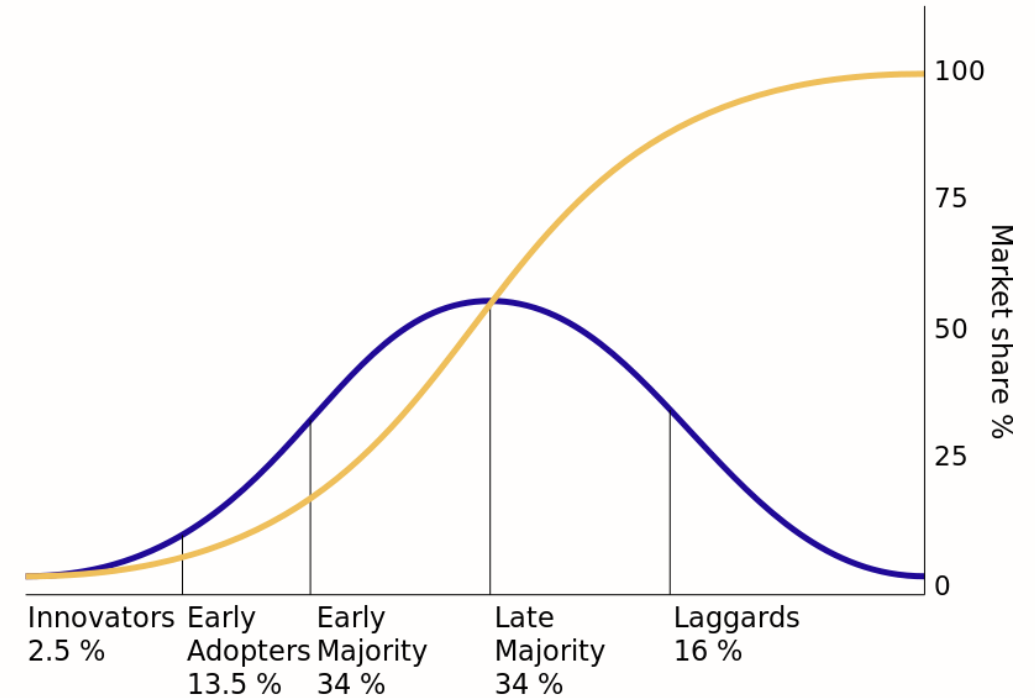
- Case observations
- Videos and lectures
- Procedural training
 - Wet lab models
 - Animal
 - Cadavers
- Proctoring/preceptoring

Surgeon Perspective

Surgeon Perspective: Adopting New Technology

Many Scenarios:

- Device – pre-existing or new?
- Procedure – on- or off-label?
- Risk – high, medium, low?
- IRB – yes or no?
- IDE – yes or no?
- Where are you on the adoption curve?

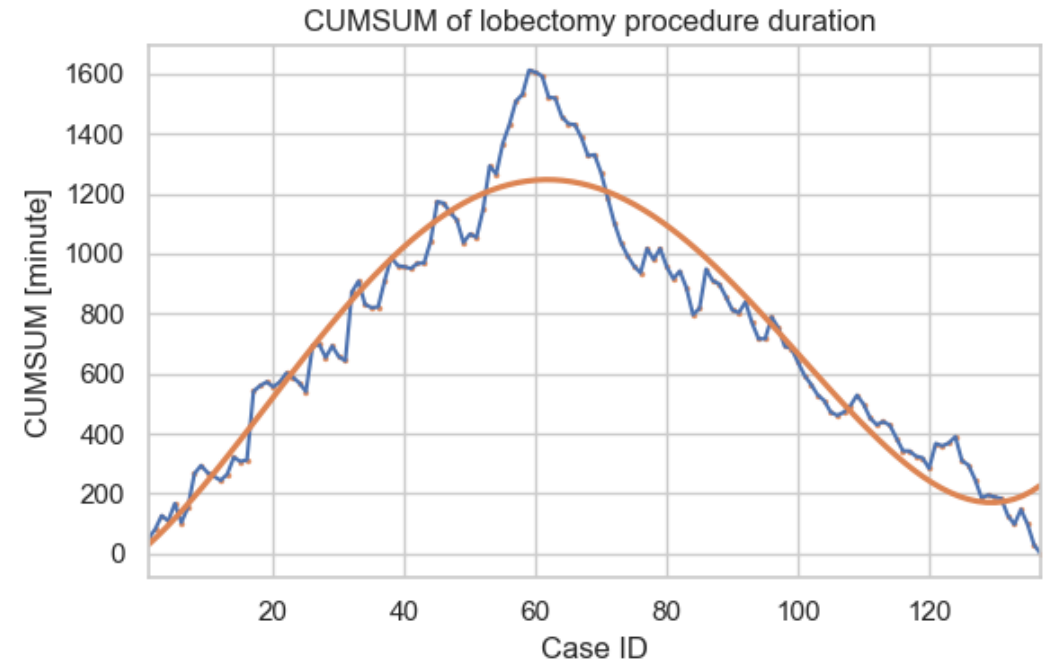


Requirements for Surgeon to Adopt a New Technology

- Board-certification
- Credentialed at hospital
- Completed industry-led technical training
- Complete surgeon-led operative training
- Proctoring or preceptoring (hospital regulated) for privileging

Learning Curve

- Patient selection is critical early in one's experience
- Surgery is a team sport
- Deliberate practice
- Monitor outcomes
- Leadership support is critical



My Learning Curve Through
First 140 Robotic Lobectomies

Developing Expertise: Anders Ericsson

Mental Representations

1. Observing and defining expert performance
2. Translating observation into actions
3. Monitoring performance

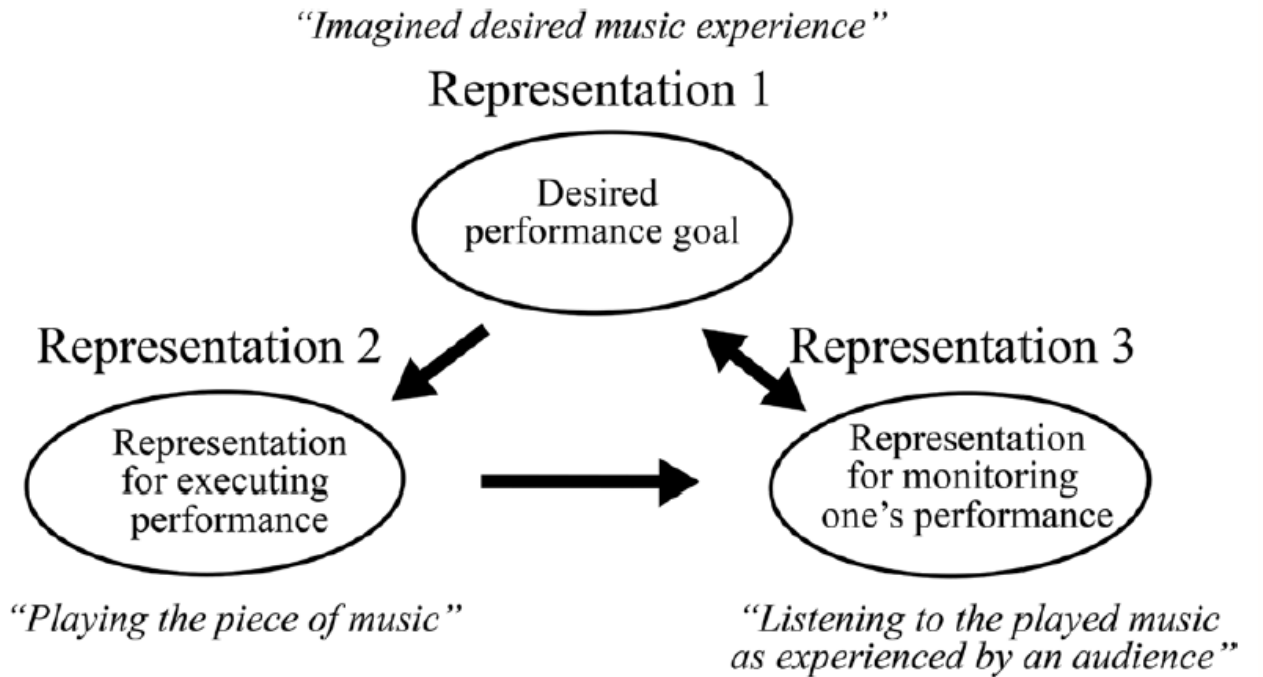
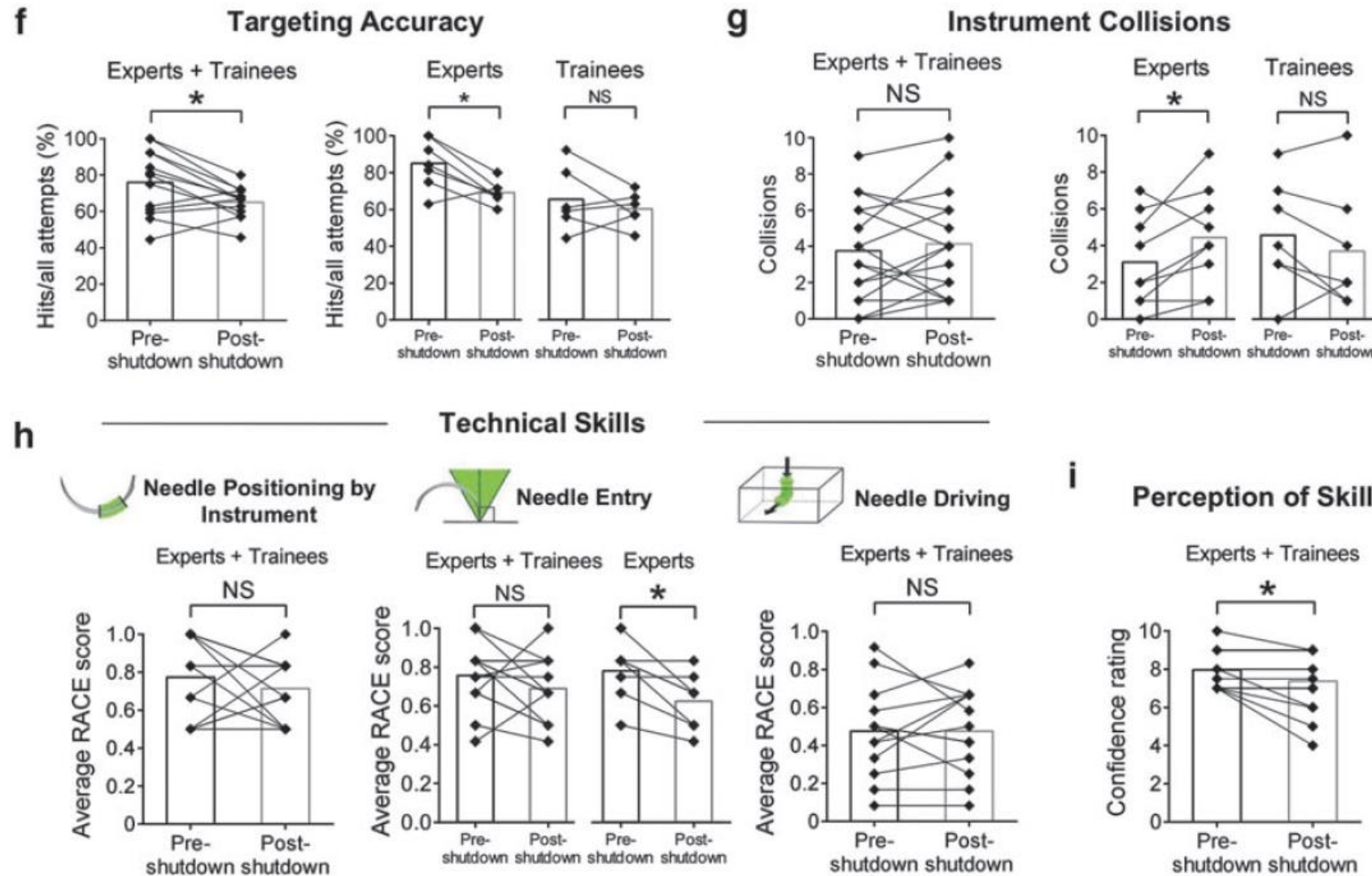


Figure 2 Three types of internal representations that mediate expert music performance and its continued improvement during practice. (Adapted from Figure 6, Ericsson KA. The scientific study of expert levels of performance: General implications for optimal learning and creativity. High Ability Stud. 1998;9:92.)

Robotic Console Skill Decay is Real



Median Weekly
Robotic Caseload
5.5 to 1.0

Intervention for Success

Preceptor

Proctor

Coach

Mentor

Community Support and Feedback

- Social media
- Society meetings and programs
- Industry
- Technology
 - Remote case observations
 - Teleproctoring
 - Video review



Off-Label Use

- FDA does not regulate the practice of medicine
- Could expose the surgeon and hospital to medicolegal liability
- May need IRB
- May need IDE (especially for company training and support)

Hospital Perspective

Credentialing vs. Privileging

Credentialing:

Education, experience, and training substantiated to become appointed member of a hospital staff

Privileging:

Granted permission by hospital to perform a procedure or a specific service

Robotic Surgery Credentialing

- Institute for Surgical Excellence (ISE)
- 28 robotic surgery experts
- Delphi process
- >80% agreement: consensus

Expert Consensus Recommendations for Robotic Surgery Credentialing

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Objective: To define criteria for robotic credentialing using expert consensus.

Background: A recent review of institutional robotic credentialing policies identified significant variability and determined current policies are largely inadequate to ensure surgeon proficiency and may threaten patient safety.

Methods: Twenty-eight national robotic surgery experts were invited to participate in a consensus conference. After review of available institutional policies and discussion, the group developed a 91 proposed criteria. Using a modified Delphi process the experts were asked to indicate their agreement with the proposed criteria in three electronic survey rounds after the conference. Criteria that achieved 80% or more in agreement (consensus) in all rounds were included in the final list.

Results: All experts agreed that there is a need for standardized robotic surgery credentialing criteria across institutions that promote surgeon proficiency. Forty-nine items reached consensus in the first round, 19 in the second, and 8 in the third for a total of 76 final items. Experts agreed that privileges should be granted based on video review of surgical performance and attainment of clearly defined objective proficiency benchmarks. Parameters for ongoing outcome monitoring were determined and recommendations for technical skills training, proctoring, and performance assessment were defined.

Conclusions: Using a systematic approach, detailed credentialing criteria for robotic surgery were defined. Implementation of these criteria uniformly across institutions will promote proficiency of robotic surgeons and has the potential to positively impact patient outcomes.

Keywords: credentialing criteria, Delphi process, expert consensus, robotic surgery, surgeon credentialing, surgeon proficiency

(*Ann Surg* 2022;276:88–93)

procedures and have cautioned that the ongoing diffusion of this relatively new technology should be monitored so that it does not lead to diminished patient safety.^{3,4} Indeed, prior studies have suggested there may be an increased risk for patient complications during the introduction of new technology, including robotic surgery, though this remains to be identified in prospective trials.^{5–7}

To ensure safe surgical practice and safe introduction of new technologies, the Joint Commission requires institutions to have specific credentialing policies the development of which, however, is the responsibility of the institution.⁸ In 2013, the US FDA conducted a small-scale survey of 11 surgeons which revealed a lack of standardization in the credentialing processes at their respective institutions.⁹ Specialty societies have suggested relevant guidelines to address gaps and lack of standardization in robotic surgery privileging and credentialing, however, none of these are uniform and the current uptake of such guidelines by hospital credentialing committees is unknown.^{10–14} Further, existing guidelines tend to be specialty specific, which may limit their generalizability.

Indeed, in a recent review of a representative sample of 42 US hospital credentialing policies by our group, we identified significant variability in credentialing policies for robotic surgery.¹⁵ Importantly, existing credentialing policies were deemed inadequate to ensure surgeon proficiency and the development and implementation of standardized credentialing guidelines was recommended to optimize patient safety and outcomes.¹⁵ There are legal implications from the lack of a standardized approach, and it is therefore not surprising that recent lawsuits have argued that institutional robotic surgery credentialing processes are not sufficient to ensure patient safety.¹⁶

As a response to this existing lack of standardization for credentialing in robotic surgery that may threaten patient safety

Initial Credentialing Requirements

Initial Credentialing Requirements	% Agreement	Round
Board eligibility or specialty certification	90.0%	1
Chair support letter	82.6%	2
Basic cognitive training in robotic surgery	100.0%	1
Cognitive training on specific robotic device for which requesting privileges	96.7%	1
Specialty specific cognitive training on robotic surgery	91.3%	
Basic robotic technical skills training	100.0%	1
Robotic device specific technical training	100.0%	1
Specialty specific skills training on robotic procedures	83.3%	1
Specialty specific non-technical skills training in robotic surgery	91.3%	
OR observation of procedure specific cases for which requesting privileges	90.0%	1
Initial cases preceptored/ proctored (both basic and advanced)*	93.3%	1

Initial Credentialing Requirements	% Agreement	Round
Initial cases performed with experienced co-surgeon with surgeon seeking privileges in an assistant role until proficiency demonstrated. Subsequent cases performed as primary surgeon with co-surgeon in assistant role again until proficiency demonstrated	86.7%	1
Review of first several cases performed by an independent expert	93.3%	1
Random audit of initial cases via video and chart review	80.0%	1
Objective procedure-specific performance benchmarks met/ proficiency demonstrated outside the OR	100.0%	1

Re-Credentialing Requirements

Maintenance of Privileges Requirements	% Agreement	Round
Annual robotic case volume	90.0%	1
Complication rates	96.7%	1
Estimated blood loss	92.6%	3
Operative time and total room time	83.3%	1
Return to the OR	93.3%	1
Conversion rate to open surgery	86.7%	1
Readmission rates	86.7%	1
Operative costs	85.2%	3

These parameters should be monitored after initial credentialing and have expected/acceptable performance criteria set; if such criteria are not met a surgeon performance audit should automatically be triggered; random audits of surgeon should also be routinely performed.

OR, operating room.

Additional Recommendations: Credentialing

Additional Recommendations	% Agreement	Round
Simulation should be used if performance concerns arise after review: both for assessment and training	90.0%	1
Separate credentialing for basic and advanced robotic procedures	91.3%	2
Proficiency should be demonstrated in basic cases first before advanced privileges approved	83.3%	1
Digital media policy should exist in all institutions to allow for video review of performance as an ongoing assessment tool	90.0%	1
A dedicated Robotic Steering/Program committee should be required at each institution; they should be responsible both for the credentialing of surgeons and the OR team	86.7%	1
Random performance audits can be done via video review of surgeon's procedures	93.3%	1
Video review should be done by independent entity	90.0%	1
Assessment of proficiency should be done by procedural video review and using objective metrics	100.0%	1
A national independent database for robotic surgery outcomes should be created	83.3%	1
Surgeons should share the cost of development and maintenance of this database	82.6%	2
Industry should share the cost of development and maintenance of this database	87.0%	2
Industry should share the cost of ensuring surgeon proficiency	82.6%	2
Hospitals should share the cost of ensuring surgeon proficiency	82.6%	2
Instrument tracking (automated performance metrics) is beneficial for assessing surgeon proficiency; eye tracking is not	95.7%	2
Objective proficiency metrics should be developed for each procedure and standardized to be applicable to all robotic platforms	93.3%	1
The OR team besides the surgeon should also participate in credentialing for participation in robotic procedures	83.3%	1
Evaluation of surgeon performance by an independent evaluator using OSATS is appropriate	80.0%	1
Preceptors should be different than proctors	92.6%	3
Preceptors/ proctors should be able to participate in procedures if needed for training and patient safety reasons	90.0%	1
Industry should not select proctors*	93.3%	1
Proctors should be specialty specific	90.0%	1
Proctors should be independent	95.7%	2
Specialty specific procedure training should not be developed by device makers	90.0%	1
Device training should be developed by device makers	86.7%	1
Device training developed by industry should be peer reviewed by specialty societies	95.7%	2
Advanced training should be developed by non-profit education organizations	80.0%	1
*National specialty societies should select proctors reached 74.1% agreement.		

“[L]ittle to no quality data are available for most new technology and advanced procedures to support assigning a specific number of cases for privileging.”

STS EXPERT CONSENSUS STATEMENT

The Society of Thoracic Surgeons Expert Consensus Statement: A Tool Kit to Assist Thoracic Surgeons Seeking Privileging to Use New Technology and Perform Advanced Procedures in General Thoracic Surgery

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STS Checklist for Privileging – Any New Device

- ☐ Verification of knowledge and skills assessment
 - ABTS-eligible or ABTS-certified surgeon
 - Documented completion of a course or didactic session
 - For recent graduates of an accredited program, case logs and a program director letter attesting to competence
- ☐ Team management
 - Draft of implementation program complete
 - Education plan for team members complete
 - Crisis management plan complete
- ☐ Institutional collaboration
 - IRB and/or institutional innovative care/new technology committee approval
- ☐ Monitoring of outcomes
 - Participation in a continuous quality improvement committee and/or morbidity/mortality conference
 - Participation in an auditable database (eg, National Surgical Quality Improvement Program, STS National Database, Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative) or registry or shared database that is accessible by the host institution
 - Demonstration of ability to present accurate and detailed morbidity and mortality rates to administration upon request
- ☐ Patient-centered transparency
 - Provide appropriate consent forms for IRB and/or innovative committee approval
 - Provide the patient information on the risks and benefits of the new procedure, alternative treatments, general costs (ie, to the patient or payer, or both), and comparative effectiveness of the new technology vs existing treatment options
 - Provide the patient with information on the surgeons training and experience to date

Academia Perspective

IDEAL-D

- Idea
- Development
- Exploration
- Assessment
- Long-term follow up
- Device innovation

REVIEW PAPER

OPEN

IDEAL-D Framework for Device Innovation *A Consensus Statement on the Preclinical Stage*

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Objective: To extend the IDEAL framework for device innovation, IDEAL-D, to include the preclinical stage of development (stage 0).

Background: In previous work, the IDEAL collaboration has proposed frameworks for new surgical techniques and complex therapeutic technologies, the central tenet being that development and evaluation can and should proceed together in an ordered and logical manner that balances innovation and safety.

Methods: Following agreement at the IDEAL Collaboration Council, a multidisciplinary working group was formed comprising 12 representatives from healthcare, academia, industry, and a patient advocate. The group conducted a series of discussions following the principles used in the development of the original IDEAL framework. Importantly, IDEAL aims for maximal transparency, optimal validity in the evaluation of primary effects, and minimization of potential risk to patients or others. The proposals

were subjected to further review and editing by members of the IDEAL Council before a final consensus version was adopted.

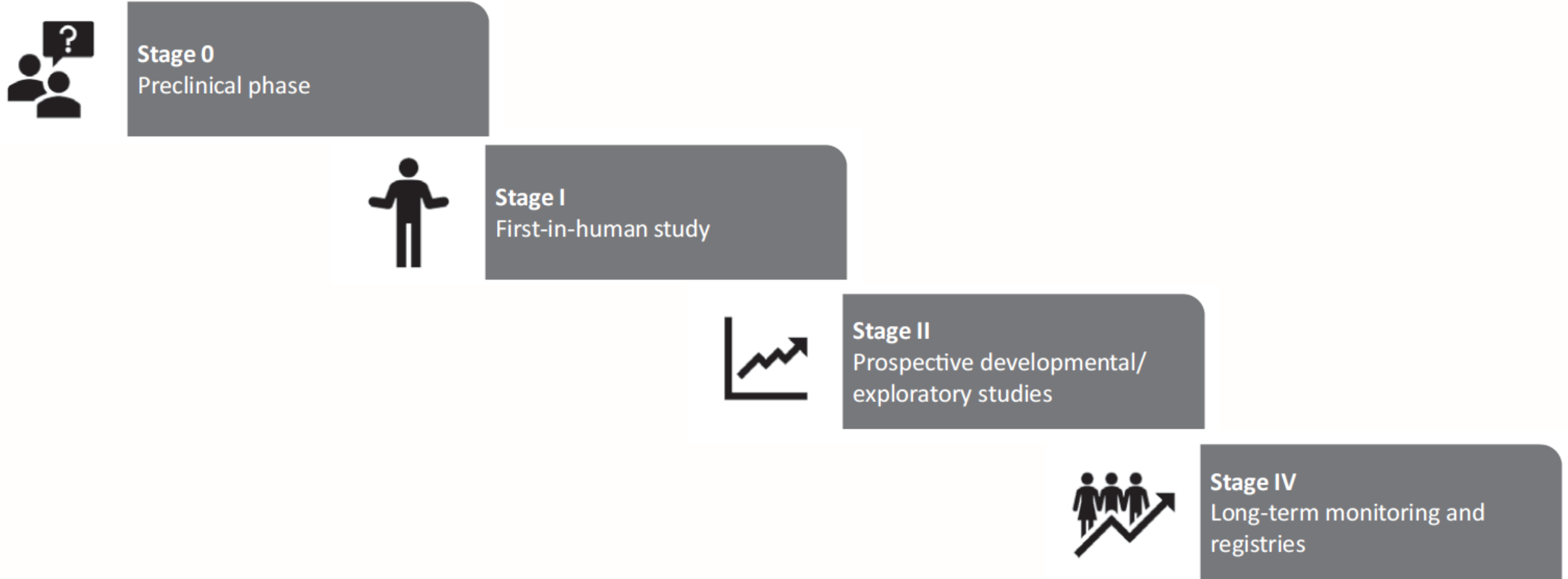
Results: In considering which studies are required before a first-in-human study, we have: (1) classified devices according to what they do and the risks they carry, (2) classified studies according to what they show about the device, and (3) made recommendations based on the principle that the more invasive and high risk a device is, the greater proof required of their safety and effectiveness before progression to clinical studies (stage 1).

Conclusions: The proposed recommendations for preclinical evaluation of medical devices represent a proportionate and pragmatic approach that balances the de-risking of first-in-human translational studies against the benefits of rapid translation of new devices into clinical practice.

Keywords: devices, first-in-human, IDEAL, innovation, preclinical, regulation

(*Ann Surg* 2022;275:73–79)

IDEAL-D Stages of Development



Example

- Authors developed RAMIE technique at their hospital
- Outcomes of each sequential case
- Patient selection explained (including exclusion)
- Highlight changes to technique each time introduced

The IDEAL prospective development study format for reporting surgical innovations. An illustrative case study of robotic oesophagectomy



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H I G H L I G H T S

- This paper demonstrates the use of the IDEAL Prospective Development Study format for presenting early work on surgical procedures.
 - We show how transparency in reporting changes during development can allow others to benefit from the authors experience.
 - The findings are of special interest to upper GI surgeons interested in using a robotic approach for oesophageal resection.
-

A R T I C L E I N F O

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A B S T R A C T

Background: The early development of innovative surgical procedures is usually reported as retrospective case series, wasting opportunities to provide useful information and introducing bias. We present a report of an innovative procedure in development, using the Prospective Development Study (PDS) format recommended by the IDEAL Collaboration.

Methods: We report the development of robotically assisted oesophagectomy by a two-surgeon team from the first robotic case onwards. Key outcomes (blood loss, robotic operating time, lymph node yield, length of stay and complications) are prospectively reported for each patient sequentially. Reasons for rejecting cases for robotic surgery are explained. All changes to technique or indication are highlighted, showing when they occurred and explaining why they were instituted.

Results: The first robotic oesophagectomy was attempted in December 2009. Subsequently 55 oesophagectomies were undertaken, 34 using the robot and 21 without it. Seven deliberate changes in technique occurred during the series. Nodal yield increased markedly after adopting formal mediastinal node dissection and clipping of the thoracic duct. No obvious trends were noted in other outcomes. The robot facilitated Intra-thoracic anastomosis, but mediastinal node dissection showed no advantages due to loss of haptic sensation. Complication rates, R0 rates and nodal yield were considered acceptable.

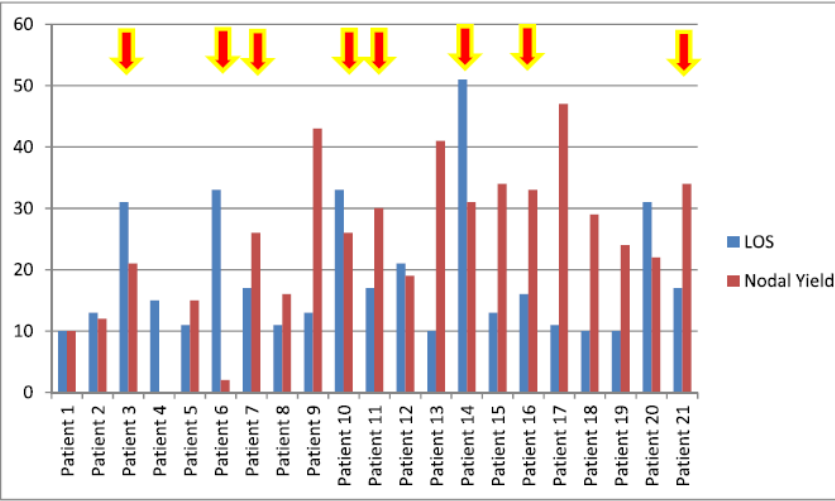
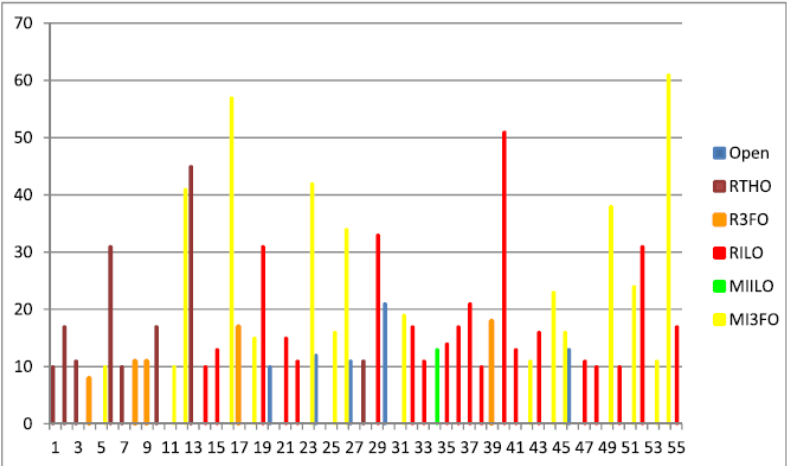
Discussion: Presenting the development experience in this way improved the clarity of transmission of the main learning points for other surgeons, eliminated bias from selective reporting and explained other types of selection bias. The IDEAL Prospective Development Study has clear advantages over standard case series format for presenting uncontrolled early study data from innovative procedures.

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Details of individual cases.

No	LOS	Neoadj	Operation	Notes & complications	Nodes
1	10	CRXT	RTHO	Laparoscopic exploration only – inoperable (M1): Transhiatal gastric herniation, repaired laparoscopically	
2	17	CRXT	RTHO	None	6
3	11	CRXT	RTHO	None	12
4	8	No	R3FO	Diagnostic thoracoscopy only – inoperable (T4b): preoperative diagnosis leiomyoma. None	
5	10	CRXT	MBFO	Cervical anastomotic leak type 2*	9
6	31	CRXT	RTHO	Fistula from gastric tube, repaired at 2nd op.	9
7	10	CRXT	RTHO	Elective conversion to laparotomy	19
8	11	CRXT	R3FO	Cervical anastomotic leak type 1	9
9	11	CRXT	R3FO	None	14
10	17	CRXT	RTHO	Cervical anastomotic leak type 1	10
11	10	CRXT	MBFO	Previous Nissen fundoplication. None	16
12	41	CRXT	MBFO	Anastomotic leak type 4, progressing to gastrobronchial fistula	7
13	45	CRXT	RTHO	Anastomotic leak type 3 & gangrenous cholecystitis. Died	16
14	10	CRXT	RILO	None	10
15	13	CRXT	RILO	None	12
16	57	No	MBFO	Second primary Ca in lung: Cardiopulmonary failure, impossible to extubate. Died	15
17	17	CRXT	R3FO	None	8
18	15	CRXT	MBFO + Chole	Elective conversion to thoracotomy	17
19	31	No (cardio)	RILO	Anastomotic leak type 3	21
20	10	CXT	OTHO (colon interposition)	None	9
21	15	No (benign)	RILO	Op for Stenosing ulcer. None	
22	11	No	RILO	Conversion to thoracotomy (pleural adhesions)	15
23	42	CRXT	MBFO	Forced conversion (haemorrhage) to thoracotomy. Chylothorax	1
24	12	No (cardio)	RTHO	None	18
25	16	No	MBFO	Cervical anastomotic leak type 1	25
26	34	CRXT	MBFO	Multi-organ failure, died	19
27	11	No (benign)	O3FO	None (previous Ivor-Lewis 6 years before)	
28	11	CRXT	RTHO (OTHO 2nd time)	Tako-tsubo cardiac failure, recovered	18
29	33	CRXT	RILO	M1 disease: Chylothorax - died from CVA	2
30	21	No (benign)	O3FO (L thoracot)	Oesophagectomy to treat oesophago-jejunal leak after total gastrectomy. None	
31	19	No	MBFO	None	26
32	17	CRXT	RILO	Anastomotic leak type 3, endoprosthesis	26
33	11	CRXT	RILO	CRXT was 1 year previously. None	16
34	13	CRXT	MILO	None	43
35	14	CXT	RILO	None	26
36	17	CRXT	RILO	Effusion, Pig-tail pleural drain	30
37	21	CRXT	RILO	Conversion to thoracotomy (pleural adhesions)	19
				Effusion, Pig-tail pleural drain	
38	10	CXT	RILO	None	41
39	18	CRXT	R3FO	Anastomotic leak type 2	31
40	51	CRXT	RILO	Anastomotic leak type 3/ARDS. Died	38
41	13	CRXT	RILO	None	34
42	11	CRXT	MBFO-coloplasty	None	29
43	16	CRXT	RILO	Pig-tail pleural drain	33
44	23	CRXT	MBFO + chole	Pleural effusion: tube	24
45	16	CRXT	MBFO	Anastomotic leak type 4. Reoperation. Died	28
46	13	No (age)	OTHO	None	49
47	11	No (age)	RILO	None	47
48	10	CRXT	RILO	None	29
49	38	No (uT1N0)	MBFO	Anastomotic leak type 4. Reoperation	41
50	10	No (HGD)	RILO	None	24
51	24	CRXT	MBFO	None	55
52	31	CRXT	RILO	None	22
53	11	CRXT	MBFO + chole	None	29
54	61	CRXT	MBFO	Chylothorax. Reoperated	31
55	17	CRXT	RILO	Pig-tail pleural drain	34

Notes.
1. No complications 30/55 = 54.5%.
2. Anastomotic leaks: 12/55 = 21.8% classified according to Larburu et al. [20]. [3 Type I (radiological); 2 Type II(cervical); 4 Type III (thoracic); 3 Type IV (ischemia)].
3. Median length of stay: 15 days (IQ range: 11–23.5).



Formal mediastinal lymphadenectomy with thoracic duct clipping adopted.

Union of specimen and gastric tube abandoned

Use of robot in thorax confined to anastomosis.

Patient Perspective

Informed Consent

- Patient wants robotic mitral repair
- Surgeon will do it but has only done 1 case
- How much to disclose?

First in line for robotic surgery: Would you want to know?

Check for updates

Y. Joseph Woo, MD,^a John R. Handy, Jr, MD,^b and Robert M. Sade, MD^c

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Read at the 44th Annual Meeting of the Western Thoracic Surgical Association, Goleta, California, June 27-30, 2018.

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0022-5223/\$36.00

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<https://doi.org/10.1016/j.jtcvs.2018.11.025>

The safety, effectiveness, and durability of robotic mitral valve repair have been well documented and, despite increased operating room time, have been found to have some advantages over other repair techniques.¹ The adoption of robotic mitral valve repair has been widespread in part because of patients' preferences and demands, and in part because of marketing pressures in a competitive health care environment.² As robotic approaches are more widely adopted in response to these factors, the number of surgeons who are relatively inexperienced in robotic techniques increases.

This situation leads to an ethical problem when a patient wants robotic surgery and the surgeon is able to do it but has performed only a limited number of such operations: How much detail about the surgeon's experience must be disclosed during the informed consent process? This question was explored in the form of a debate at the 44th Annual Meeting of the Western Thoracic Surgical Association. The debate was focused on the hypothetical case of a nervous patient.



Robotic cardiac surgery requires a large integrated team in the operating room.

Central Message

A controversial aspect of informed consent is the question of whether a surgeon's personal experience should be disclosed to patients routinely.

See Commentary on page 1941.

second, once acquired, one of their group would be trained to perform robotic-assisted minimally invasive mitral valve replacement and repair (MIMVR). They designated the youngest surgeon of the group, Dr Hal Asimov, who had been with them for 5 years. He was chosen because he performed both cardiac and thoracic procedures and was generally seen as the best video-assisted thoracoscopic surgeon in the group. He had also been an All-American basketball player in college, had been a champion video-gamer throughout his school years, and was an accom-

Society or Payer Perspective

Do all surgeons have the right to adopt new technology?

Considerations:

- Wide dissemination vs. centers of excellence
- Relationship between volume and outcomes
- Cost effectiveness and efficiency
- How much adoption has already occurred? How much evidence has accumulated?

Conclusion

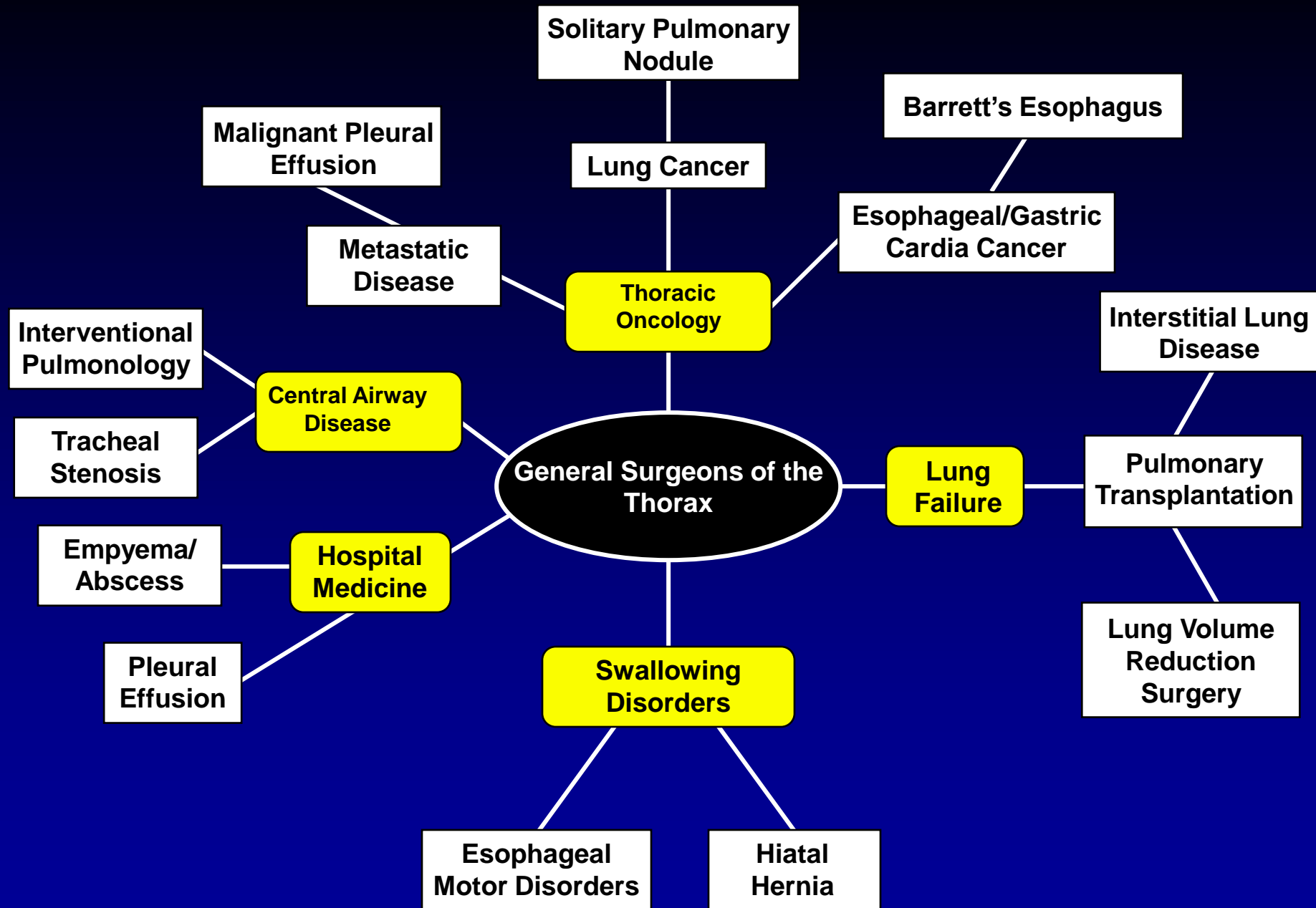
- Use of a novel medical device is a complex interplay of industry, surgeons, hospitals, governing bodies, and societies
- A company can market, sell, train, and support use of the device as long as procedure is on-label and used according to the IFU
- A surgeon can deviate from the labeling and IFU but the company cannot be involved outside of an IDE
- The responsibility of the hospital is significant and leads to variability
- IDEAL-D is the recommend framework by which new device outcomes should be measured and reported

Teaching An Old Dog A New Trick?

Sudish Murthy, MD, PhD, FACS, FCCP
Daniel and Karen Lee Endowed Chair in Thoracic Surgery
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No relevant disclosures

GTSC 2023













This Invite Usually Reserved for...

This Invite Usually Reserved for...

- **Famous Emeritus**

This Invite Usually Reserved for...

- ~~Famous Emeritus~~

This Invite Usually Reserved for...

- **Famous Emeritus**
- **Societal Leader with Keen Insight**

This Invite Usually Reserved for...

- Famous Emeritus
- ~~Societal Leader with Keen Insight~~



This Invite Usually Reserved for...

- **Famous Emeritus**
- **Societal Leader with Keen Insight**
- **That Dinosaur Who hasn't gotten a **PLAN B** after Stoking the Boilers for quite some time**

What's NOT New?

Murthy, Sudish - Central

Filter by Status

Total: 22

Preview

		Pr...	En...	Status	Status Details	Time	Proc/Visit Type	Notes	Department	Sched Status
				Signed	Checked out: 11:12 AM	8:20 AM	Provider Specialty Phone Call	phone Lung nodule	THORMN	Completed
				Signed	Checked out: 11:12 AM	8:40 AM	Provider Specialty Phone Call	phone Malignant neoplasm of breast in female, estrogen receptor positive, unspecified laterality, u...	THORMN	Completed
				Signed	Checked out: 9:08 AM	9:00 AM	Video Spec Est	TRACHEAL STENOSIS/GERD EST VIRTUAL F/U TO DISCUSS TESTS RESULTS PER REBEC...	THORMN	Completed
				Signed	Checked out: 9:26 AM	9:20 AM	Est Patient	FOLLOW UP	THORMN	Completed
				Signed	Checked out: 11:08 AM	9:40 AM	Pre Op	-or- SM 3/6/23 Robotic Assisted Esophagectomy	THORMN	Completed
				Signed	Checked out: 10:19 AM	10:00 AM	Con Patient	Mesothelioma coord/w Oncology per phone enc	THORMN	Completed
				Signed	Checked out: 1:02 PM	10:20 AM	Pre Op	-or- SM 3/3/23 POP Note..No covid needed per Rebecca	THORMN	Completed
				Signed	Checked out: 11:08 AM	11:00 AM	Con Patient	Venous lymphatic malformation CONSULT W/PFTS COORD W/CARDIO PER REBECCA'S TEL...	THORMN	Completed
				Not Seen	No Show	11:20 AM	Con Patient	Esophageal Cancer New Consult - No Testing prior per Rebecca tele	THORMN	No Show
				Signed	Checked out: 11:57 AM	11:40 AM	Con Patient	Hiatal Hernia Consult per Rebecca	THORMN	Completed
				Signed	Checked out: 12:12 PM	12:40 PM	Con Patient	Lung Nodule and COPD CONSULT W/ DOBUT ECHO, CPET PER REBECCA'S TELE 1ST AVAIL...	THORMN	Completed
				Signed	Checked out: 1:46 PM	1:00 PM	Con Patient	GERD post lung txp CONSULT NO TESTS PER REBECCA'S TELE R/S FROM 1/12/23 & 1/19/2...	THORMN	Completed
				Signed	Checked out: 12:14 PM	1:40 PM	Est Patient	Lung Nodules follow-up + cct	THORMN	Completed
				Signed	Checked out: 1:24 PM	2:00 PM	Con Patient	Hiatal Hernia Consult w/pfts per Rebecca	THORMN	Completed
				Signed	Checked out: 2:49 PM	2:20 PM	Con Patient	GERD CONSULT W/PFTS PER REBECCA'S TELE R/S FROM 1/26/23 & 2/9/23 PER PT'S REQ	THORMN	Completed
				Signed	Checked out: 2:02 PM	2:40 PM	Con Patient	Gastroesophageal reflux disease without esophagitis Achalasia and cardiospasm New Consult w/...	THORMN	Completed
				Signed	Checked out: 3:28 PM	3:00 PM	Con Patient	Esophageal Dysplasia per phone enc Note.. triaging Pet Scan	THORMN	Completed
				Signed	Checked out: 3:59 PM	3:20 PM	Pre Op	-or- SM 3/6/23 Robotic Left Lung Resection, segment vs lobe	THORMN	Completed
				Signed	Checked out: 4:14 PM	3:40 PM	Con Patient	Lung nodule [R91.1]	THORMN	Completed
				Signed	Checked out: 4:28 PM	4:00 PM	Con Patient	Hiatal hernia CONSULT W/TBE, PFTS PER SCOTT'S TELE	THORMN	Completed
				Signed	Checked out: 11:57 AM	4:20 PM	Pre Op	Robotic Assisted Esophagectomy OR 3/3/2023	THORMN	Completed
				Signed	Checked out: 5:45 PM	4:40 PM	Con Patient	Lung Mass Metastatic Rectal cancer CONSULT W/PFTS PER REBECCA'S TELE PFTS DONE 2/...	THORMN	Completed

Murthy, Sudish - Central

Filter by Status

Total: 14



	Pr...	En...	Status	Status Details	Time	Proc/Visit Type	Notes	Department	Sched Status
		No	Scheduled		9:00 AM	EGD DIAGNOSTIC [GI9]		HLDHC	Scheduled
		No	Scheduled		9:30 AM	EGD DIAGNOSTIC [GI9]		HLDHC	Scheduled
		No	Scheduled		10:00 AM	EGD DIAGNOSTIC [GI9]		HLDHC	Scheduled
		No	Scheduled		10:30 AM	EGD DIAGNOSTIC [GI9]	Malignant neoplasm of lower third of esophagus (HCC) [C15.5]	HLDHC	Scheduled
	●	No	Scheduled		11:00 AM	Est Patient	Lung nodule Follow up after testing Add on per Paula	THORHL	Scheduled
	●	No	Scheduled		11:20 AM	Con Patient	Malignant neoplasm of mediastinum (HCC) [C38.3] Mediastinal mass [J98.59] New Con w/ Labs,...	THORHL	Scheduled
	●	No	Scheduled		11:40 AM	Est Patient	Follow up	THORHL	Scheduled
	●	No	Scheduled		12:00 PM	Con Patient	Gastroesophageal reflux Barium completed 2/28	THORHL	Scheduled
	●	No	Scheduled		12:20 PM	Con Patient	Neoplasm of lung Personal history of DVT (deep vein thrombosis) CONSULT W/PFTS (PENDING...	THORHL	Scheduled
	●	No	Scheduled		12:40 PM	Provider Specialty Phone Call	Phone call Lung nodule	THORHL	Scheduled
	●	No	Scheduled		1:00 PM	Con Patient	Esophageal Mass H&P need for EUS per phone enc	THORHL	Scheduled
	●	No	Scheduled		1:20 PM	Provider Specialty Phone Call	Phone visit Review imaging	THORHL	Scheduled
	●	No	Scheduled		1:30 PM	Provider Specialty Phone Call	phone visit Lung nodule OK'D PER REBECCA	THORHL	Scheduled
	●	No	Scheduled		1:40 PM	Video Spec Est	Diaphragmatic hernia without obstruction and without gangrene Follow up Testing done locally	THORHL	Scheduled

		Pr...	En...	Status	Status Det...	Time	Proc/Visit Type	Notes	Department	Sched Status
			No	Scheduled	OR69	12:00 AM	ESOPHAGECTOMY W/ PHARYNGOGASTROSTOMY...		CTH	Scheduled
			No	Scheduled		8:20 AM	Con Patient	Encounter for other preprocedural examination [Z01.818...	THORMN	Scheduled
			No	Scheduled		9:00 AM	Con Patient	Reflux Consult no test Add per Rebecca's tele GPS Rep...	THORMN	Scheduled
			No	Scheduled		9:40 AM	Con Patient	Lung nodule Consult per Rebecca	THORMN	Scheduled
			No	Scheduled		10:00 AM	Con Patient	Lung nodules CONSULT/PRE OP W/PFTS ADD PER R...	THORMN	Scheduled
			No	Scheduled		10:20 AM	Est Patient	Post-thoracotomy pain Follow up	THORMN	Scheduled
			No	Scheduled		10:40 AM	Con Patient	Mucor post COVID mucormycosis Consult per Rebecca	THORMN	Scheduled
			No	Scheduled		11:00 AM	Pre Op	robotic assisted esophagectomy or 3/22/2023	THORMN	Scheduled
			No	Scheduled		11:20 AM	Con Patient	Achalasia and cardiospasm [K22.0] New Con w/ PFTs p...	THORMN	Scheduled
			No	Scheduled		11:40 AM	Con Patient	Airway malacia Consult per Rebecca	THORMN	Scheduled
			No	Scheduled		12:00 PM	Con Patient	Lung Nodule per phone enc date requested	THORMN	Scheduled
			No	Scheduled		12:20 PM	Con Patient	Encounter for other preprocedural examination Broncho...	THORMN	Scheduled
			No	Scheduled		12:40 PM	Con Patient	Malignant neoplasm of esophagus, unspecified location...	THORMN	Scheduled
			No	Scheduled		1:00 PM	Con Patient	Hiatal Hernia, GERD	THORMN	Scheduled
			No	Scheduled		1:20 PM	Pre Op	robotic assisted resection of ectopic parathyroid	THORMN	Scheduled
			No	Scheduled		1:20 PM	Est Patient	Lung Nodule Note.. triaging pet scan date requested	THORMN	Scheduled
			No	Scheduled		1:30 PM	Pre Op	robotic assisted right lung resection or 3/20/2023	THORMN	Scheduled
			No	Scheduled		1:40 PM	Con Patient	LVRS per Rebecca's phone enc date requested	THORMN	Scheduled
			No	Scheduled		2:00 PM	Pre Op	egd in the OR OR 3/17/2023	THORMN	Scheduled
			No	Scheduled		2:20 PM	Con Patient	Mass, chest [R22.2]	THORMN	Scheduled
			No	Scheduled		2:40 PM	Est Patient	Post induction follow-up after testing. Note..triaging echo...	THORMN	Scheduled
			No	Scheduled		3:00 PM	Pre Op	Robotic Assisted Esophagectomy OR 3/21/2023	THORMN	Scheduled
			No	Scheduled		3:20 PM	Con Patient	Multiple lung nodules per phone enc	THORMN	Scheduled
			No	Scheduled		3:40 PM	Con Patient	Mediastinal mass CONSULT W/PFTS PER REBECCA'...	THORMN	Scheduled

	Pr...	En...	Status	Status Det...	Time	Proc/Visit Type	Notes	Department	Sched Status
	No		Scheduled	OR69	12:00 AM	ESOPHAGECTOMY W/ PHARYNGOGASTROSTOMY...		CTH	Scheduled
	No		Scheduled		8:20 AM	Con Patient	Encounter for other preprocedural examination [Z01.818...	THORMN	Scheduled
	No		Scheduled		9:00 AM	Con Patient	Reflux Consult no test Add per Rebecca's tele GPS Rep...	THORMN	Scheduled
	No		Scheduled		9:40 AM	Con Patient	Lung nodule Consult per Rebecca	THORMN	Scheduled
	No		Scheduled		10:00 AM	Con Patient	Lung nodules CONSULT/PRE OP W/PFTS ADD PER R...	THORMN	Scheduled
	No		Scheduled		10:20 AM	Est Patient	Post-thoracotomy pain Follow up	THORMN	Scheduled
	No		Scheduled		10:40 AM	Con Patient	Mucor post COVID mucormycosis Consult per Rebecca	THORMN	Scheduled
	No		Scheduled		11:00 AM	Pre Op	robotic assisted esophagectomy or 3/22/2023	THORMN	Scheduled
	No		Scheduled		11:20 AM	Con Patient	Achalasia and cardiospasm [K22.0] New Con w/ PFTs p...	THORMN	Scheduled
	No		Scheduled		11:40 AM	Con Patient	Airway malacia Consult per Rebecca	THORMN	Scheduled
	No		Scheduled		12:00 PM	Con Patient	Lung Nodule per phone enc date requested	THORMN	Scheduled
	No		Scheduled		12:20 PM	Con Patient	Encounter for other preprocedural examination Broncho...	THORMN	Scheduled
	No		Scheduled		12:40 PM	Con Patient	Malignant neoplasm of esophagus, unspecified location...	THORMN	Scheduled
	No		Scheduled		1:00 PM	Con Patient	Hiatal Hernia, GERD	THORMN	Scheduled
	No		Scheduled		1:20 PM	Pre Op	robotic assisted resection of ectopic parathyroid	THORMN	Scheduled
	No		Scheduled		1:20 PM	Est Patient	Lung Nodule Note.. triaging pet scan date requested	THORMN	Scheduled
	No		Scheduled		1:30 PM	Pre Op	robotic assisted right lung resection or 3/20/2023	THORMN	Scheduled
	No		Scheduled		1:40 PM	Con Patient	LVRs per Rebecca's phone enc date requested	THORMN	Scheduled
	No		Scheduled		2:00 PM	Pre Op	egd in the OR OR 3/17/2023	THORMN	Scheduled
	No		Scheduled		2:20 PM	Con Patient	Mass, chest [R22.2]	THORMN	Scheduled
	No		Scheduled		2:40 PM	Est Patient	Post induction follow-up after testing. Note..triaging echo...	THORMN	Scheduled
	No		Scheduled		3:00 PM	Pre Op	Robotic Assisted Esophagectomy OR 3/21/2023	THORMN	Scheduled
	No		Scheduled		3:20 PM	Con Patient	Multiple lung nodules per phone enc	THORMN	Scheduled
	No		Scheduled		3:40 PM	Con Patient	Mediastinal mass CONSULT W/PFTS PER REBECCA'...	THORMN	Scheduled
	No		Scheduled		4:00 PM	Con Patient	RUL lung cancer Consult per Scott	THORMN	Scheduled
	No		Scheduled		4:20 PM	Est Patient	CHRONIC AIRWAY OBSTRUCTION Emphysematous b...	THORMN	Scheduled

As a Surgeon

- 500+ LTx
- 1500+ Anatomic Lung Rx
- 400+ Esophagectomy
- 100+ Tracheal Resections
- 50+ residents
- >10,000 operations **with** residents





About your score





About your score

Raymond/Raja













Molar right upper (M1), 7/19/2021 3:42:11 PM, 8-bit grayscale







Molar right upper (M1), 7/19/2021 3:42:11 PM, 8-bit grayscale







The Ask

- **What Have I learned Given All the Miles on my Tires**
 - **How have I adapted to changing conditions**
 - **What Worked?**
 - **What Failed?**

The Ask

- What Have I learned Given All the Miles on my Tires
 - How have I adapted to changing conditions
 - What Worked
 - What Failed
- What has Changed that Forced me to Change?

What Has Changed?

- Disease Presentations?
 - More Stage I NSCLCa
 - More Resectable Stage IIIa
 - More Induction Esoph Ca
 - Increase in complication management
 - NO BARRETT's Operations

What Has Changed?

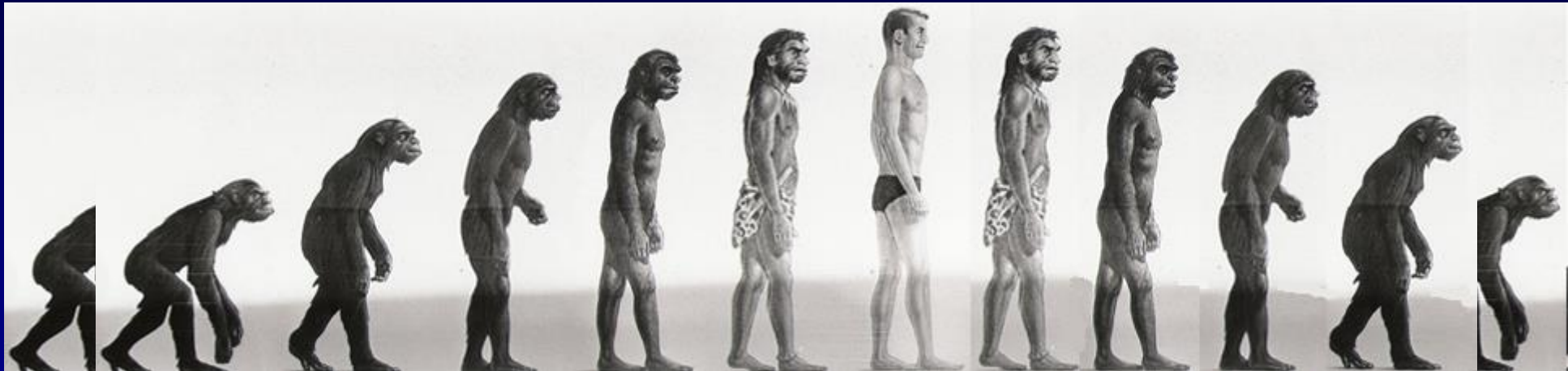
- **Third Space Endoscopy**
- **Dissemination of Minimally invasive ops**
- **ImmunoTx**
- **Robotics**
- **Patient Reported outcomes**
- **Resident Education**
- **Work Force Inequity**

What Has Changed?

- Third Space Endoscopy
- Dissemination of Minimally invasive ops
- ImmunoTx
- Robotics
- Patient Reported outcomes
- Resident Education
- Work Force Inequity
- **JUST TO LIST A FEW!!!**

How Do you Keep Current?

What Happens as You Age



Health/Life

- Ran 10K races
 - Ran the Treadmill
 - Elliptical
 - Spin Bike
 - Rower
 - Recumbent Cyclers

What Happens as You ~~Age~~ Mature as a Surgeon?

What Happens as You ~~Age~~ Mature as a Surgeon?

- **Barring Unforeseen Circumstances**
 - **You generally Get Better**
 - **Knowledge of Surgical Anatomy**
 - **Knowledge of Diseases**
 - **Judgment**

What Happens as You ~~Age~~ Mature as a Surgeon?

- Barring Unforeseen Circumstances
 - You generally Get Better
 - Knowledge of Surgical Anatomy
 - Knowledge of Diseases
 - Judgment
- **Vastly Improved Efficiency**

Improved Efficiency

- Far Less Surgical Anxiety
- Far Greater Intellectually Curiosity
- Far More Time to Learn New Things

Improved Efficiency

- Far Less Surgical Anxiety
- Far Greater Intellectually Curiosity
- Far More Time to Learn New Things
- **Job Satisfaction!!!**

Job Satisfaction

- **Reduced WORK-LIFE Imbalance**

Job Satisfaction

- Reduced ~~WORK-LIFE~~ Imbalance

Job Satisfaction

- Reduced **LIFE** Imbalance

Job Satisfaction

- Reduced **LIFE** Imbalance
- **MENTORING**
 - Faculty
 - Residents
 - Medical Students
- Innovation

Job Satisfaction

- Reduced **LIFE** Imbalance
- **MENTORING/SPONSORING**
 - Faculty
 - Residents
 - Medical Students
- Innovation

Introducing New Tech into the Practice

- **Top Down Dissemination**
- **Most Senior Surgeons are Stewards**
 - **Robotics**
 - **Third Space Endoscopy**
 - **Cadaveric Bone/Titanium Reconstruction**
 - **V-V ECMO**

At The End of the Day

- Improved Safety
- Improved Efficacy
- Improved Satisfaction
- PATIENTS FIRST

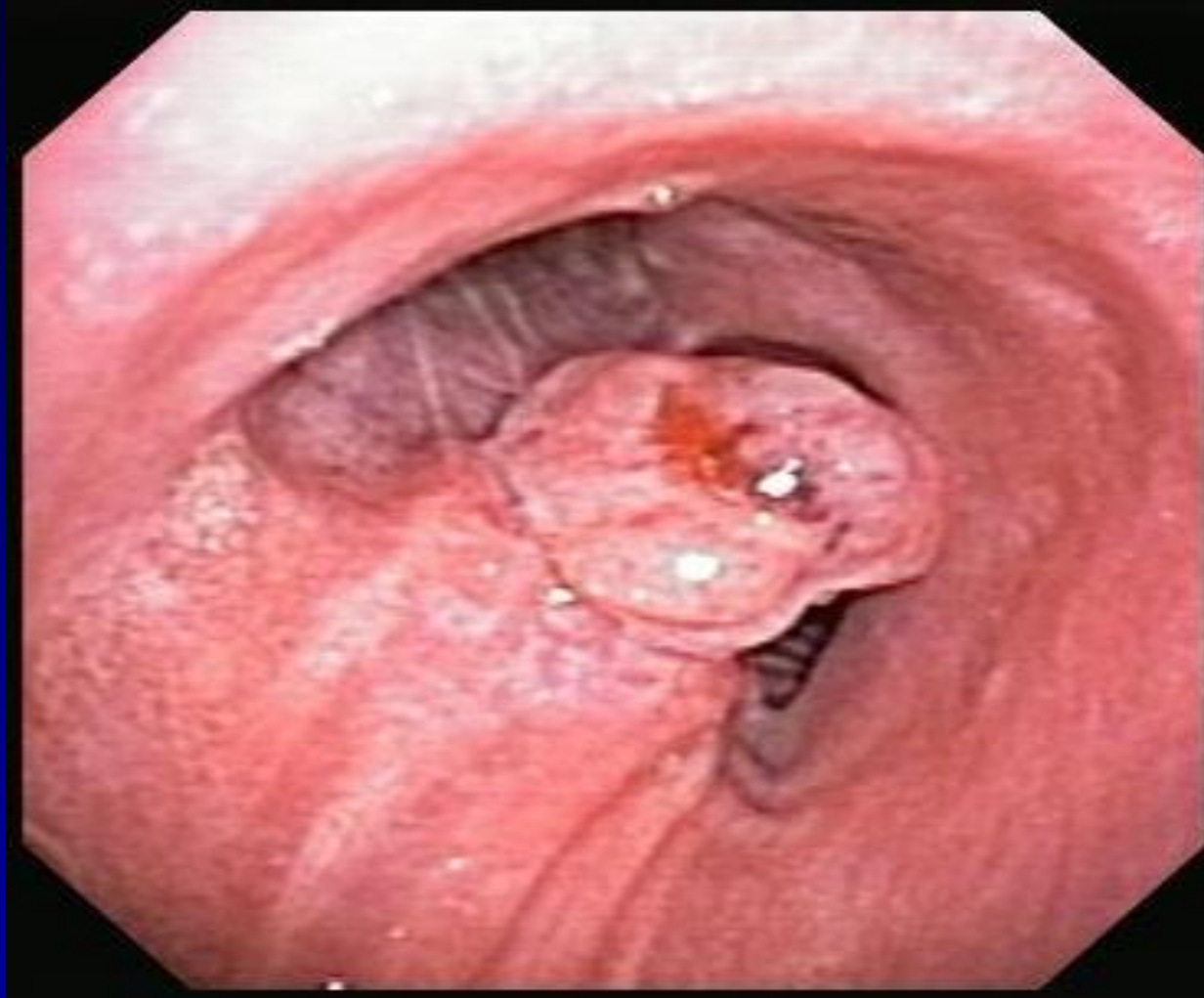
Case

- 57-year-old man
- For 3 months
 - Dyspnea
 - Hoarseness
 - Intermittent hemoptysis
- Past medical history
 - 80 pack-years of tobacco use
 - Mild pulmonary obstruction

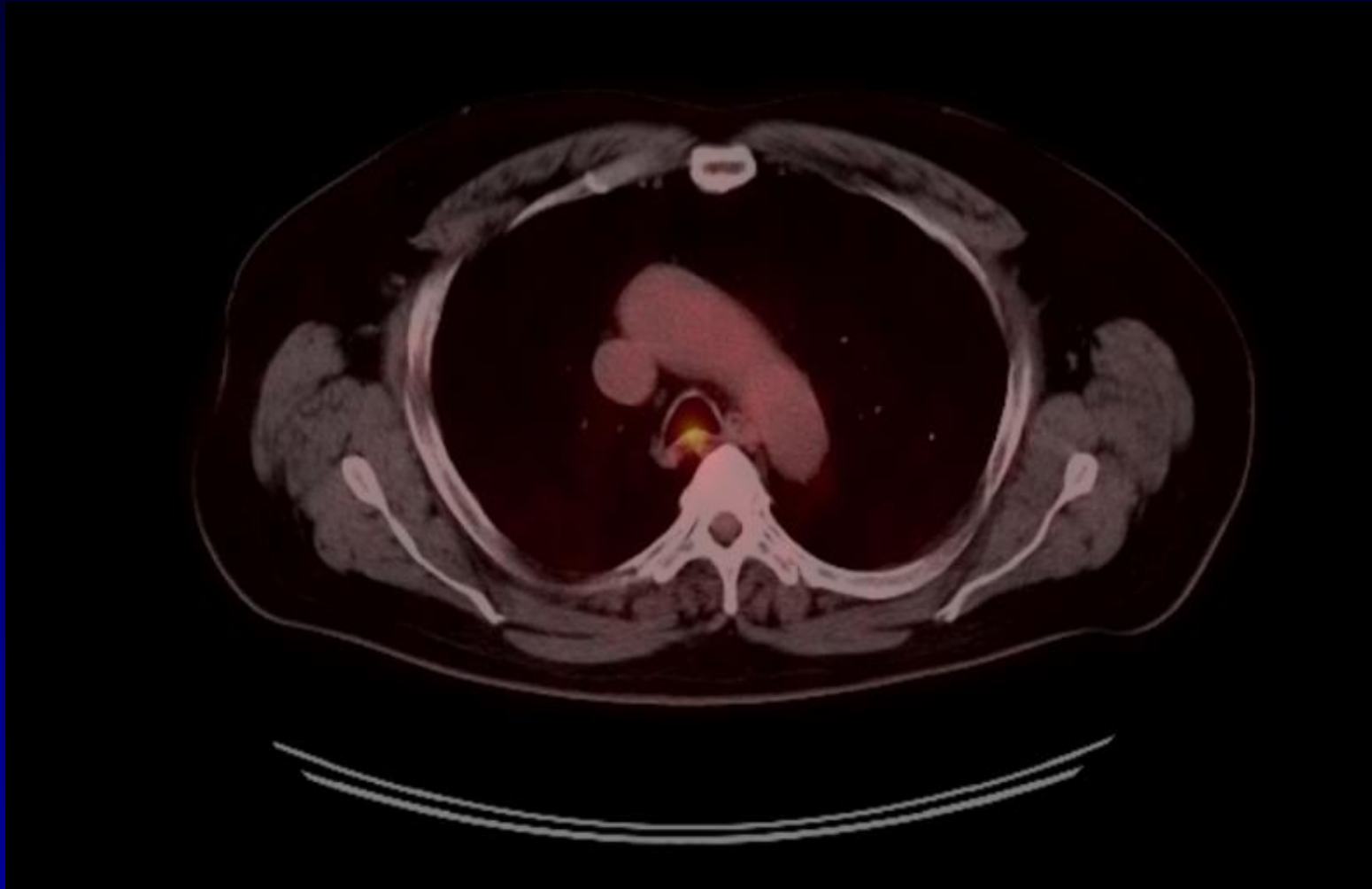
Preoperative Work-up

- **Diagnostic bronchoscopy**
- **PET – CT scan**
- **Therapeutic bronchoscopy**

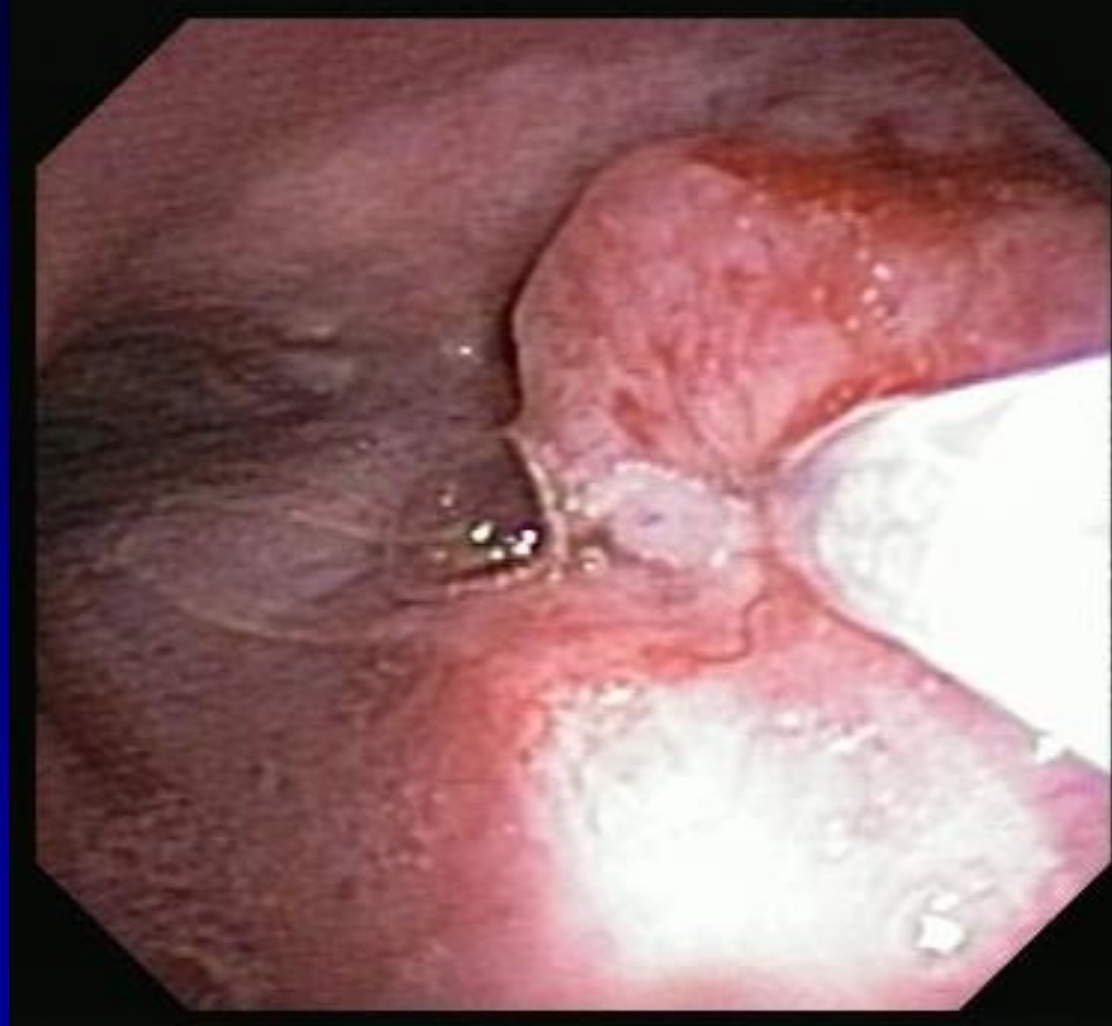
Diagnostic Bronchoscopy



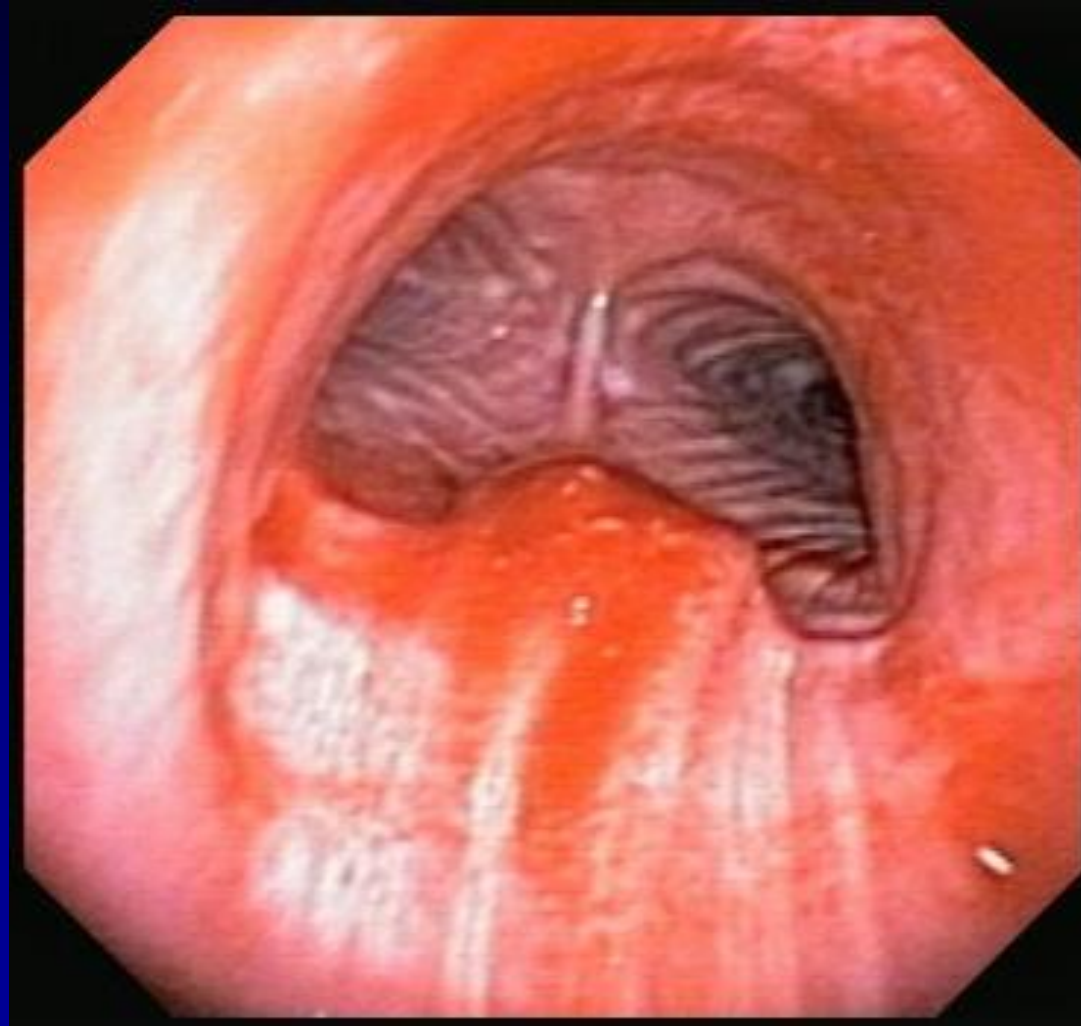
PET – CT

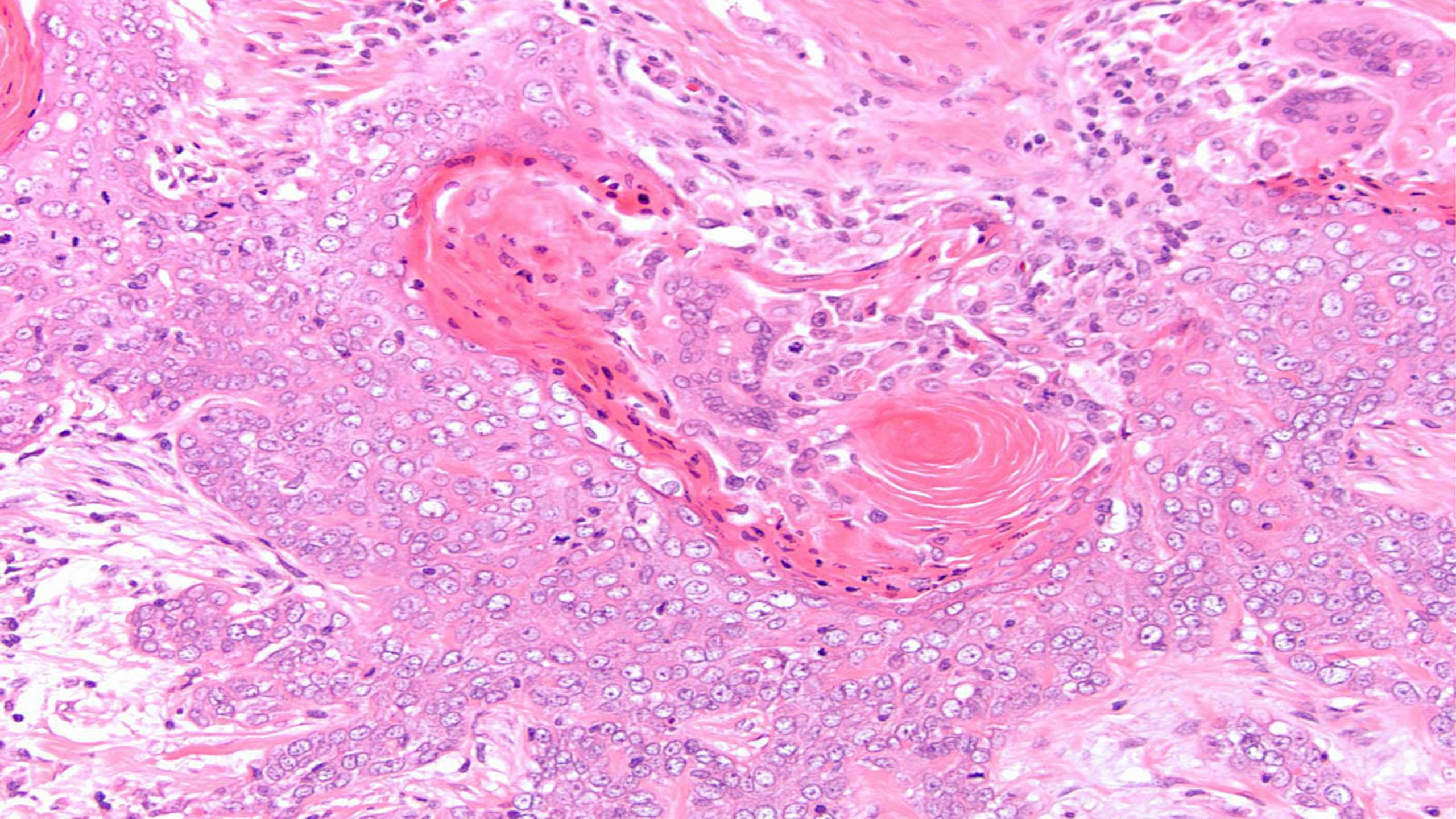


Therapeutic Bronchoscopy



Therapeutic Bronchoscopy

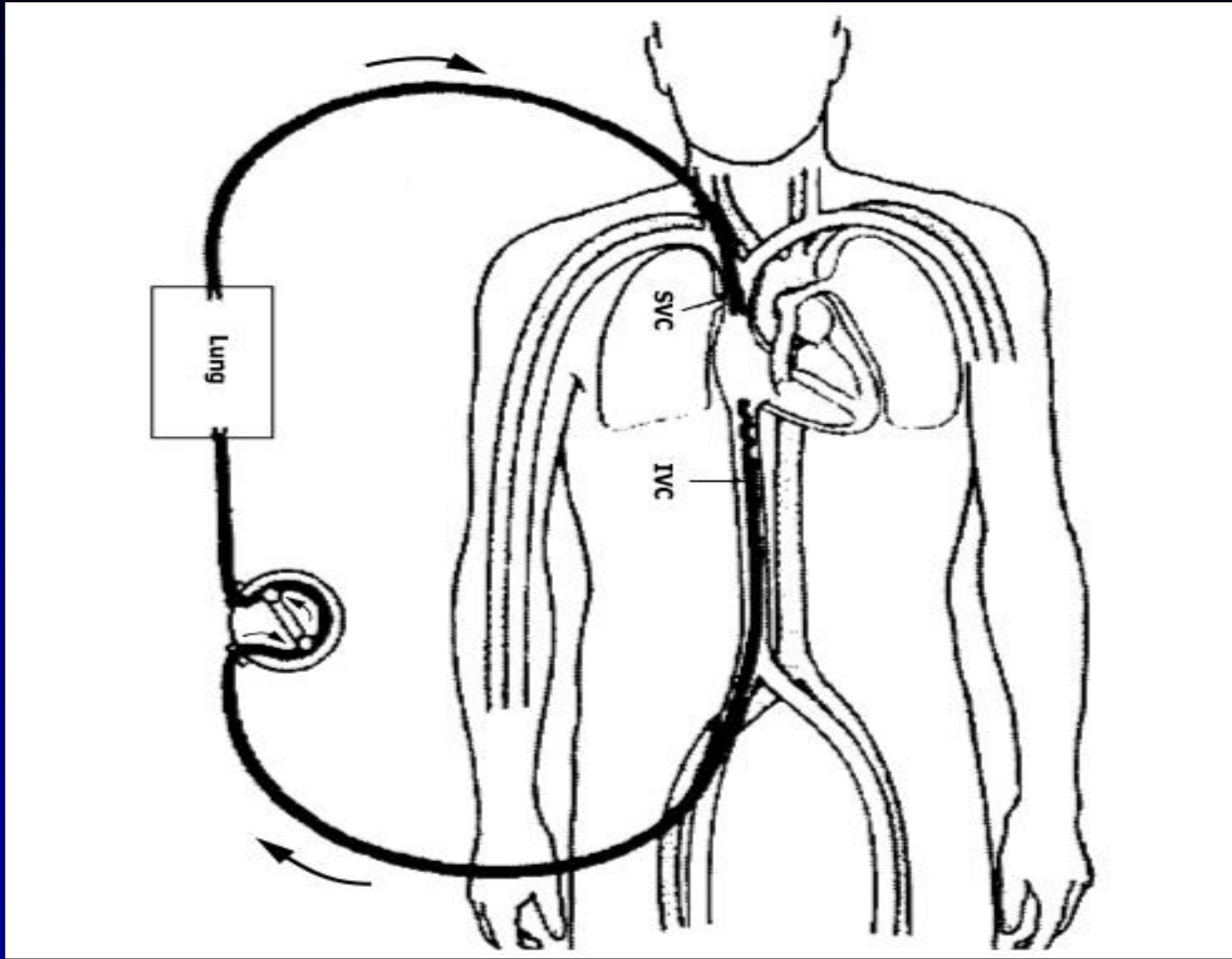


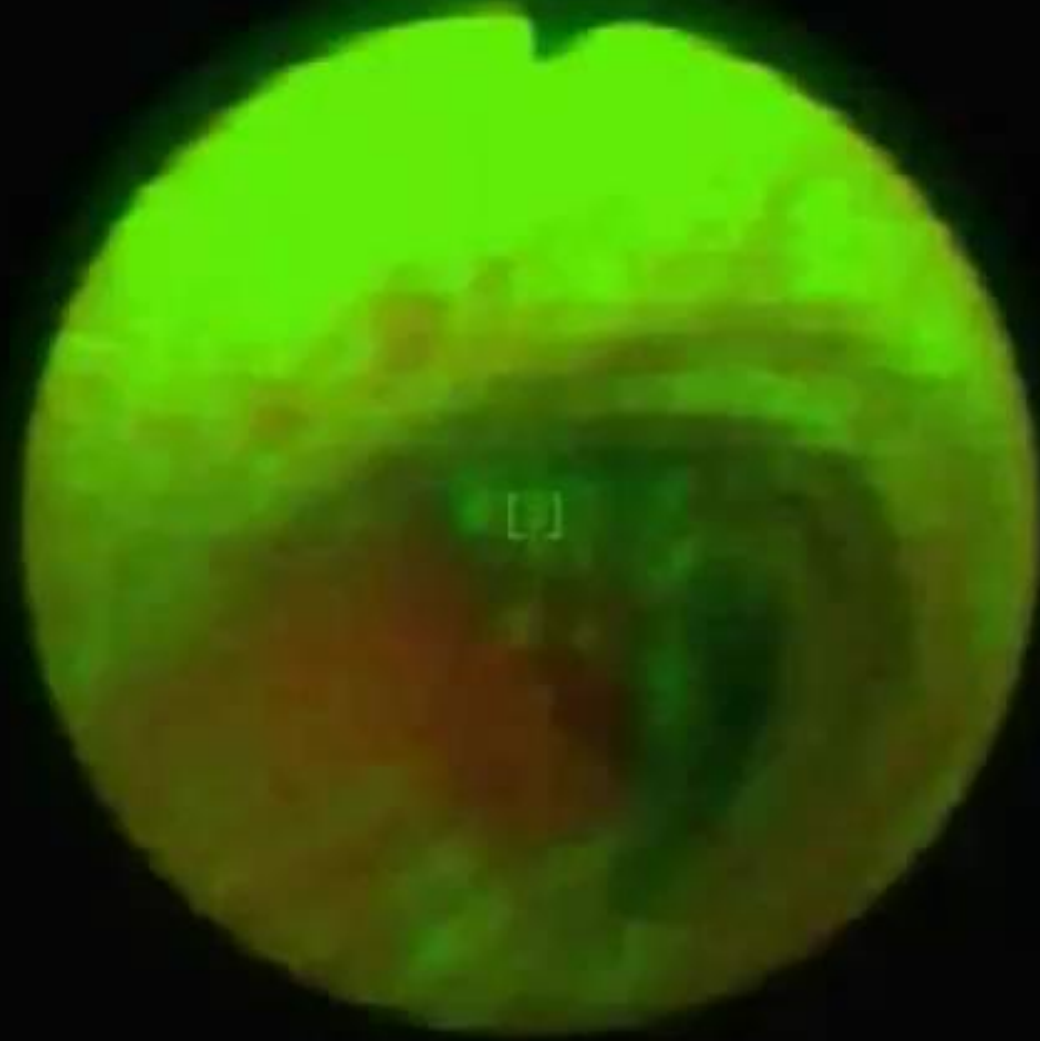


Operative Plan

- **Autofluorescence bronchoscopy**
- **Mediastinoscopy**
- **Veno-venous ECMO (18Fr-in, 24Fr-out)**
- **Right thoracotomy approach**

Veno-Venous ECMO Circuit





Postoperative Course

- **5-day hospital stay**
- **Negative margins**

Starting Point (2012)

- ONE ROOM
- ONE DAY
- PER MONTH
- 6500+ cases into my practice

Mid-Point (2016)

- ONE ROOM
- ONE DAY
- PER WEEK
- 8200 Cases into my Practice
- Added another Junior Robotic Staff (of 4)

2020

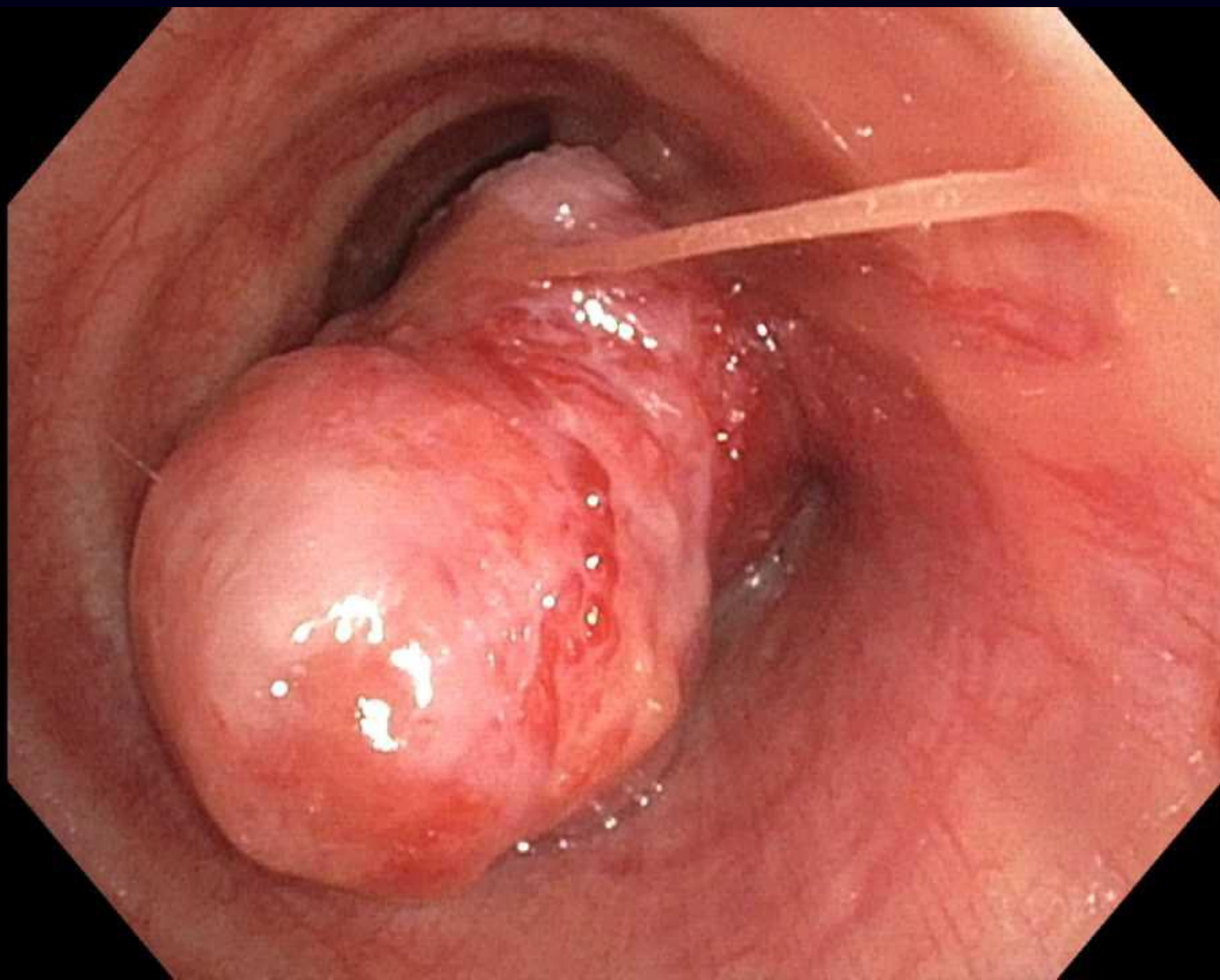
- **ONE ROBOT (One Console)**
- **At ANY TIME***
- **EVERY DAY***
- **10,000 Cases into my practice**
- **THREE EXPERIENCED ROBOTIC SURGEONS (of 7)**

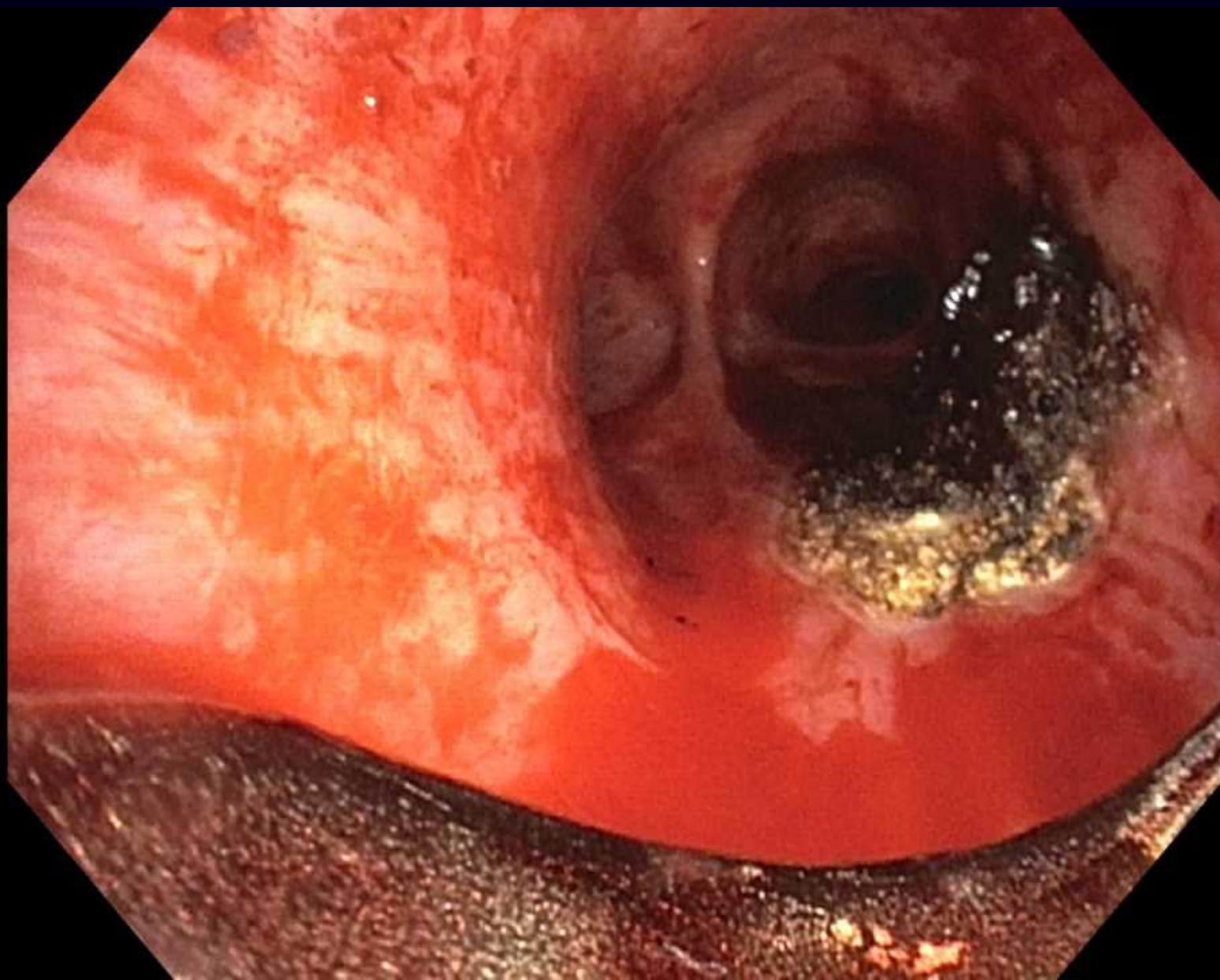
Case

- 28 year-old man
- For 3 months
 - Dyspnea
 - Intermittent hemoptysis
- Past medical history
 - NOTHING

Preoperative Work-up

- **Diagnostic bronchoscopy**
- **CCT scan**
- **Therapeutic bronchoscopy**





Case

- **Mucoepidermoid Tumor (Low Grade)**
- **Completely FIT Young Man**

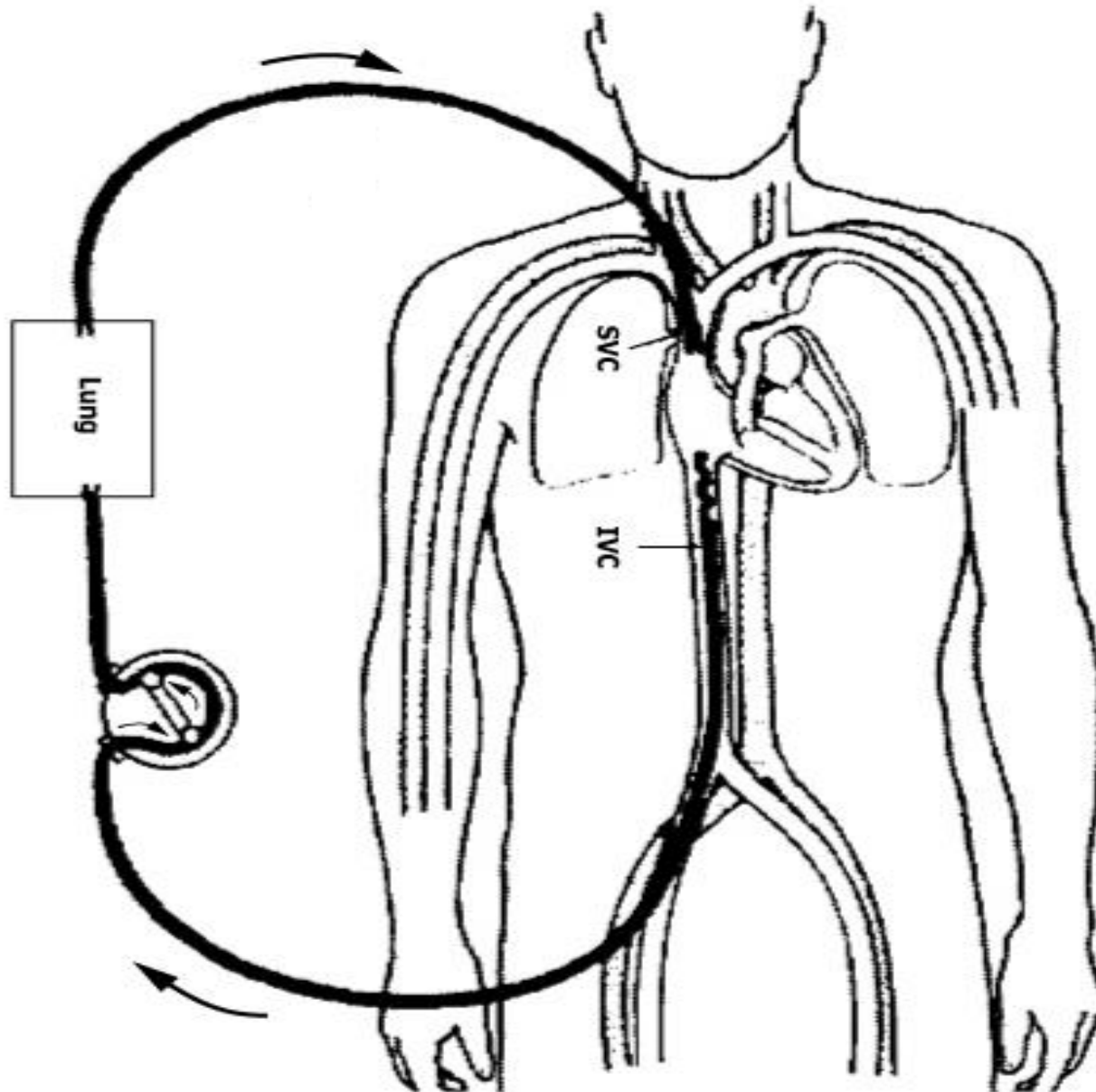
Operative Plan

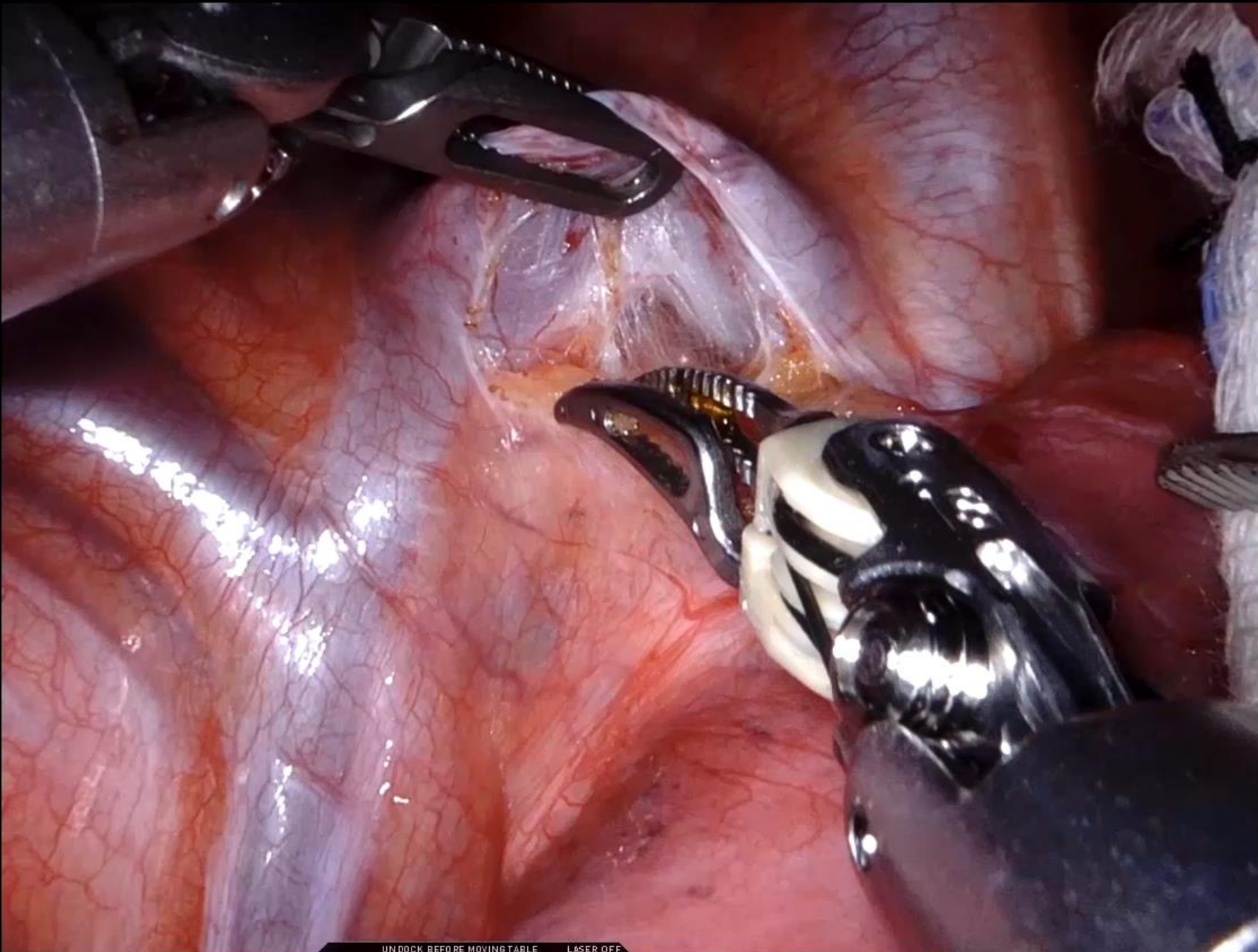
- **Flexible Bronchoscopy**
- **Mediastinoscopy**
- **Veno-venous ECMO**
 - **Right IJ (18 Fr In-flow)**
 - **Right Femoral Vein (24 Fr Out-Flow)**

Operative Plan

- Flexible Bronchoscopy
- Mediastinoscopy
- Veno-venous ECMO
 - Right IJ (18 Fr In-flow)
 - Right Femoral Vein 24 Fr Out-Flow)
- Right Robotic Distal Tracheal Resection/Reconstruction?

Veno-Venous ECMO Circuit





L

1

CADIERE FORCEPS

UNDOCK BEFORE MOVING TABLE

LASER OFF

2

1x 30°

L

3

R

MARYLAND BIPOLAR FORCEPS

COAG

4

TIP-UP FENESTRATED GRASPER

Postoperative Course

- **Unremarkable Course.**
 - **ECMO decannulated in the OR, Patient Extubated**
 - **Overnight ICU stay**
- **Negative margins on FINAL PATH**
 - **LN's at Stations 7, 8, 4R, 10R All -ve**
- **3-day hospital stay**
- **Returned to Work in 4 weeks**

If you Like what you are doing...

Change is Easy

Better! Love, Lincoln

Thank you Dr. Munk
for helping me
feel better!
Love, Jackson

Thank you!!!!

you are
amazing!
love maddie

from 11/26
Shank
11/26/88

Thank you Dr. Mendel

Thank you.
 Dr. Mumbly for seeing
 the singer on the radio.
 Thank you.

From Cannon

Dear Mr. Thawley
Thank for saving
my friends life.

Dear Dr. Munthly

Thank you for
saving my
life! You are the
best I love Care

Thank you for caring
Dr. Holifield!

Thank you,
Dr. Murthy,

Had

Thank you
for help Dr. Murphy

Thank you Dr. Muehling
for helping Mr. Oma feel
better! Love, Carson

Thank you Dr. Murphy
for helping Ms. Gena
get better!

Thank you for
Mr. Fairfield

Thank
you

Samson

Thank you Dr. Murthy



Difficulties

- **More Difficult to Graduate newer Faculty into the TRULY COMFORTABLE/CONFIDENT Surgeon Status**
 - **Can't put on call every night and less interest in LTx**
 - **This mode of post-grad educations is NOT commensurate with Optimal Life Balance**
 - **Case Immersion is thus at a retarded pace**
 - **Harder To Get the Reps in now**

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- **Cost/Efficiency Issues now Confounding issue**

Incorporating New Technology into Practice

Erin A Gillaspie, MD, MPH, FACS
Assistant Professor of Thoracic Surgery
VUMC



Disclosures

- Advisory board: BMS, Astra Zeneca, Genentech
- Speaker: Intuitive



Disclosures

- I love adventures and trying new things
- Critical to continue challenging ourselves



The Gillaspie 5 Step Approach

- Know the why/Confirm value add
- Communicate plans
- Build the team (find your champion)
- Training and practice make perfect!
- Monitor and measure outcomes

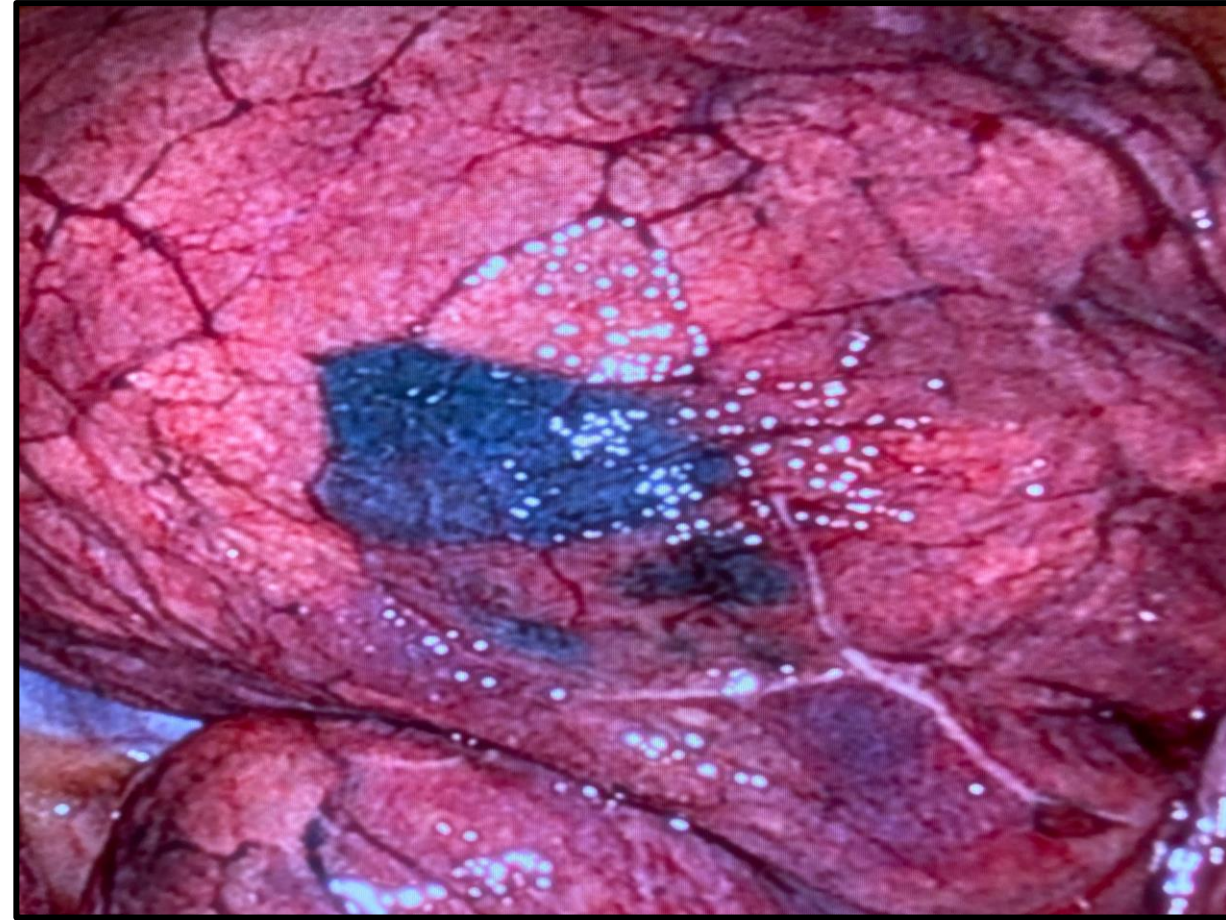


Robotic Ion Program: Biopsy and Localization



Know Your Why

- Enhance sublobar resection program
- Liberalize times technology is available



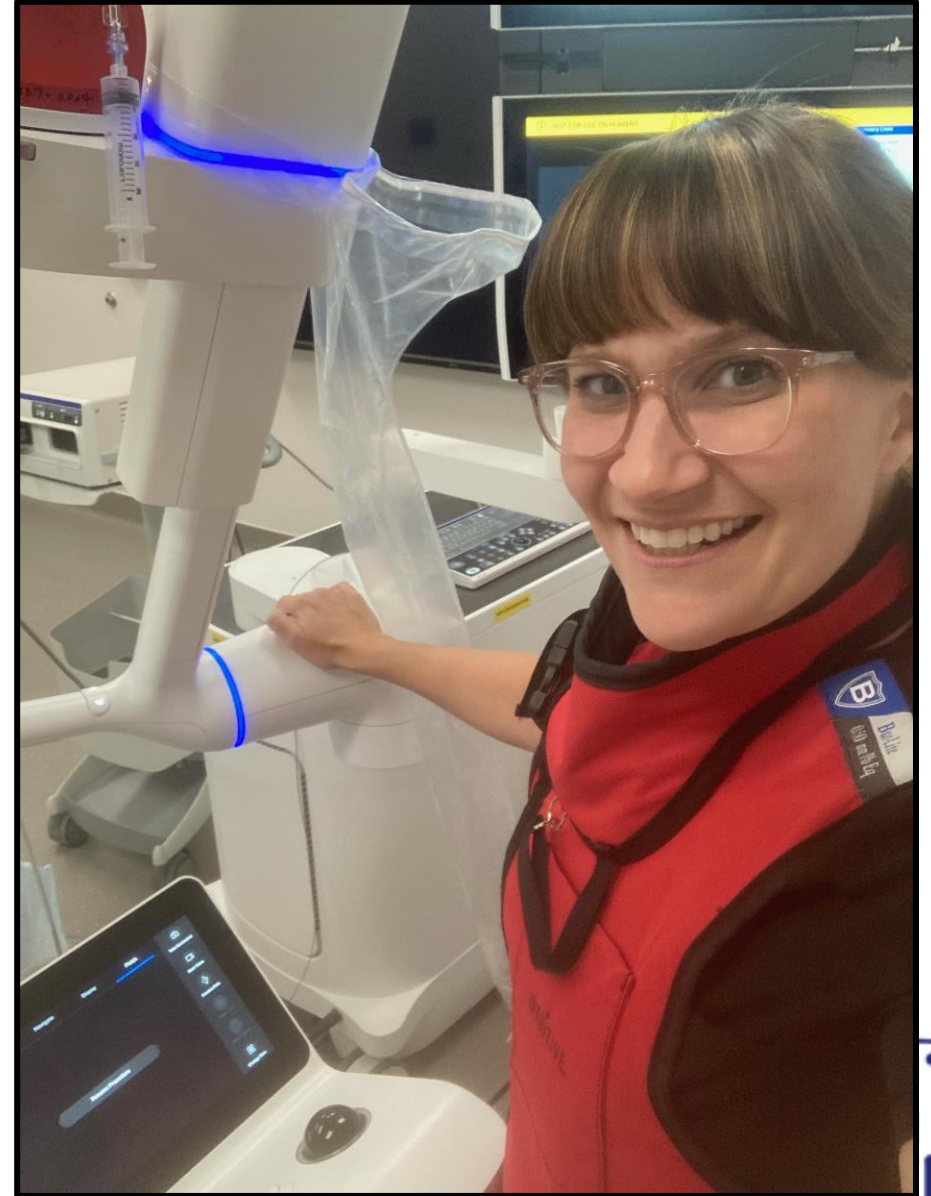
Value of the Procedure

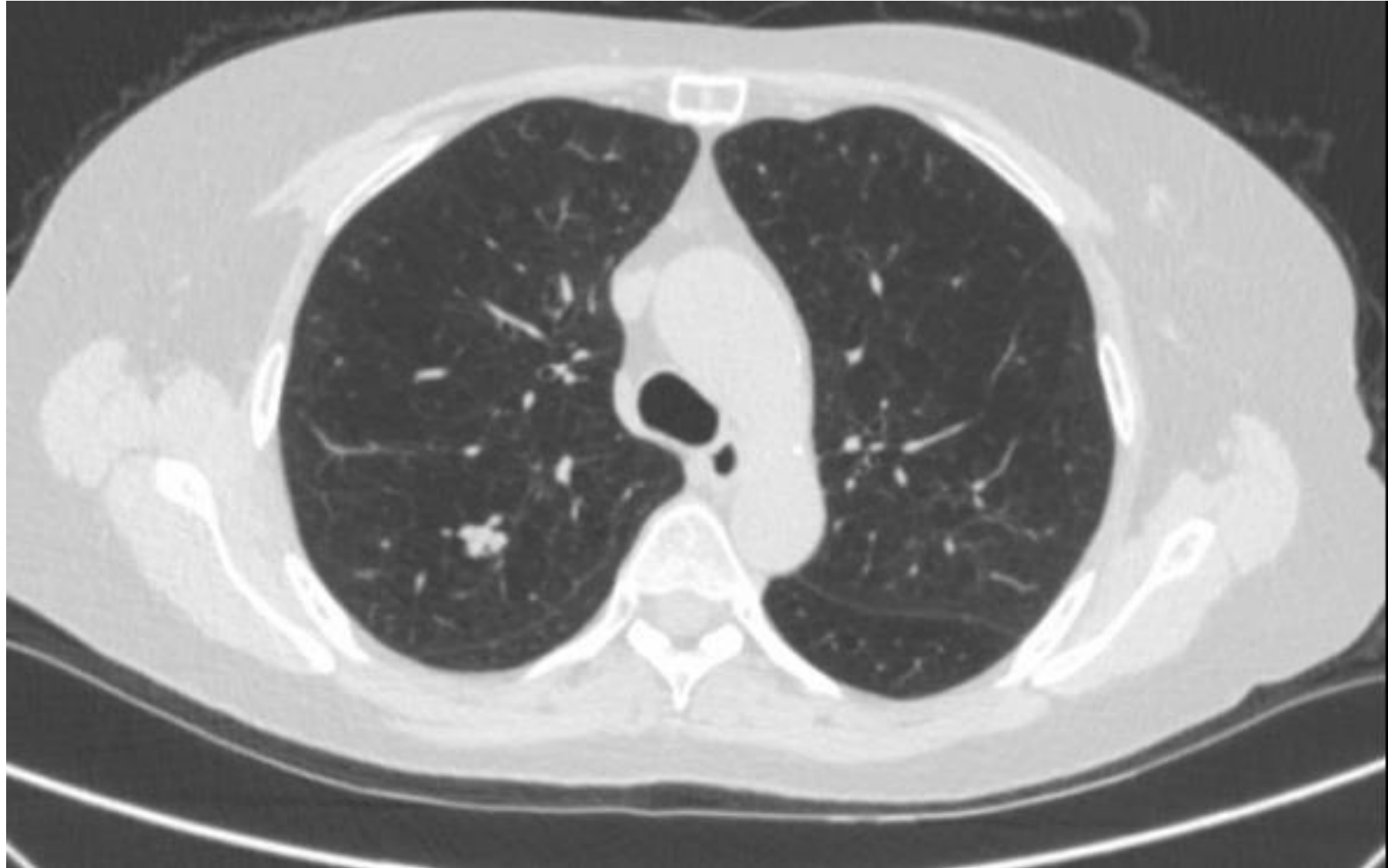
- Value add?
 - Expands a service to more patients
- Added time?
 - Decrease time
- Added cost?
 - Decreased OR time



Don't Skimp on Training

- Orientation to the technology
- In person simulation
 - Take the team along
- Proctoring to reinforce good habits
- Set up cases ahead of time
 - Use the skills or lose the skills!





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NCOR 21
2/7/2023, 1:27:47



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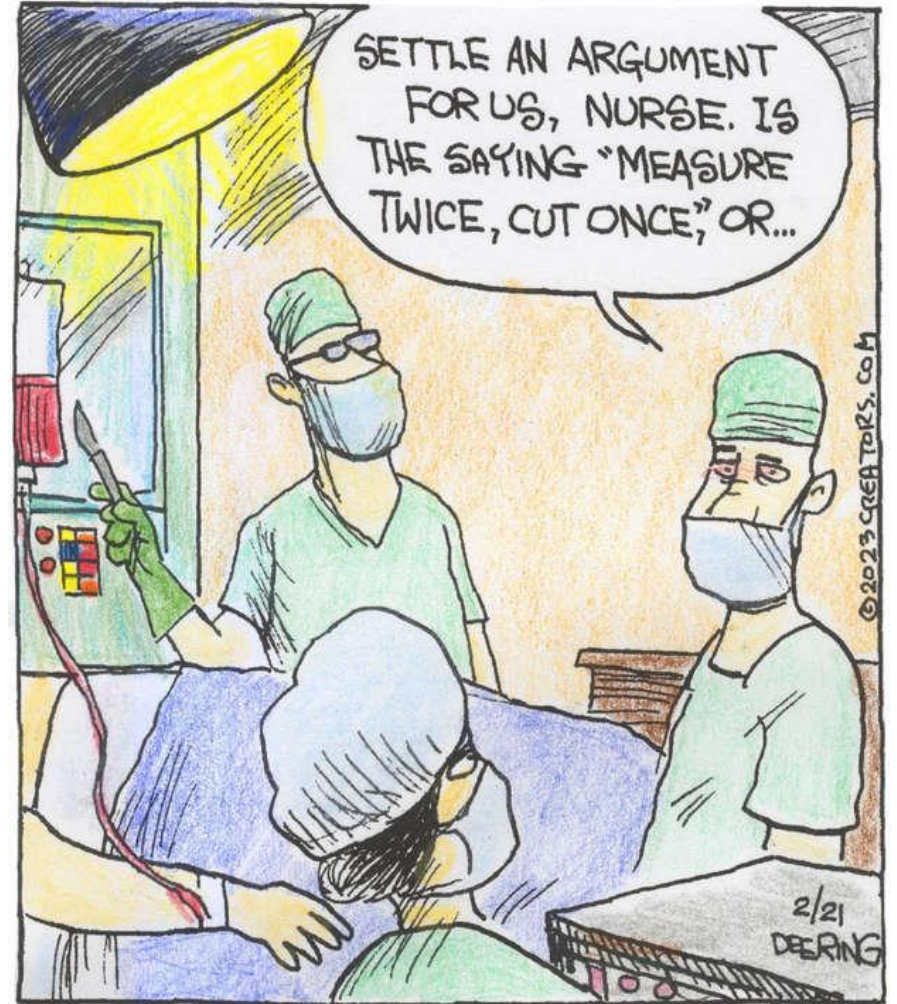
Build the Team

- Communication
- Feasibility/Availability
- Identify a Champion
- Set a time frame to begin



Monitor and Measure

- Measure efficiency
 - Average of 10 minutes
- Patient value
 - Subsolid GGO
- Additional outcomes
 - Teaching



Thank You



Learning RAMIE: A Surgeon's Journey

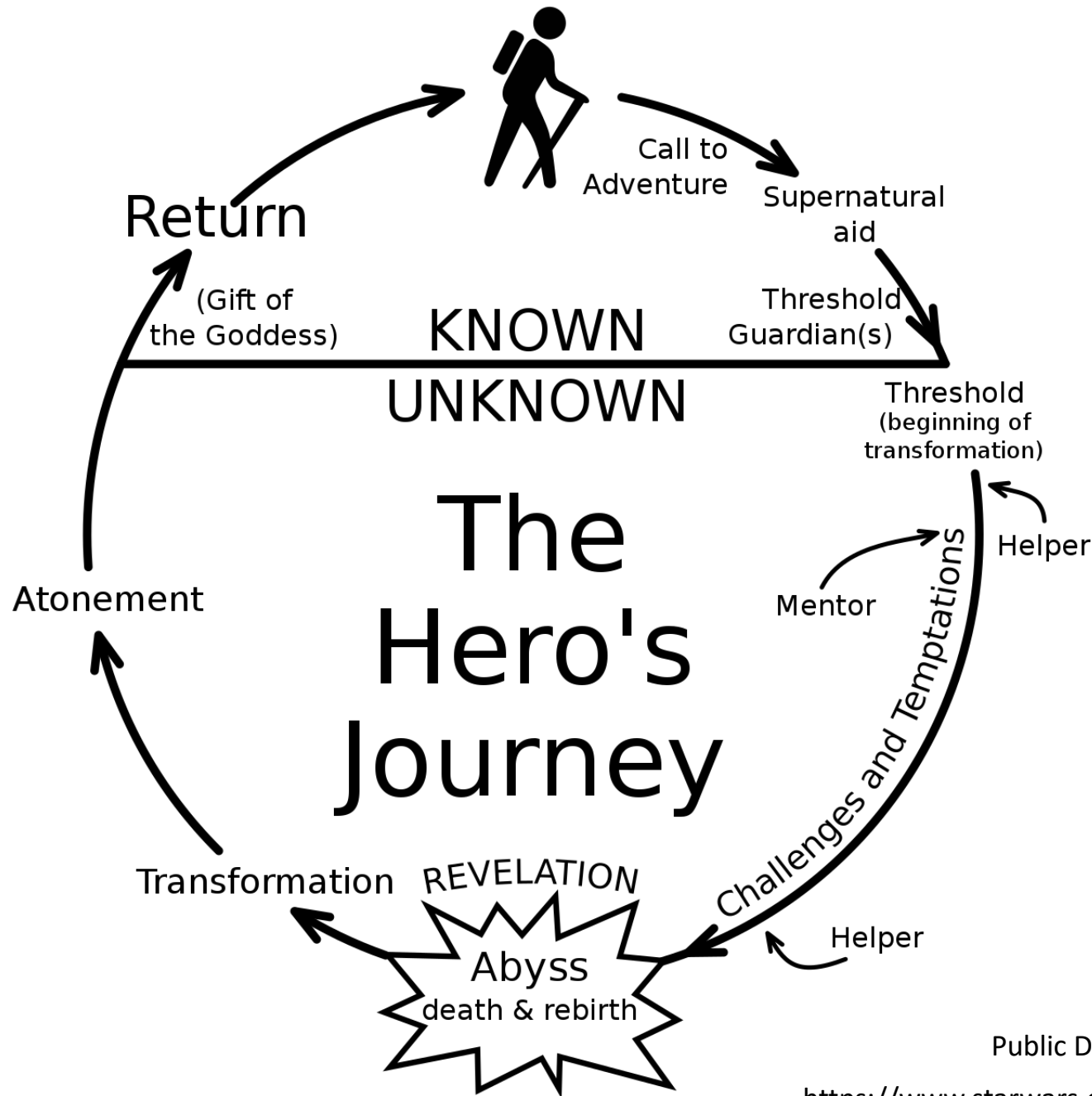
Melanie A. Edwards, MD

Thoracic Surgery Site Medical Director

Trinity IHA Cardiovascular & Thoracic Surgery,
Ypsilanti MI

Disclosures

- Astra Zeneca Advisory Panel

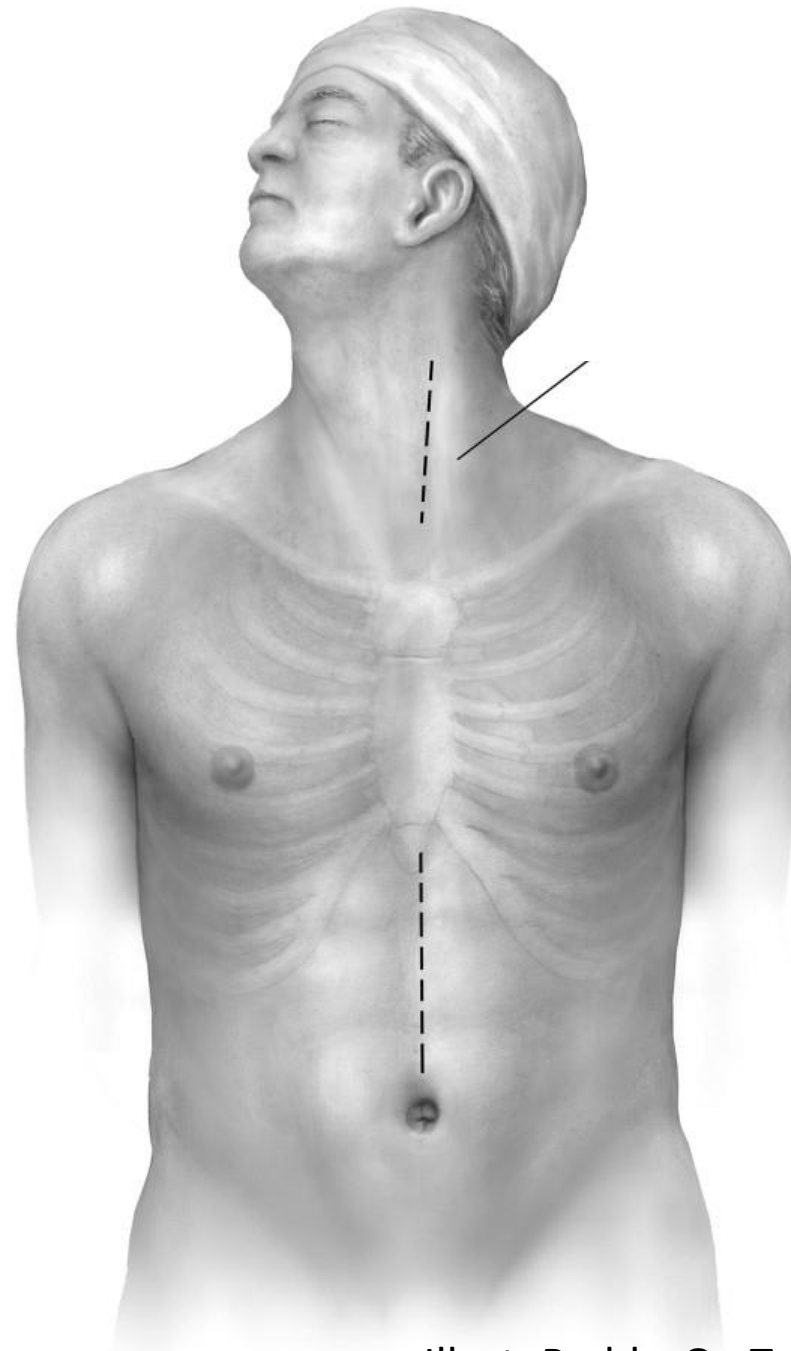


Public Domain, <https://commons.wikimedia.org/w/index.php?curid=10284342>

https://www.starwars.com/databank/luke-skywalker?image_id=5390fdd0a172d315d0004e4

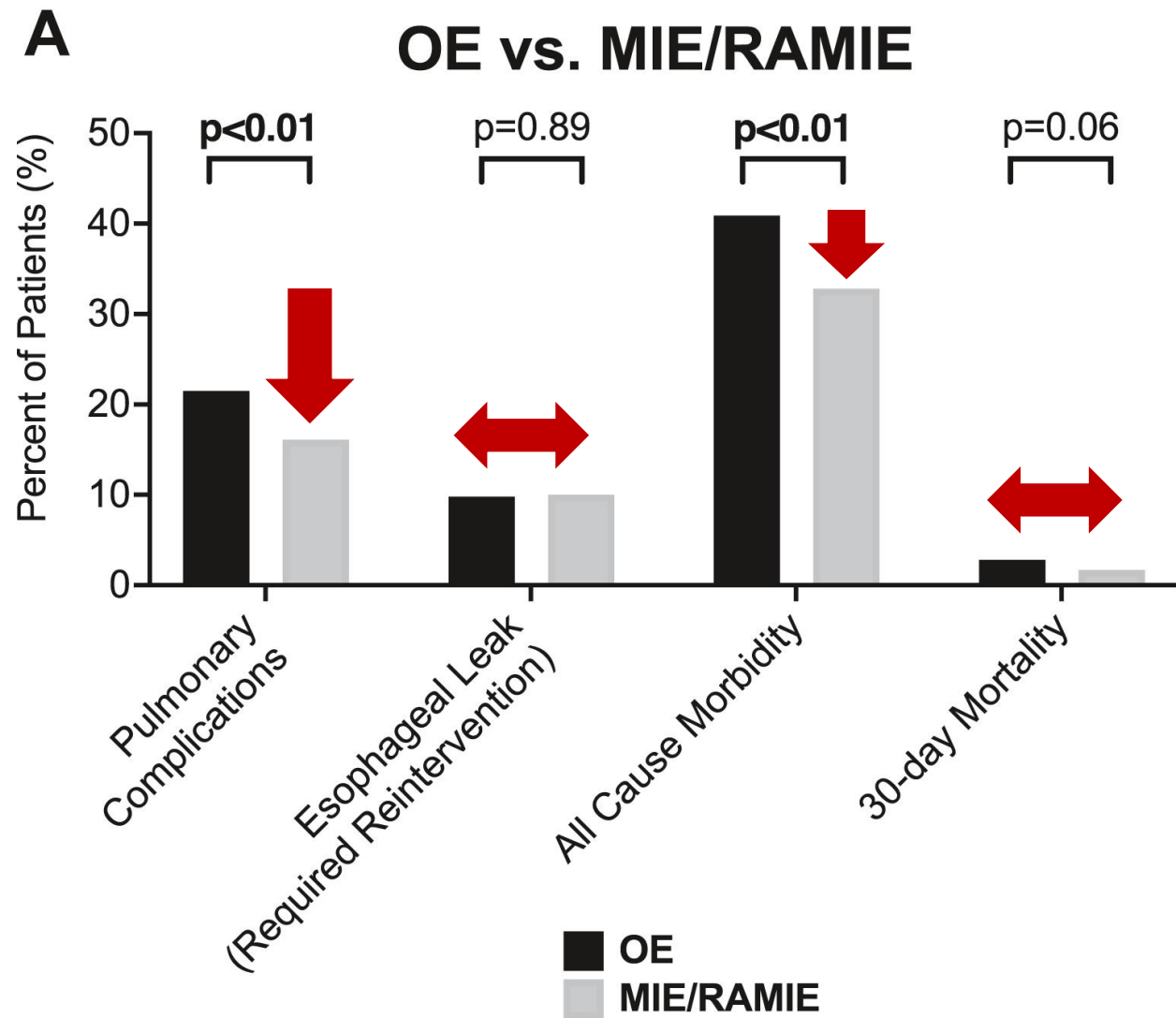


Resistance

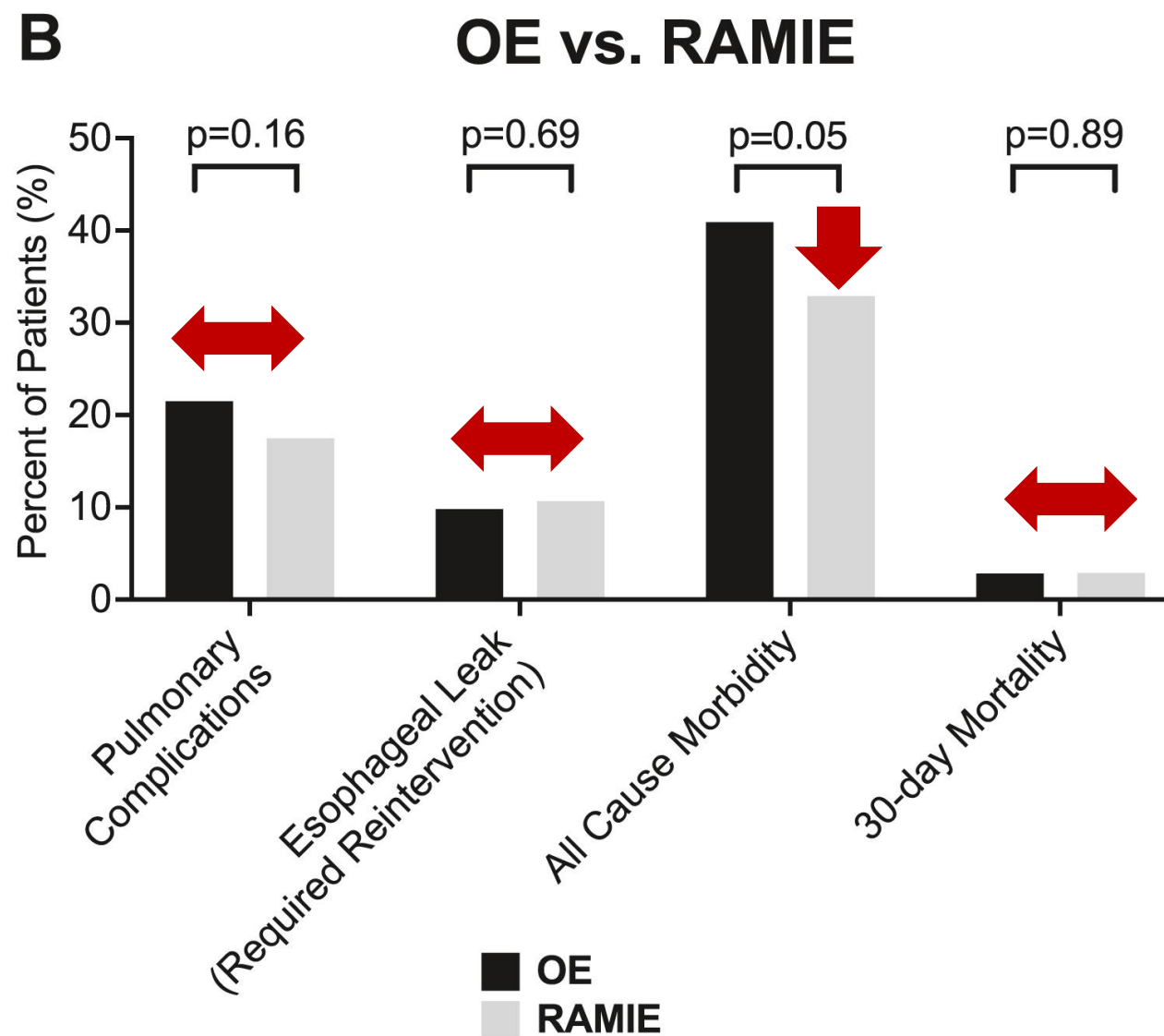


10% leak rate

The Call

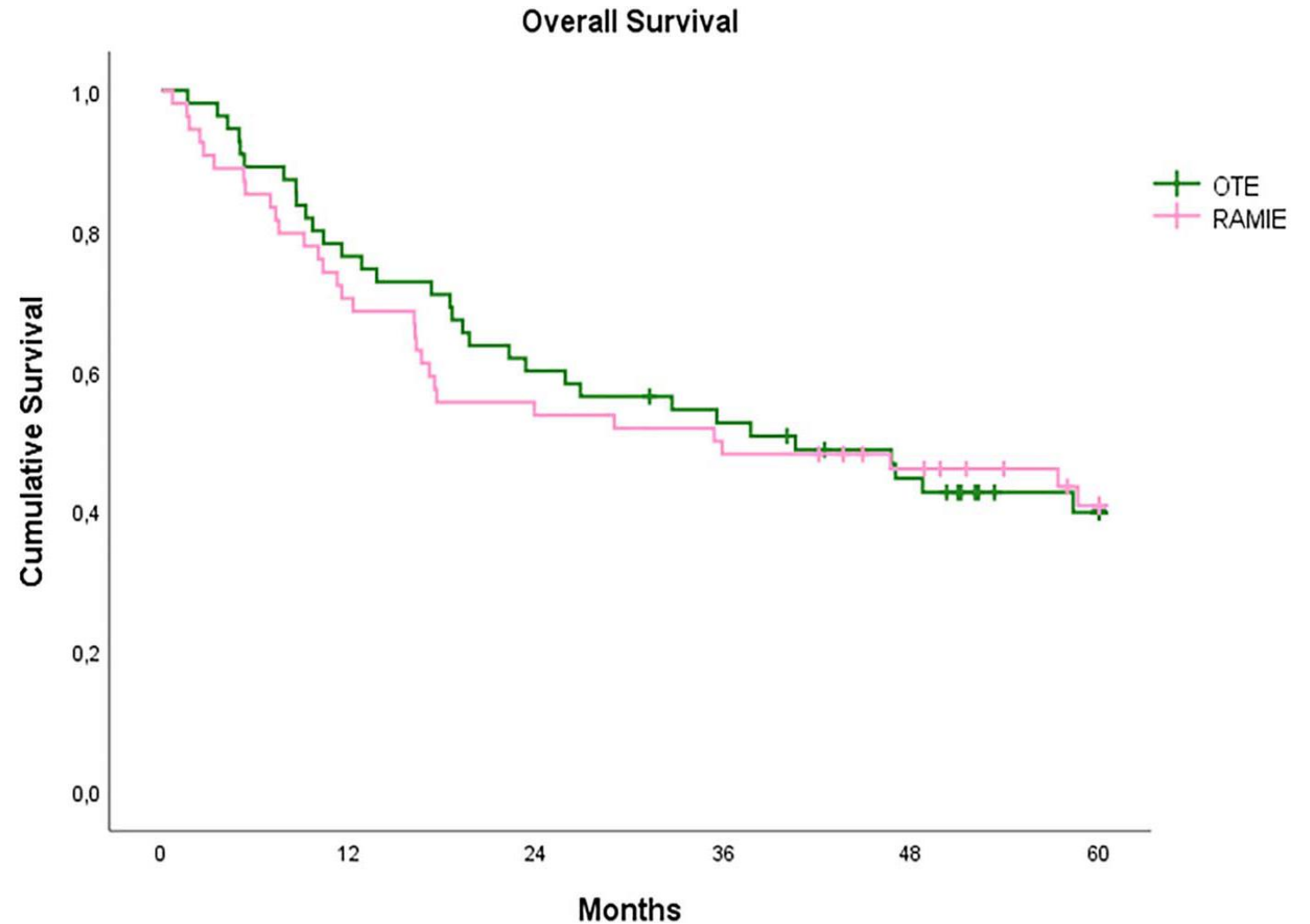


The Call



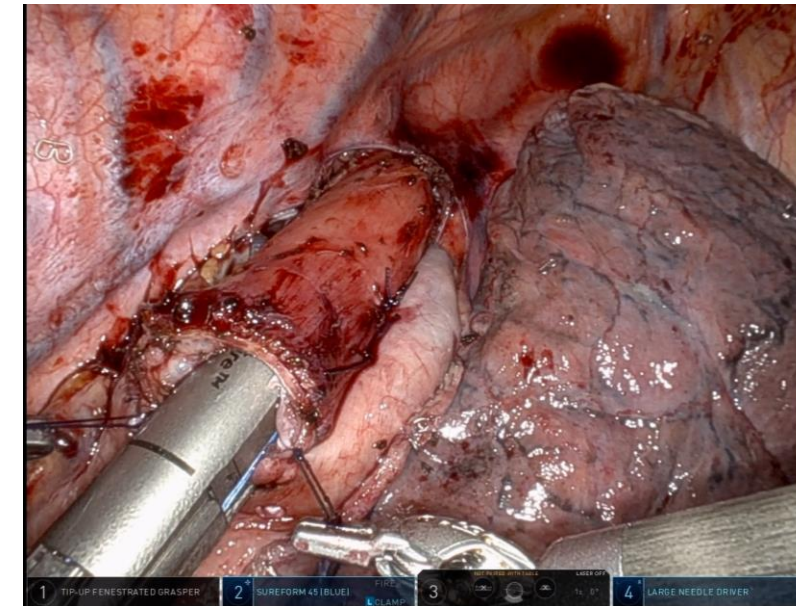
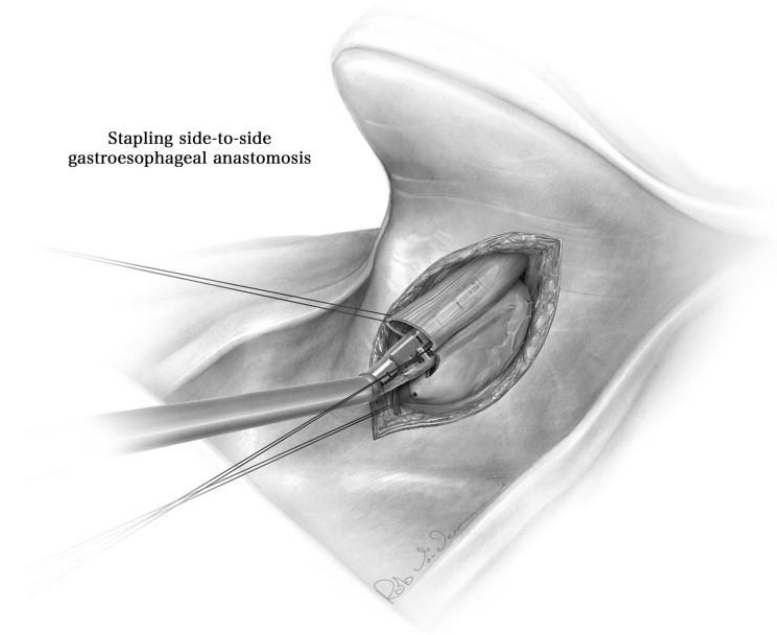
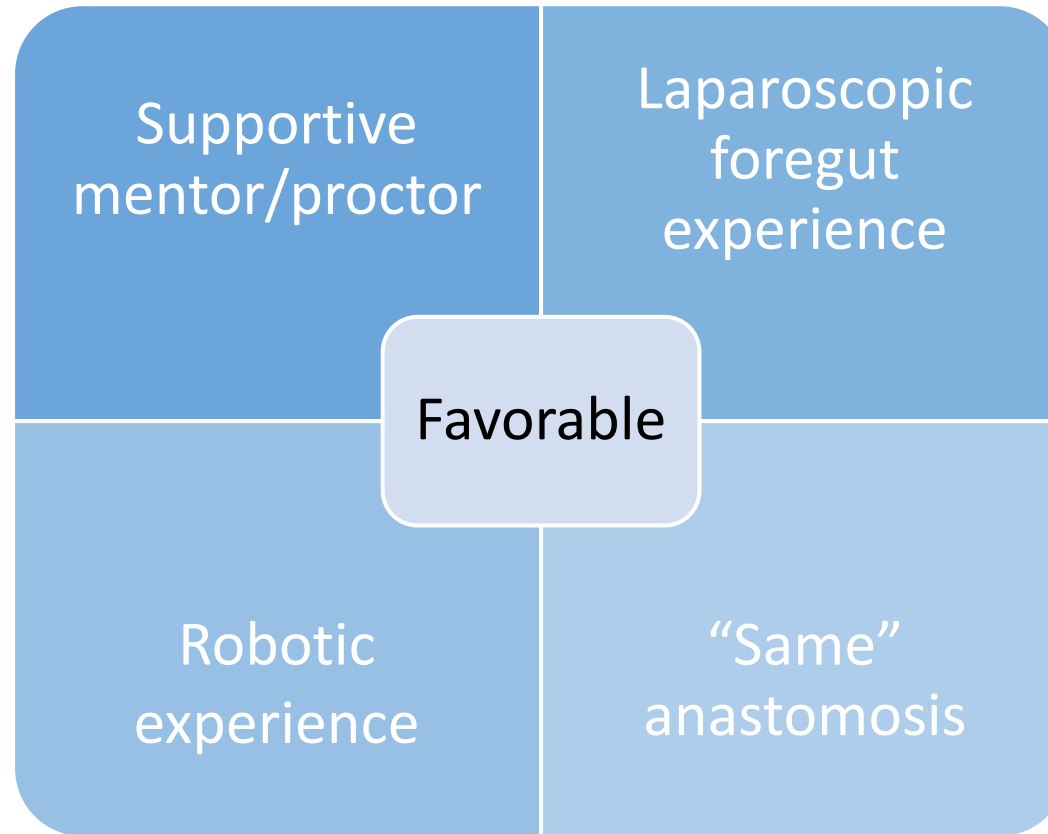
The Call

ROBOT Trial Long-Term Oncologic Outcomes





Kumari Adams, MD FACS



Hurdles

- Low volume
- Limited MIE experience
- Transition to Ivor Lewis
- “Same” anastomosis



Threshold

Benign robotic
foregut

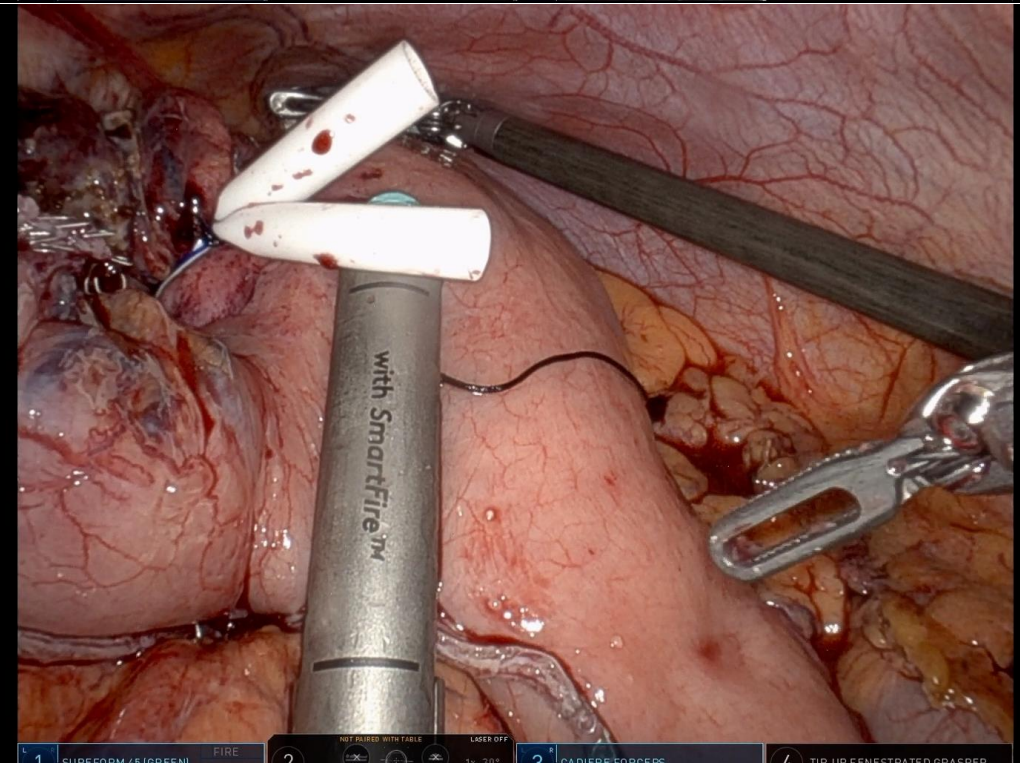
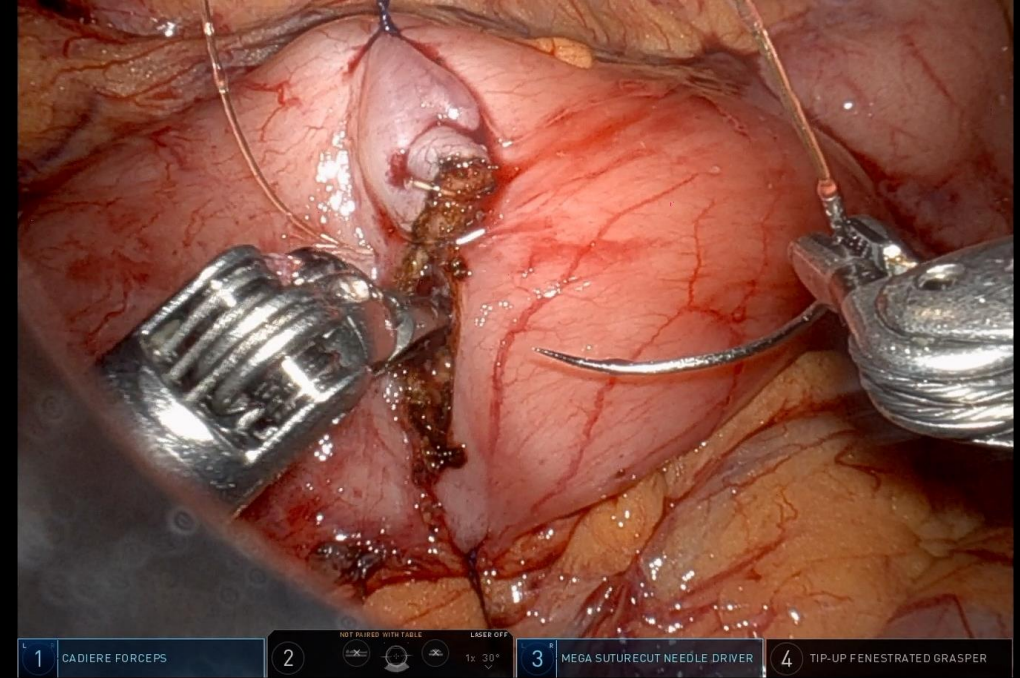
All eligible cases

At the
bedside/console
for all partner's
cases

Deep dive into the
operative steps

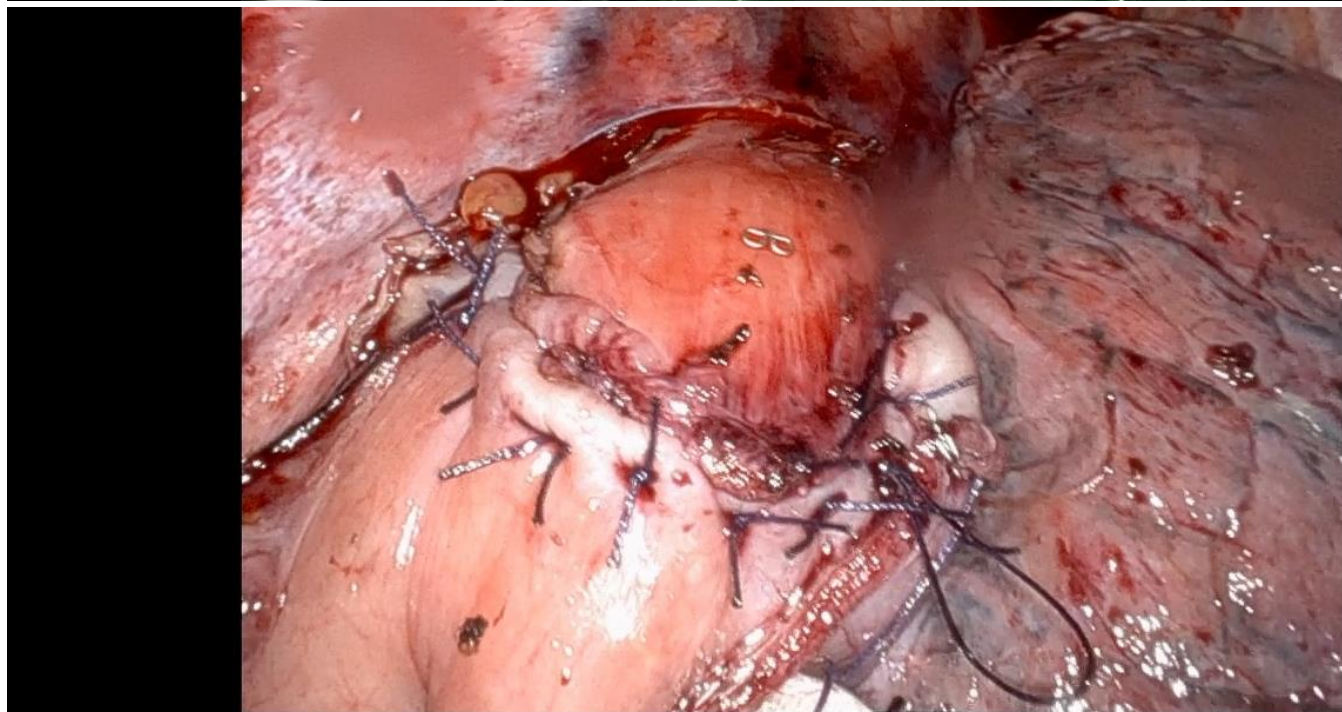
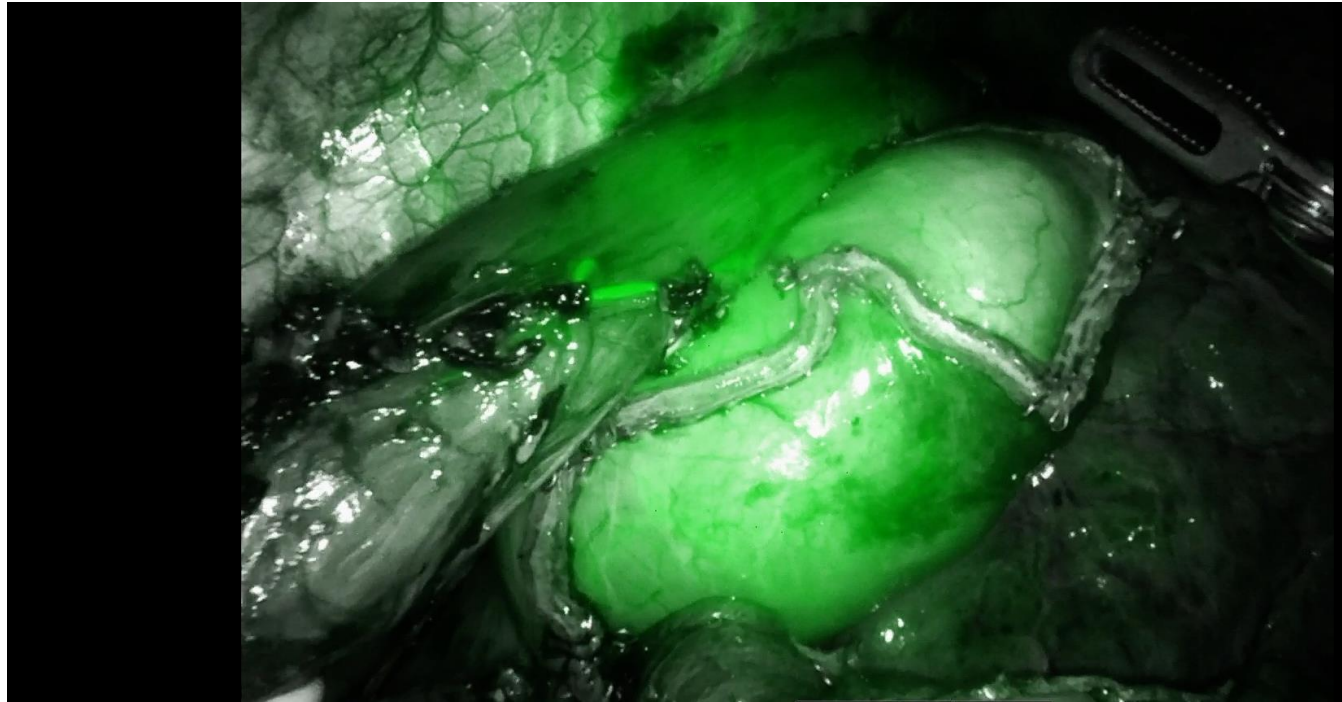


Challenges
&
Temptations



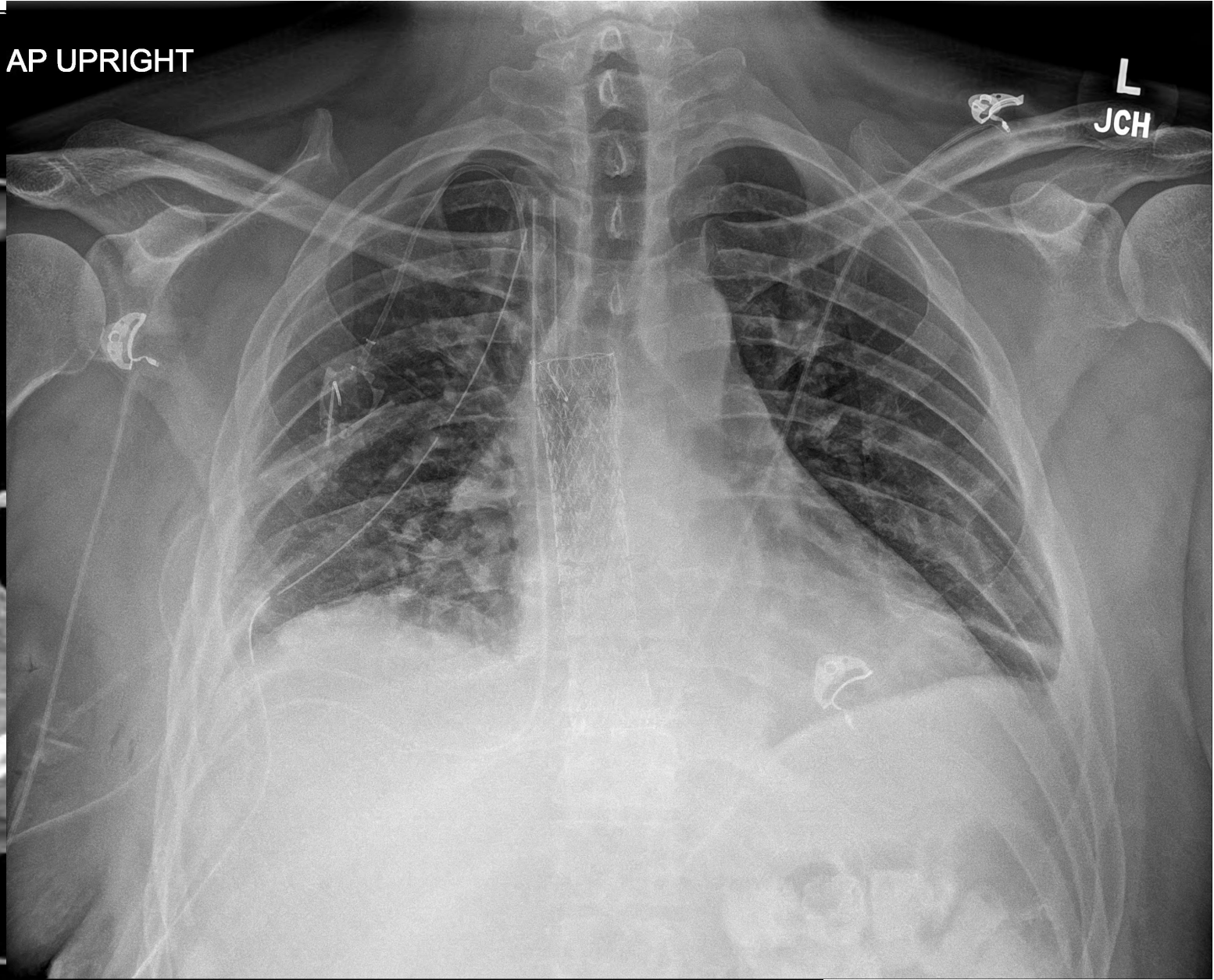
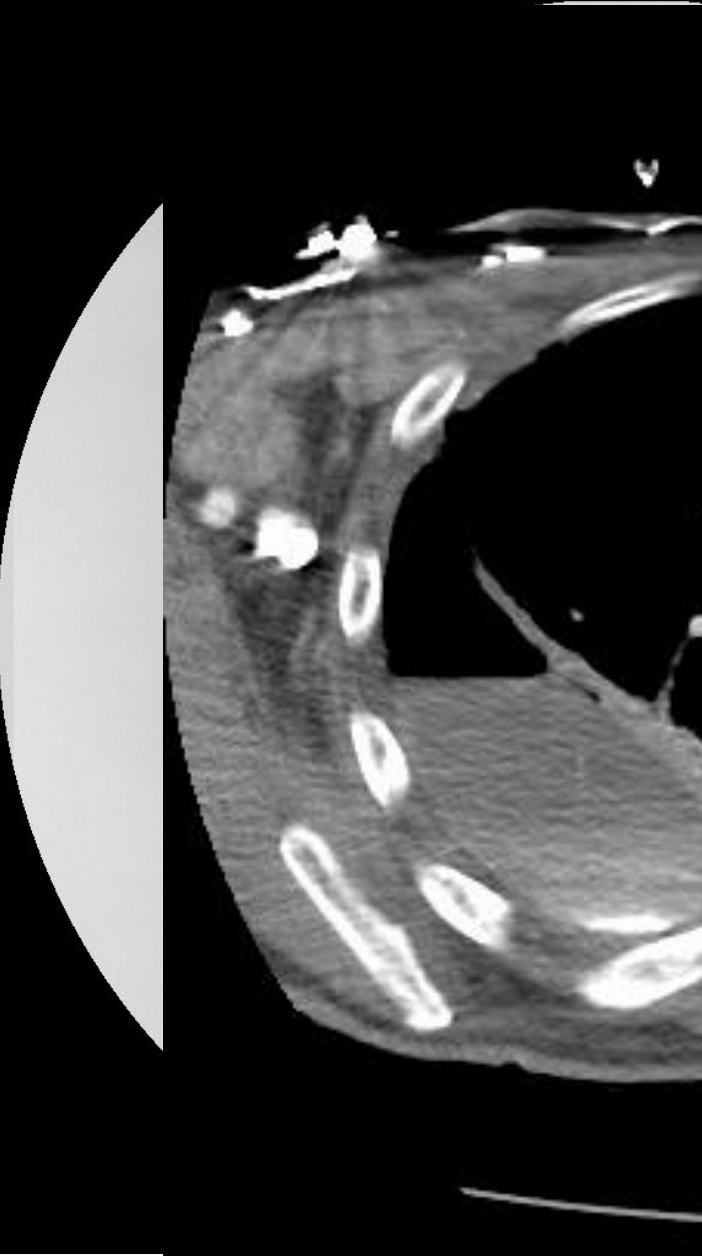
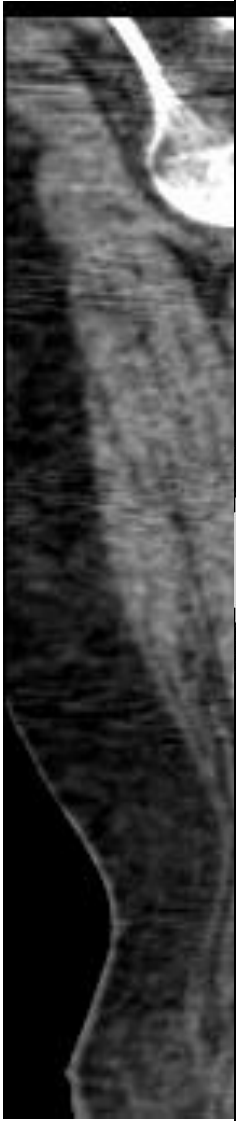


Challenges & Temptations





AND SO IT BEGINS



The Abyss



IF YOU'RE GOING THROUGH
HELL, KEEP GOING

- *Anonymous*

Preparation Matters

Patient

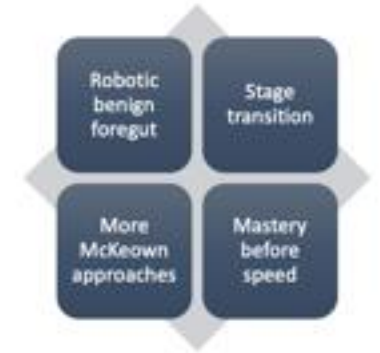
- Recovery from induction therapy

Surgeon

- Case preparation
- Sleep, physical conditioning, snacks, water



Walk Before You Run



Transformation

More is Not Better



Mobilize, Mobilize, Mobilize



Preparation Matters

Patient

- Recovery from induction therapy

Surgeon

- Case preparation
- Sleep, physical conditioning, snacks, water



Walk Before You Run

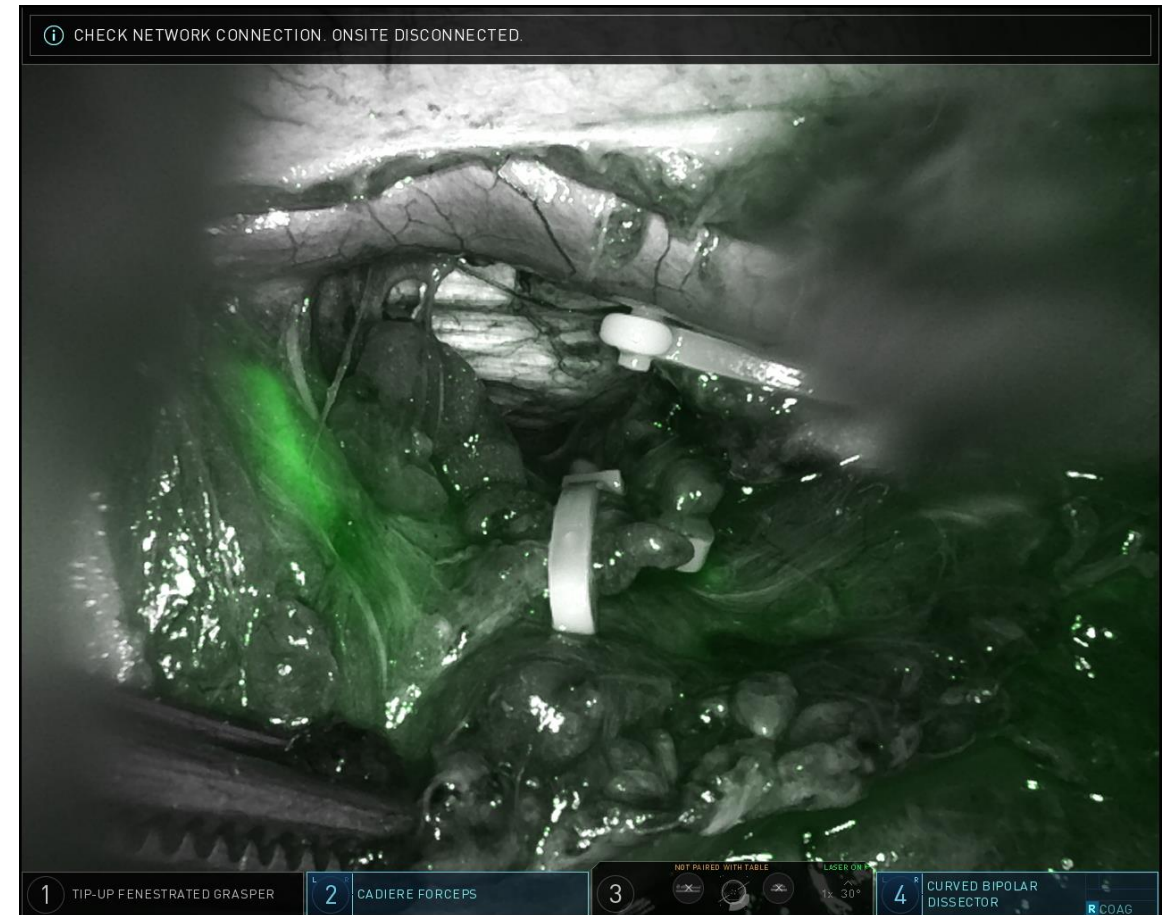
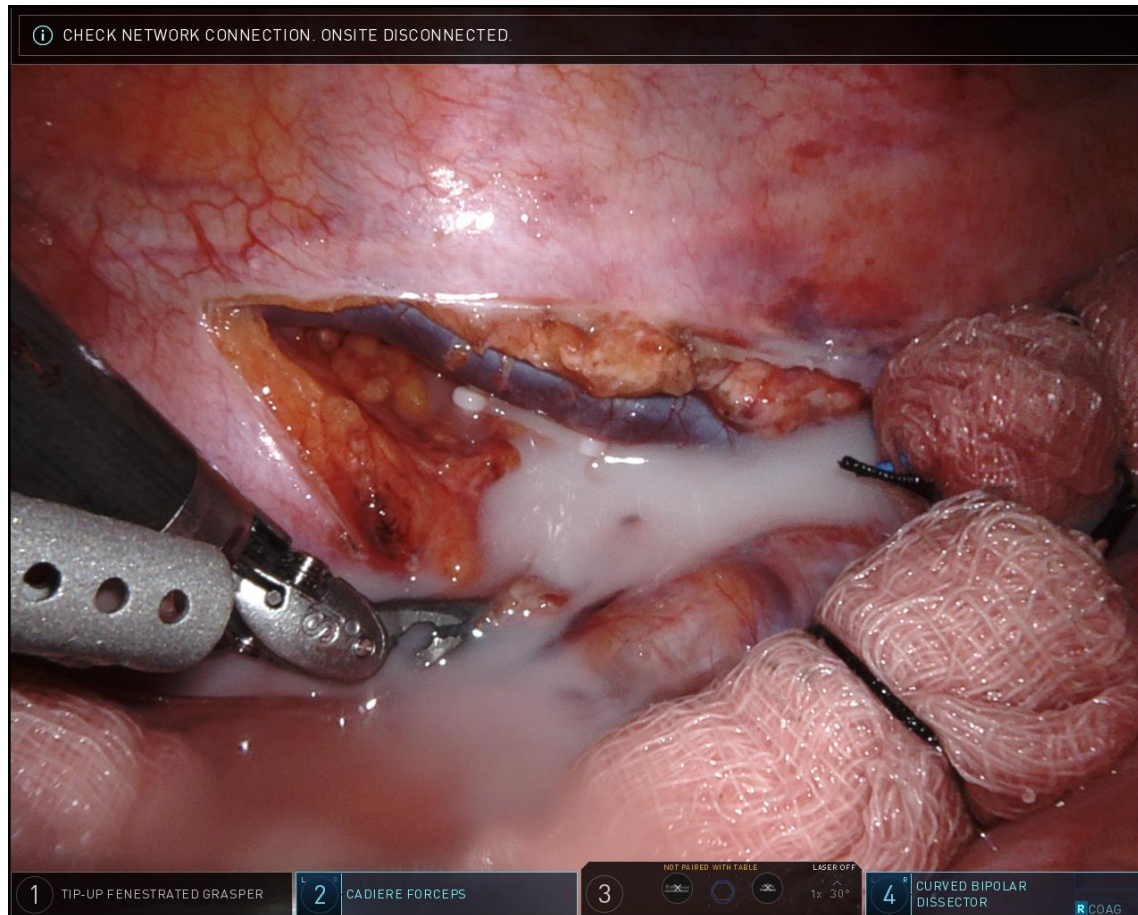
Robotic
benign
foregut

Stage
transition

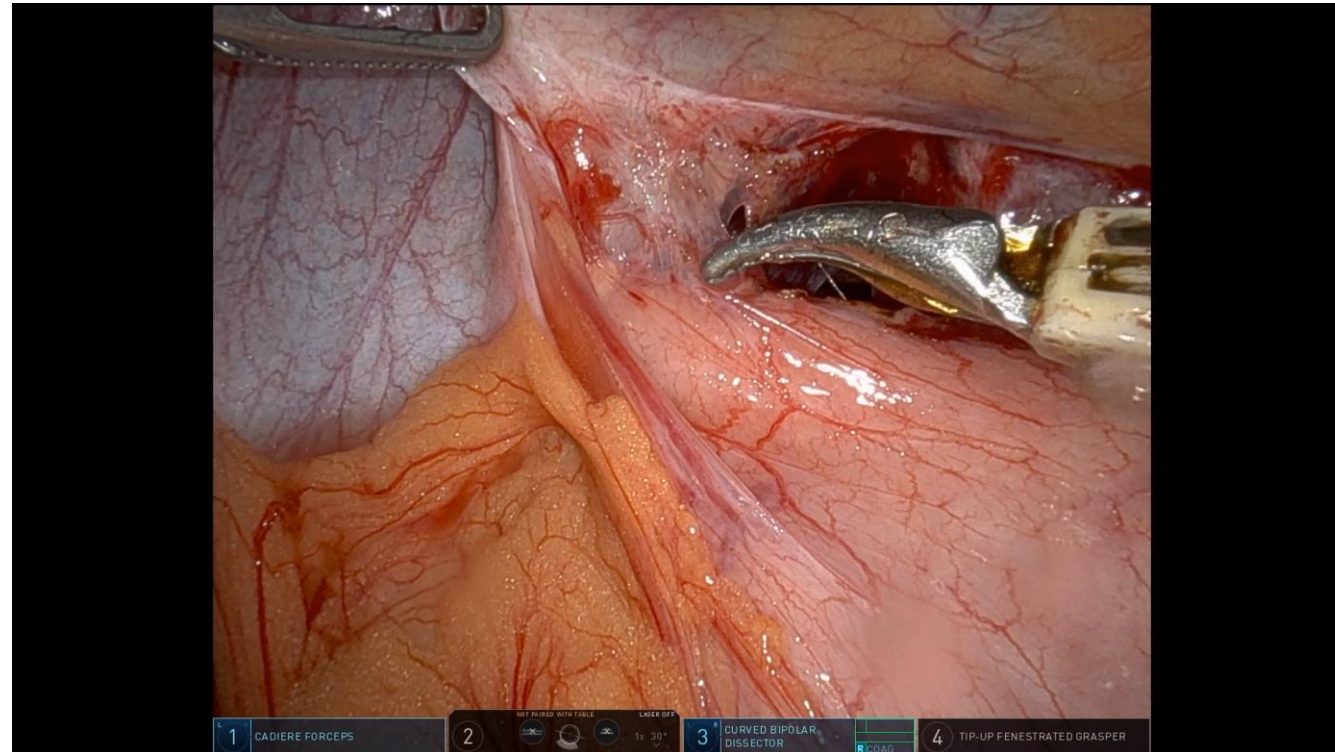
More
McKeown
approaches

Mastery
before
speed

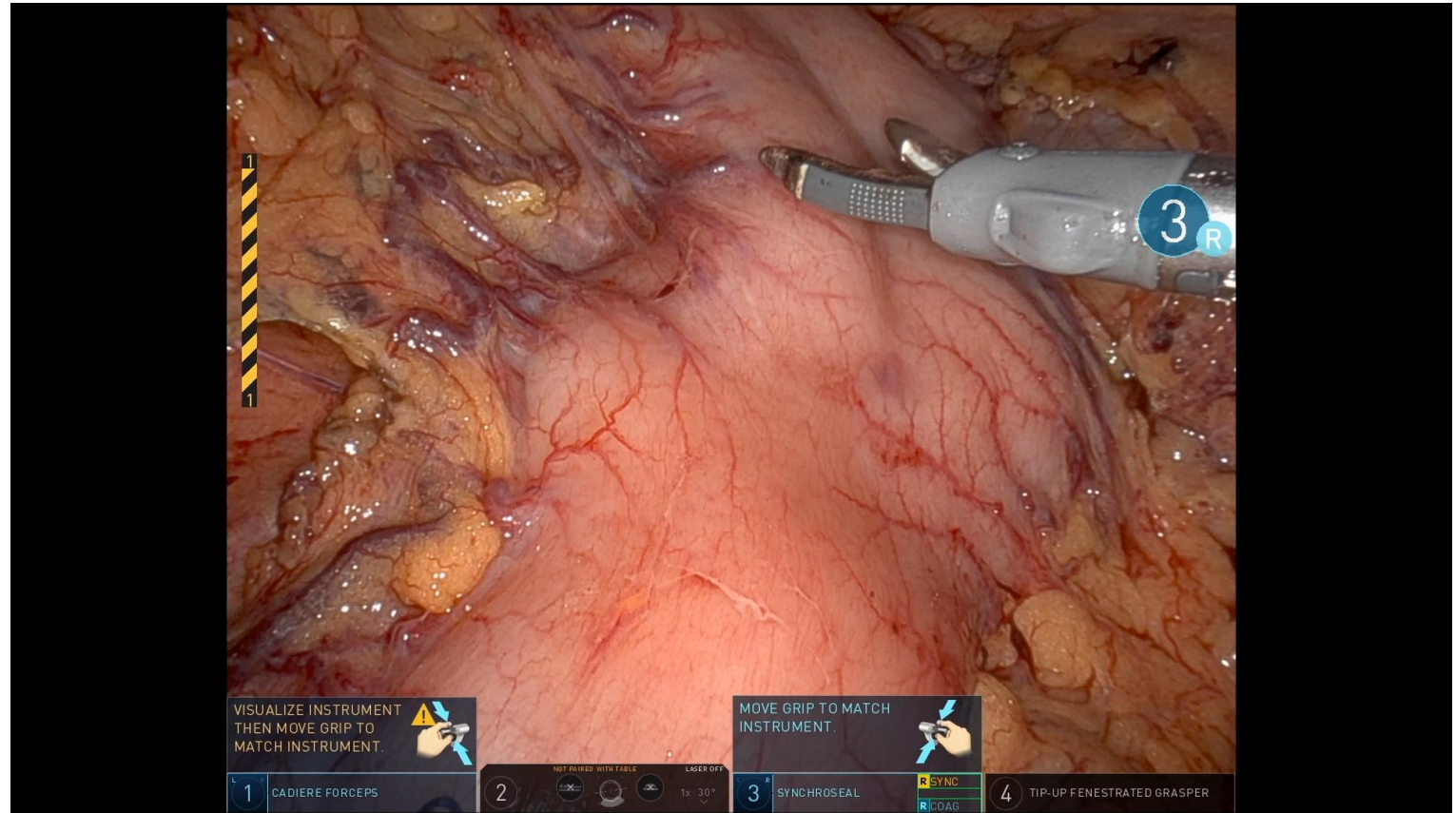
More is Not Better



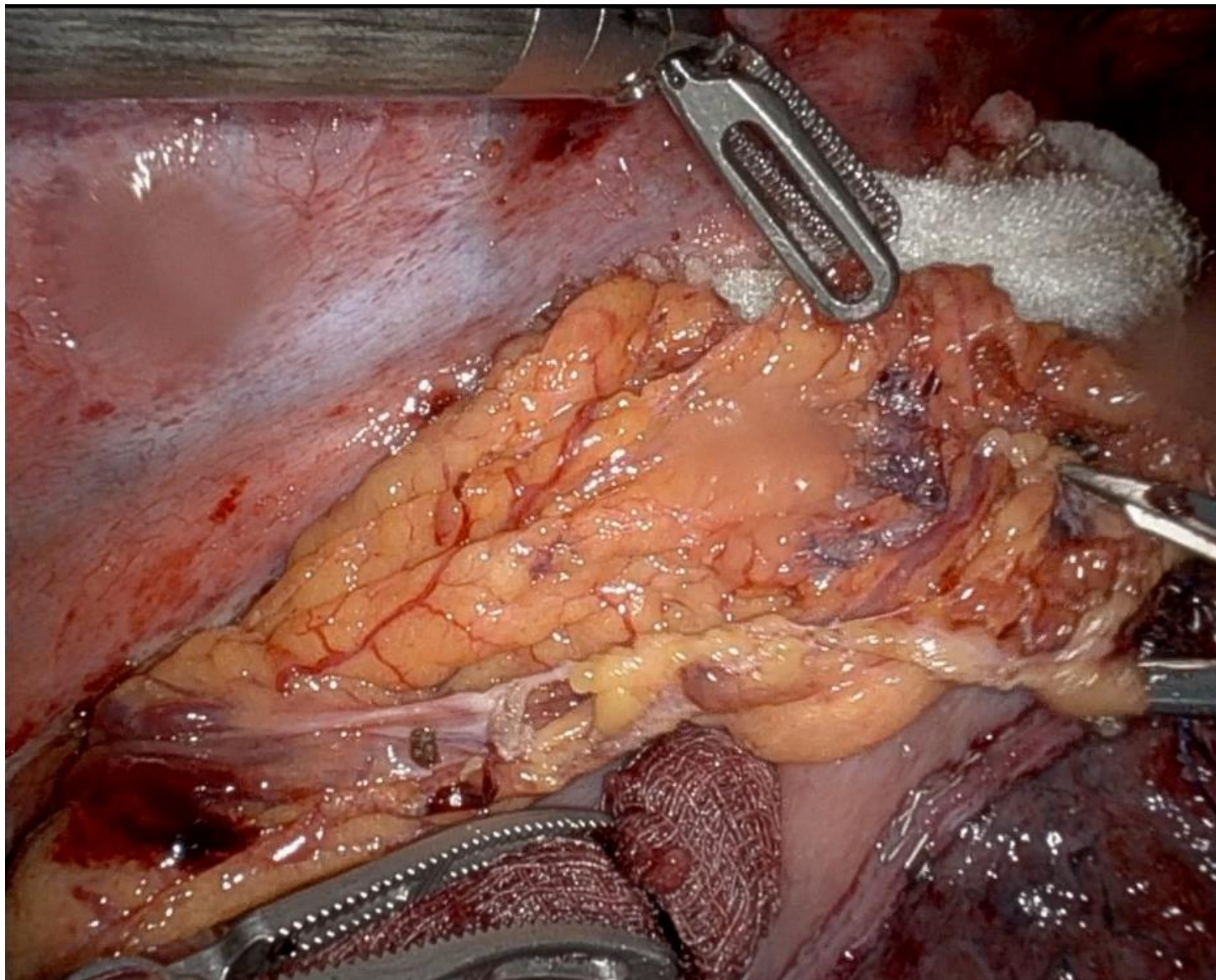
Mobilize, Mobilize, Mobilize



Pink & Green in the Belly



Flap It



RAMIE Learning Curve

Systematic Review and Meta-analysis

**Learning curve for adoption of robot-assisted minimally invasive esophagectomy:
a systematic review of oncological, clinical, and efficiency outcomes**

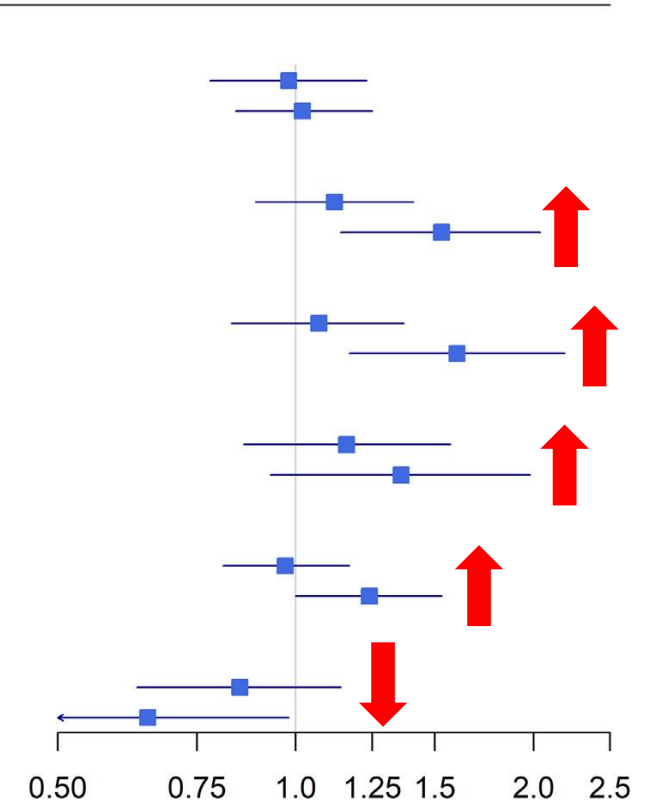
	During LC	Post LC	No. Cases for LC
Operative time (min)	249-496	215-431	16-80
Lymph node yield (no)	4-23	5-45	18-73
Leak rate (%)	12-23	2-10	80-82
30-day morbidity (%)	19-67	7-38	20-51

STSGTDB Esophagectomy US Outcomes

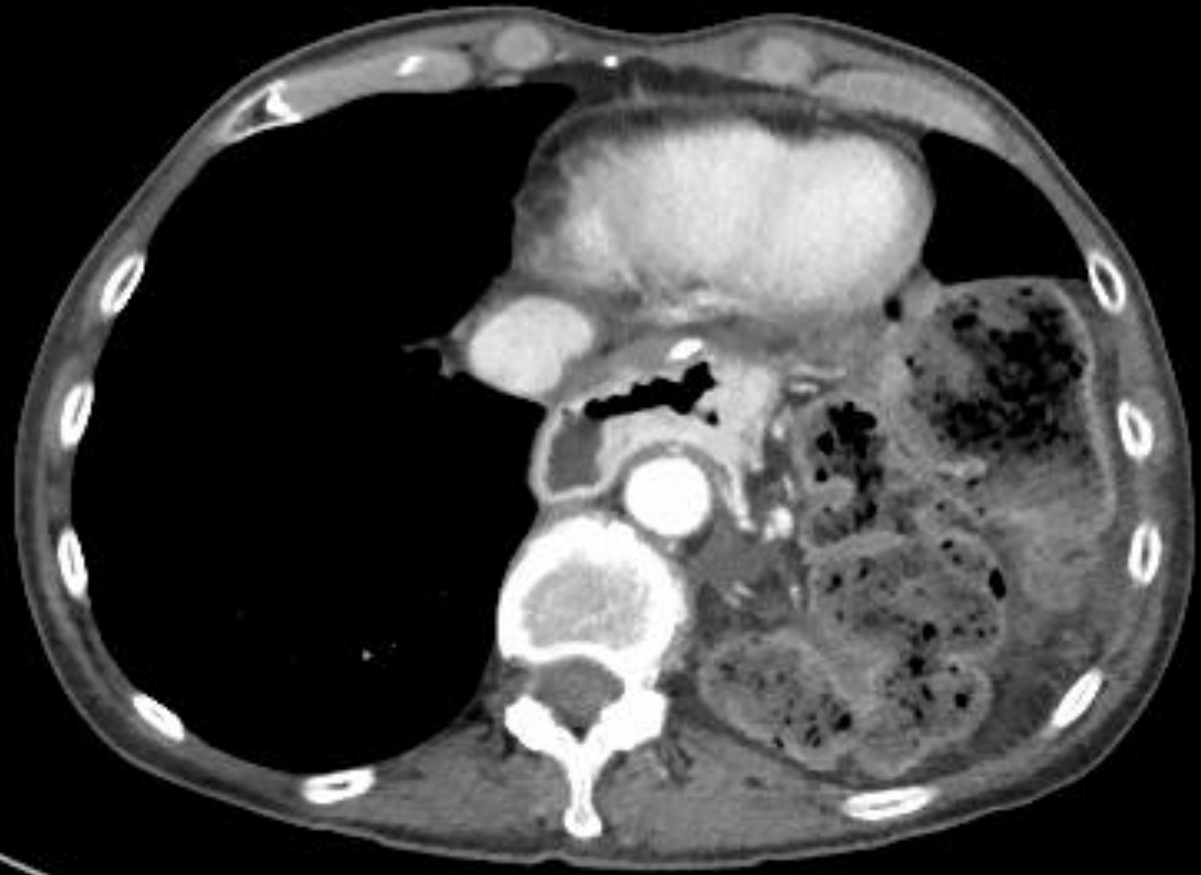
Robotic Esophagectomy Trends and Early Surgical Outcomes: The US Experience

Puja Gaur Khaitan, MD,¹ Andrew M. Vekstein, MD,^{2,3} Dylan Thibault, MS,³ Andrzej Kosinski, PhD,^{3,4} Matthew G. Hartwig, MD,² Mark Block, MD,⁵ Henning Gaissert, MD,⁶ and Andrea S. Wolf, MD, MPH⁷

Endpoint	AOR	95% CI
Pulmonary Complications		
Open	Ref	
MIE	0.98	0.78-1.23
RAMIE	1.02	0.84-1.25
Anastomotic Leak		
Open	Ref	
MIE	1.12	0.89-1.41
RAMIE	1.53	1.14-2.04
Anastomotic Leak - Surgical		
Open	Ref	
MIE	1.07	0.83-1.37
RAMIE	1.60	1.17-2.19
Anastomotic Leak - Medical		
Open	Ref	
MIE	1.16	0.86-1.57
RAMIE	1.36	0.93-1.98
Reoperation		
Open	Ref	
MIE	0.97	0.81-1.17
RAMIE	1.24	1.00-1.53
Operative Mortality		
Open	Ref	
MIE	0.85	0.63-1.14
RAMIE	0.65	0.44-0.98



Ongoing Challenges



Expert Advice

ICG: Gastroepiploic & anastomosis

Extensive Kocher

MIE experience helps

Keep same anastomosis you are comfortable with.

Every step counts



Dr. Lana Schumacher-
Beal
Director, Thoracic
Robotic Surgery, MGH

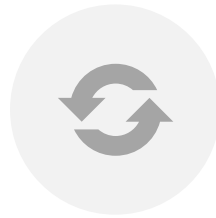
Revelation



VOLUME
MATTERS.



KEEP AS MANY
FAMILIAR ELEMENTS
AS POSSIBLE.



STAGE THE
TRANSITION.



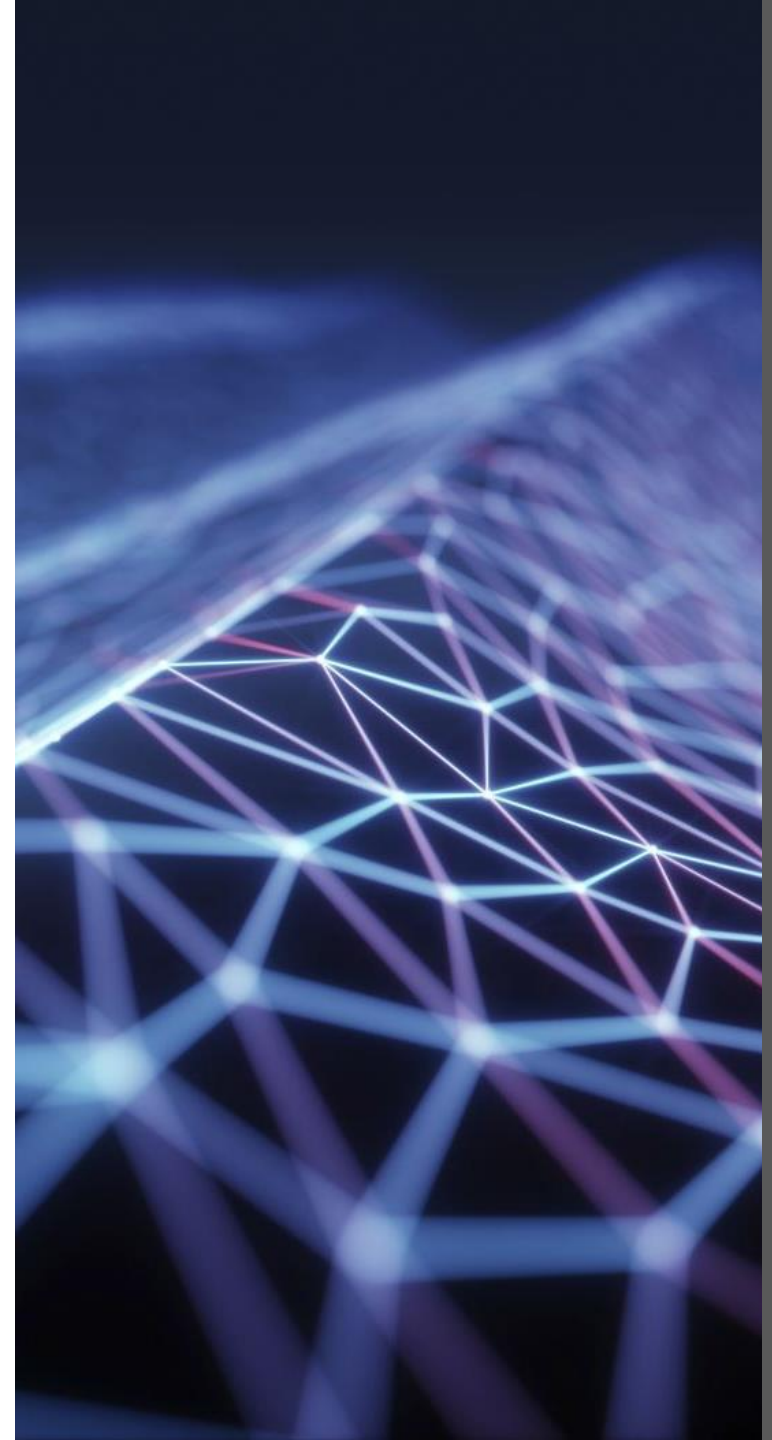
RECORD AND REVIEW
ALL CASES.



SET METRICS FOR
SUCCESS & TRACK
OUTCOMES.



KNOW WHEN TO &
WHEN NOT TO
CHANGE COURSE.



Questions?

- [Melanie Edwards@ihacares.com](mailto:Melanie_Edwards@ihacares.com)
- 617-817-1934
- Twitter: @medwards_md



GTSC Innovation Hub

Dennis Wigle

GTSC meeting, Duck Key FLA

Saturday March 11, 2023



GTSC Innovation Hub

How do we learn to use new technologies?

Connecting through company representatives vs formal courses vs colleagues

Some relatively mature systems to do this (eg. Intuitive) vs others less formal/nonexistent



GTSC Innovation Hub

What if GTSC could be a portal for accessing training in new technology?

How this could work:

Companies with new technology and training mentors accessible through GTSC Innovation Hub

GTSC innovation Hub as a “connector” for surgeons to access the training and mentorship they need to get started with trusted partners



GTSC Innovation Hub

Pilot launch 2023:

Utilize Intuitive training programs for robotic bronchoscopy and/or robotic surgery – connect through GTSC

2-3 staff surgeons in a position to dedicate time to training

2024, 2025:

Successful pilot launch

Expand with 1-2 further added companies/technologies



Mentee Profile, Criteria Requirements, & Identification Process

Ion (New to robotic Training)	Ion (Limited robotic experience w/desire to optimize skills 25- 50 cases per yr.)	DV (New to robotic Training)	DV (Limited robotic experience w/desire to optimize skills 25- 50 cases per yr.)
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Identifying potential mentees:

- Announcement sent to GTSC Members for applications
- Mentoring program committee to identify mentor & mentees
- Mentee will need to have sign-off approval by their institution (CEO/Dept Chair) & Ion/DaVinci Field Representative



Mentee Profile, Criteria Requirements, & Identification Process

Ion (New to robotic Training)	Ion (Limited robotic experience w/desire to optimize skills 25-50 cases per yr.)	DV (New to robotic Training)	DV (Limited robotic experience w/desire to optimize skills 25-50 cases per yr.)
--	---	---	--

Criteria Requirements:

- Must be able to dedicate no less than 12 months of participation of mentoring program
- Must have access to Ion and/or a 4th generation da Vinci Xi System at home institution



GTSC Innovation Hub

Pilot launch 2023:

Email communication to members Spring/early summer 2023

Goal of training starting Fall 2023

Ongoing evaluation of membership needs for further partners



GTSC Innovation Hub

Thanks & enjoy the meeting!

wigle.dennis@mayo.edu

