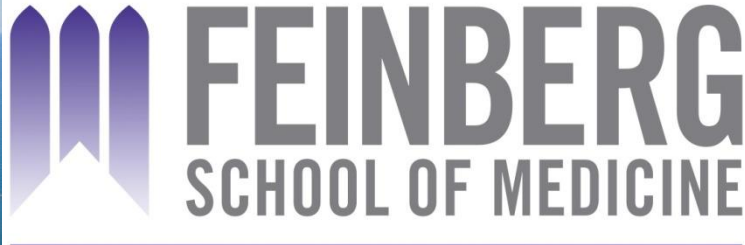


NORTHWESTERN UNIVERSITY



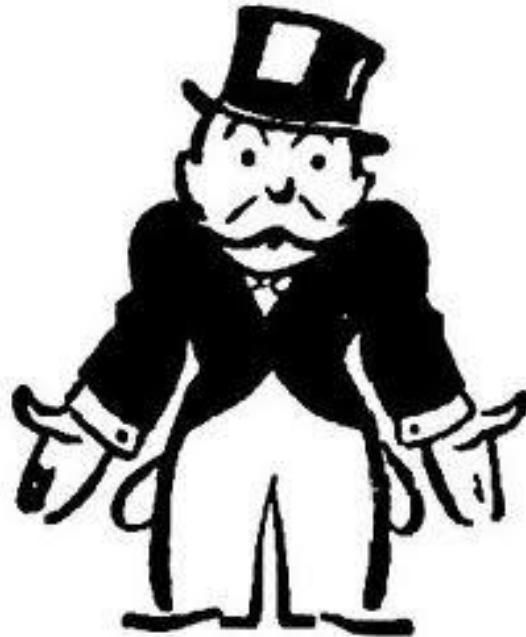
Minimally Invasive Surgery: Past, Present, and (?) Future

OSS 2015

Nathaniel J. Soper, M.D., FACS
Chicago, IL

Disclosures

Scientific Advisory Board: Transenterix, Miret Surgical
Research Support: Karl Storz Endoscopy-America
My son, Robert, is employed by Covidien, Inc.

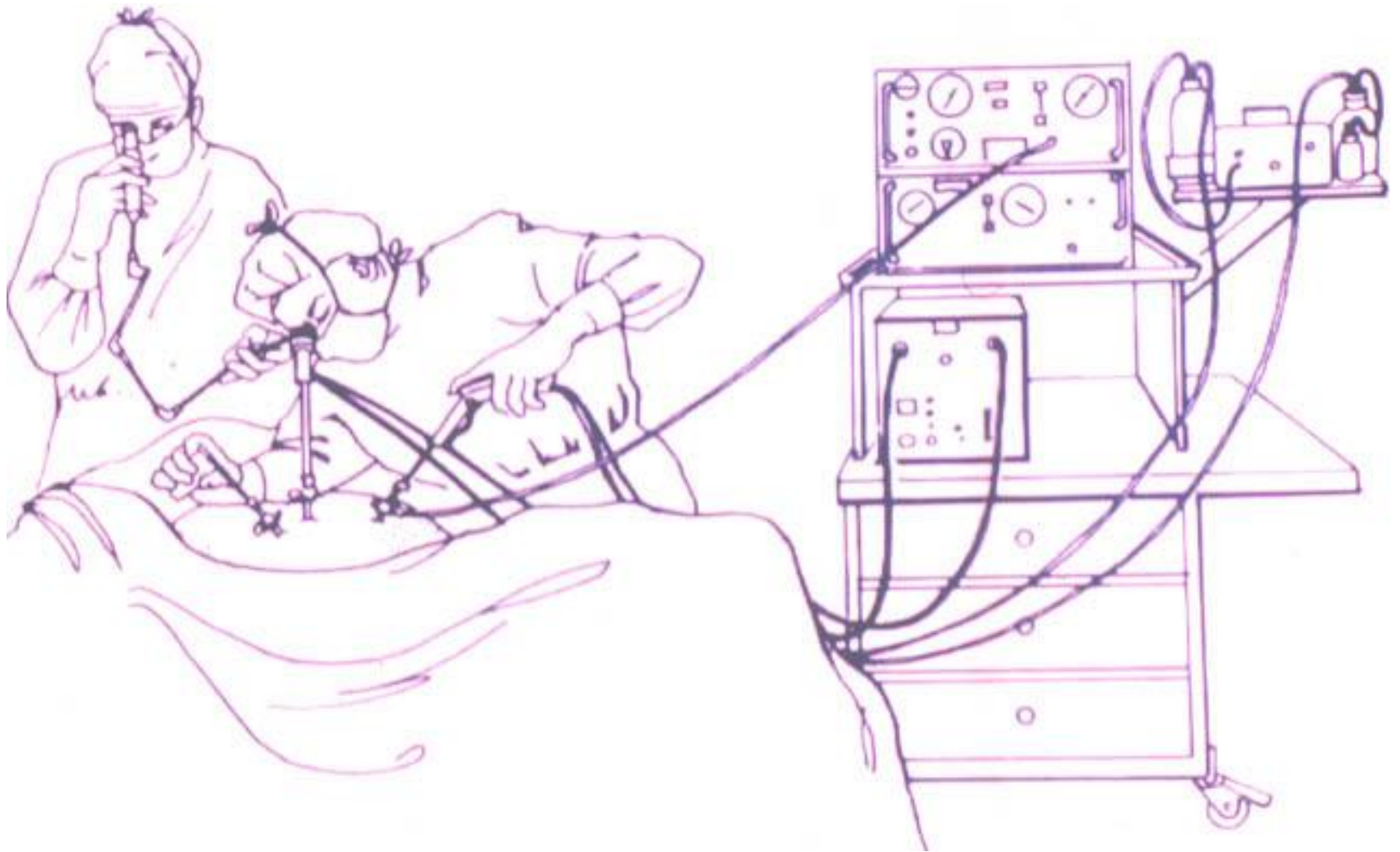


Outline

1. Personal reflections/history of MIS
2. Current status of laparoscopy
3. Endolumenal applications
4. NOTES
5. Other potential future applications of MIS

What is 'Minimally Invasive' Surgery?

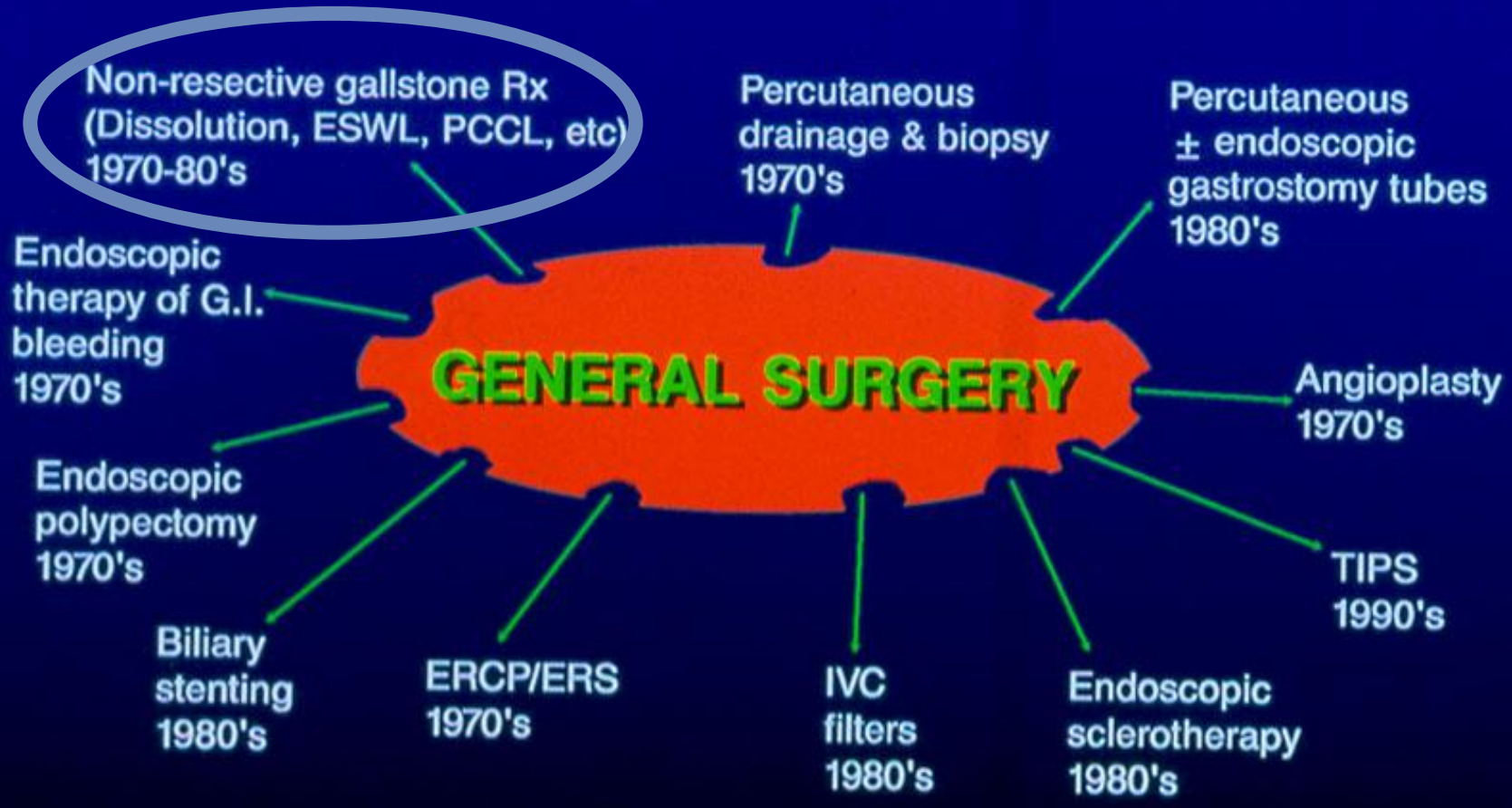
- The field of surgery in which operative interventions are performed using less traumatic approaches than traditional surgical procedures
 - a.k.a. minimal access surgery
 - e.g. laparoscopic and endoscopic surgery



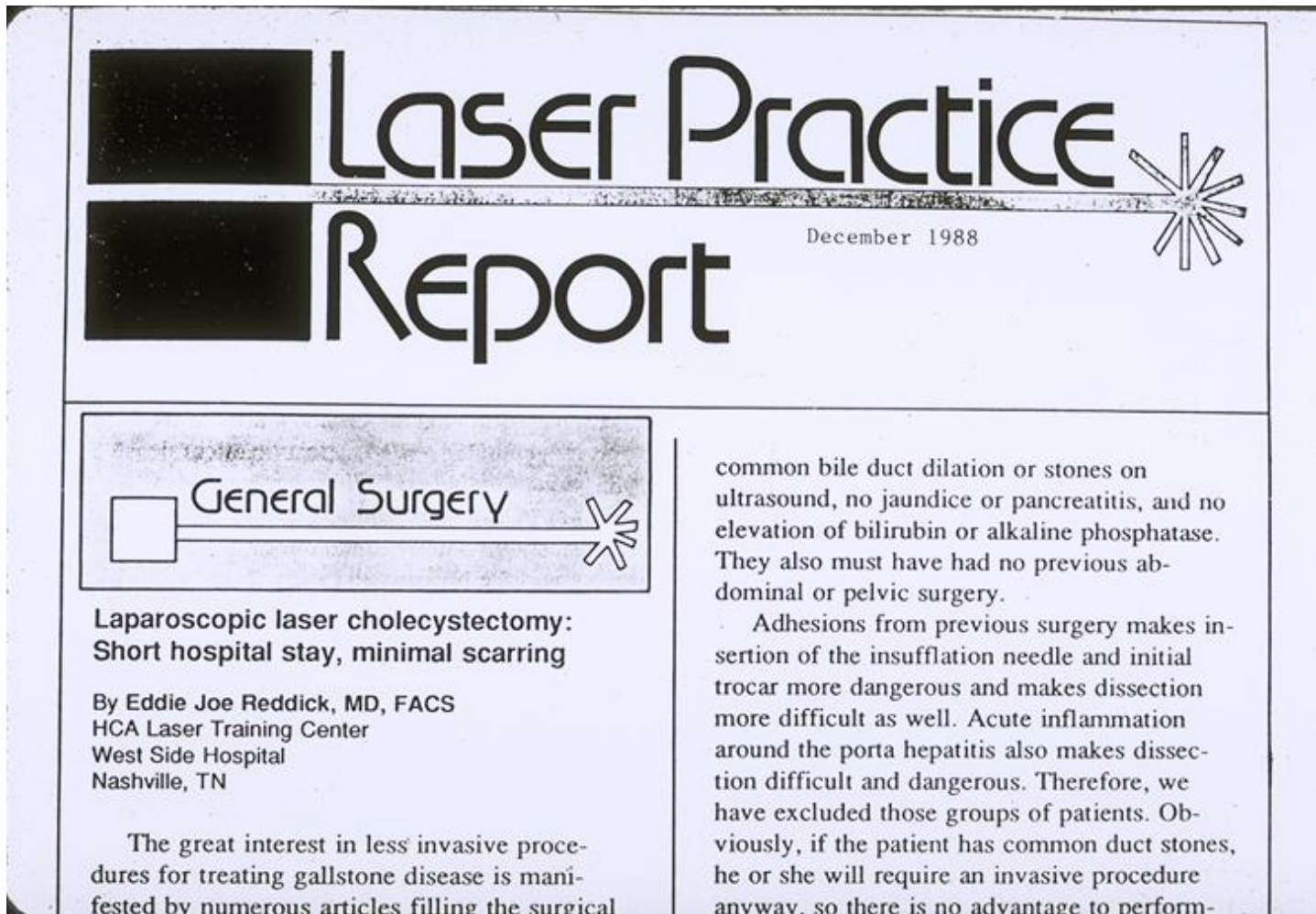


Washington University Med Center, circa 1988

EROSION OF GENERAL SURGERY BY "MINIMAL ACCESS" TECHNIQUES



First Published Report of Laparoscopic Cholecystectomy



Laser Practice
Report December 1988

General Surgery

**Laparoscopic laser cholecystectomy:
Short hospital stay, minimal scarring**

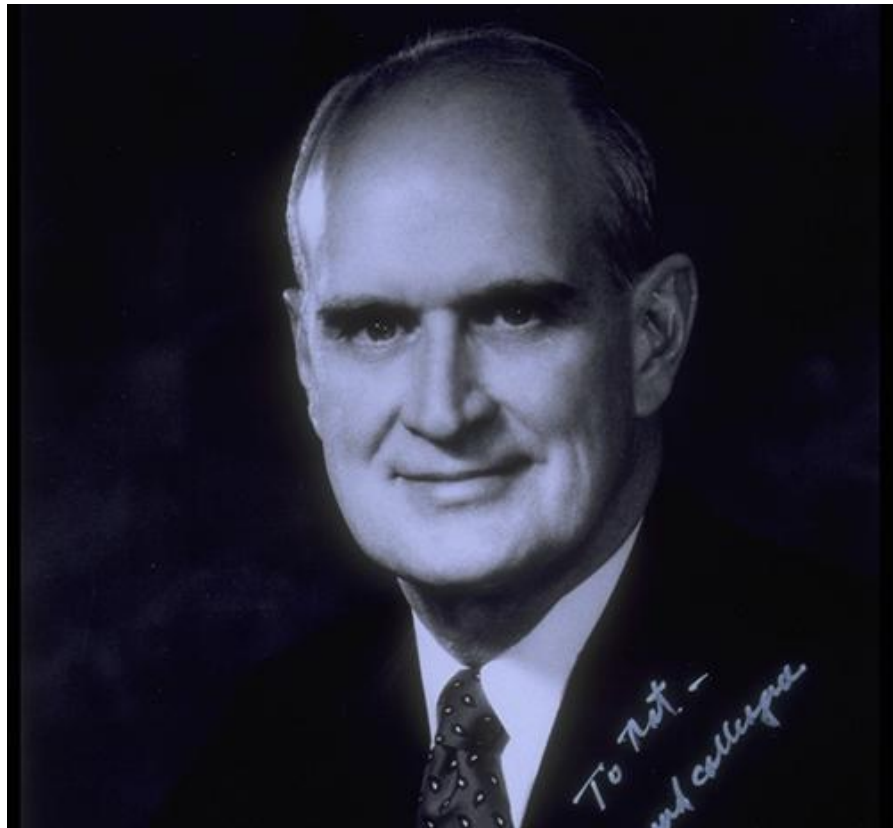
By Eddie Joe Reddick, MD, FACS
HCA Laser Training Center
West Side Hospital
Nashville, TN

The great interest in less invasive procedures for treating gallstone disease is manifested by numerous articles filling the surgical

common bile duct dilation or stones on ultrasound, no jaundice or pancreatitis, and no elevation of bilirubin or alkaline phosphatase. They also must have had no previous abdominal or pelvic surgery.

Adhesions from previous surgery makes insertion of the insufflation needle and initial trocar more dangerous and makes dissection more difficult as well. Acute inflammation around the porta hepatitis also makes dissection difficult and dangerous. Therefore, we have excluded those groups of patients. Obviously, if the patient has common duct stones, he or she will require an invasive procedure anyway, so there is no advantage to perform-

Samuel A. Wells, Jr., M.D.



Lap Chol'y: Pig Studies

Laparoscopic Cholecystectomy

Chronic Animal Studies

- 6 pigs allowed to recover
- 1 died at one week secondary to adhesive SBO
- 5 animals sacrificed at one month; performance of cholangiography, serum liver function tests and histologic examination of the liver

MAKE CHECKS PAYABLE TO:

Eddie J. Reddick, M.D.
Ste. 101, 2201 Murphy Ave.
Nashville, TN 37203

PHONE 615 340-6970

62-1254598

STATEMENT

RETURN UPPER PORTION OF
STATEMENT WITH PAYMENT

Nathaniel J. Soper, M.D.
Assistant Professor of Surgery
Washington University
School of Medicine
6108 Queeny Tower, 1 Barnes Hospital Plaza
St. Louis, MO 63110

PATIENT'S NAME

CLOSING DATE

PAGE NO.

NEW BALANCE

1,000.00

NOTE: Charges and payments not appearing on this statement will appear on next month's statement.

SHOW AMOUNT
PAID HERE \$

CHARGES APPEARING ON THIS STATEMENT ARE NOT INCLUDED ON ANY HOSPITAL BILL OR STATEMENT

DATE	EXPLANATION OF ACTIVITY	PROC. CODE	DIAG. CODE	CHARGES & DEBITS	PAYMENTS & CREDITS
9/12/89	preceptorship; laparoscopic laser cholecystectomy			1,000.00	

EDDIE J. REDDICK, M.D., F.A.C.S.
DOUGLAS O. OLSEN, M.D., F.A.C.S.

General Surgery
2201 MURPHY AVENUE, SUITE 101
NASHVILLE, TENNESSEE 37203
Telephone (615) 340-6920



September 21, 1989

Nathaniel Soper, M.D.
One, Barnes Hospital Plaza
St. Louis, MO 63110

Dear Dr. Soper:

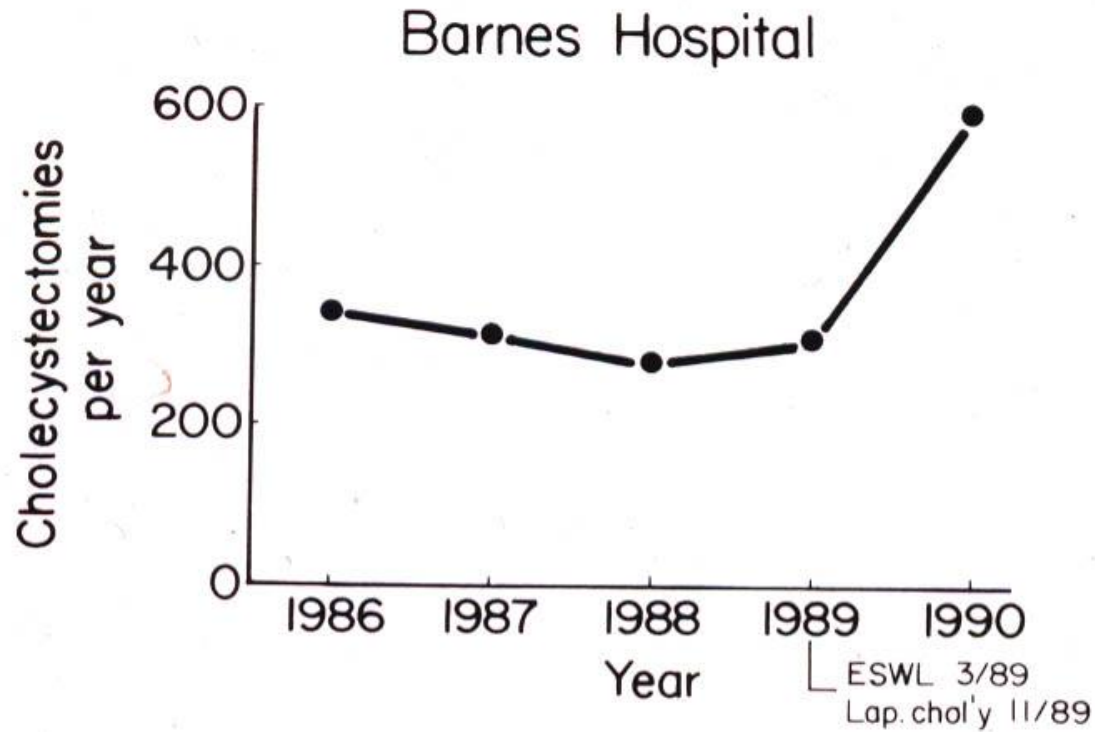
I apologize for the misunderstanding that occurred concerning the charge for the preceptorship. I not only have a surgical practice, but also have a business which teaches laser surgery not only in Nashville but around the country. Therefore, I feel that my time in teaching this procedure certainly has some monetary value.

However, I would rather have your goodwill than your money so please disregard the bill that was sent to you. You can make it up to me by buying me dinner the next time I pass through St. Louis.

Sincerely,


Eddie J. Reddick, M.D., FACS

Effect of Lap Chol'y



L.B.J. Cholecystectomy Scar







World's First Laparoscopic Nephrectomy, June 1990

Laparoscopic Cholecystectomy

The New 'Gold Standard'?

Nathaniel J. Soper, MD; Paul T. Stockmann, MD; Deanna L. Dunnegan, RN; Stanley W. Ashley, MD

• Laparoscopic cholecystectomy has rapidly been adopted by surgeons, but concerns remain about its safety, the management of common bile duct stones, and the means of appropriate training. Of 647 patients referred for cholecystectomy, preoperative endoscopic retrograde cholangiography was performed in 49 (7.6%), with 27 patients (4%) undergoing sphincterotomy and stone extraction. Traditional cholecystectomy was performed in 29 patients (4.5%). Laparoscopic cholecystectomy was attempted in 618 patients and completed successfully in 600 (97.1%). Surgical trainees functioned as the primary surgeon in 70% of cases. Technical complications occurred in three patients (0.5%), including one patient with a common bile duct laceration (0.2%). Major complications occurred in 10 patients (1.6%), with no perioperative mortality. Mean postoperative hospital stay was 1 day, with return to work or full activity a mean of 8 days after surgery. Two cases of retained common bile duct stones (0.3%) were identified. We now regard laparoscopic cholecystectomy as the "gold standard" therapy for management of symptomatic cholelithiasis.

(Arch Surg. 1992;127:917-923)

ous "hands-on" courses and a number of reports attesting to the safety of the procedure in large series of patients.⁸⁻¹⁵ Nevertheless, there are unanswered questions concerning laparoscopic cholecystectomy. Despite the low morbidity reported by early proponents of the procedure, it is feared that the rate of complications among patients whose surgeons are less experienced in performing the procedure is higher than that with open cholecystectomy.¹³⁻¹⁵ Another unresolved issue is the appropriate method of training for laparoscopic surgery. It is feared that surgical residents will not learn these techniques adequately in their training programs. Finally, the issues of whether to obtain intraoperative cholangiograms on a routine or selective basis and the appropriate techniques to manage common bile duct stones in the era of laparoscopic cholecystectomy remain to be settled. The aim of the present study was to review the early experience with laparoscopic cholecystectomy at our teaching institution, specifically assessing the role of residents, rates of morbidity and mortality, and the means by which common bile duct stones have been managed.

PATIENTS AND METHODS

Lap Choly Lay Press

Medicine

TIME, MARCH 23, 1992

The Kindest Cuts of All

Palm-size video cameras, miniaturized scissors and staplers, and minute incisions are starting to take the ouch out of surgery

By J. MADELEINE NASH BOSTON

Like a kid intent on a Nintendo game, Dr. David Sugarbaker looks not at the patient lying senseless on the operating table but at the TV positioned by her side. "I think we're right on target," he exults. Displayed on the screen is a larger-than-life section of the woman's

years," exclaims Dr. William Schuessler, a urological surgeon from San Antonio. The instrument sparking such enthusiasm is variously known as a laparoscope (when used in the abdomen), an arthroscope (when applied to the joints), a thoracoscope (when the chest is involved) and an angioscope (when the target lies inside blood vessel walls). But apart from differ-

Reddick, a retired Nashville surgeon credited with popularizing the technique, "we were committing assault and battery on our patients. It wasn't what we did to their insides, but what we did in order to get there that was the problem." Now, instead of an 8-cm to 15-cm slash down their abdomens, patients wake up with four small incisions that not only heal more quickly

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

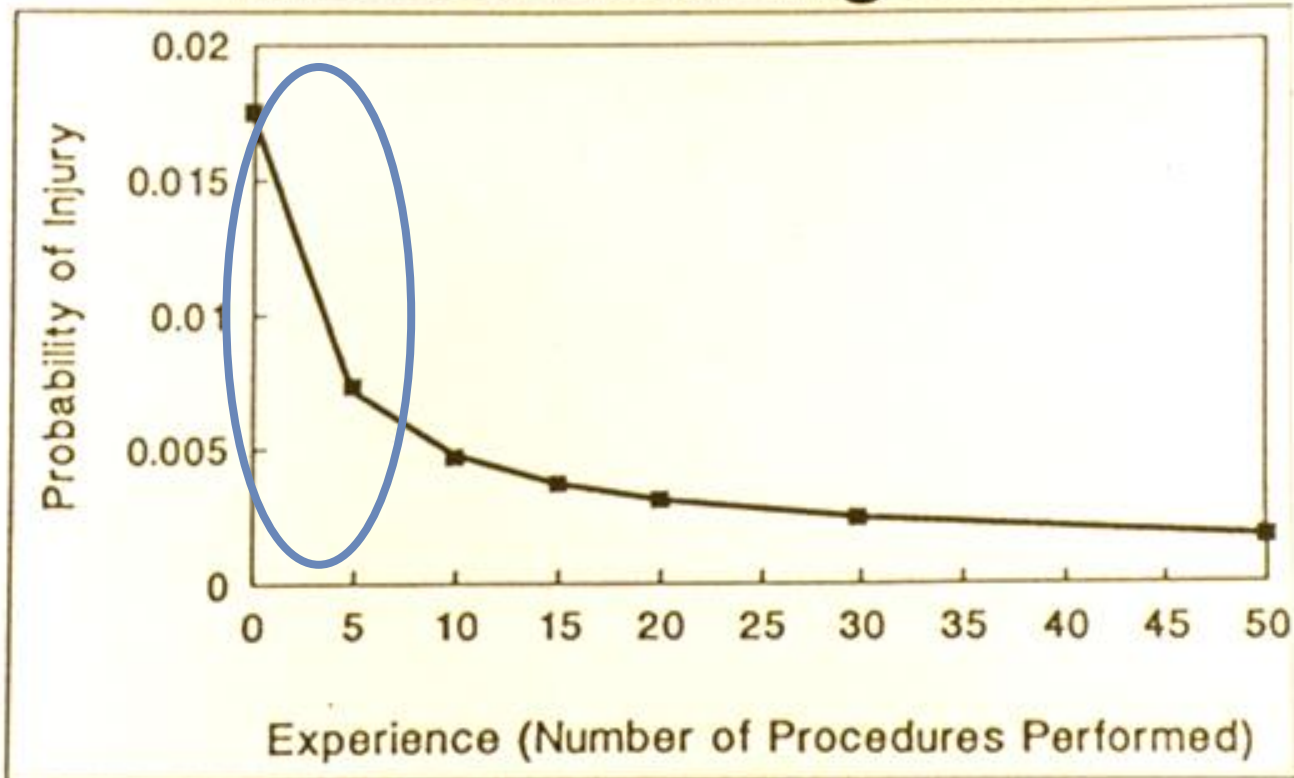
By RON WINSLOW
Staff Reporter of THE WALL STREET JOURNAL

Laparoscopic Training Oct., 1990





The L.C. Learning Curve



Southern Surgeons Club, Am J Surg 170:
55-59, 1995

Diagnosis and Management of Biliary Complications of Laparoscopic Cholecystectomy

Nathaniel J. Soper, MD, M. Wayne Flye, MD, L. Michael Brunt, MD, Paul T. Stockmann, MD,
Gregorio A. Sicard, MD, Daniel Picus, MD, Steven A. Edmundowicz, MD,
Giuseppe Aliperti, MD, St. Louis, Missouri

Lap Choly Complications

"Albany (N.Y.) Times Union, 3/22/92"

2 more deaths from video surgery

By Robert Whitaker

Staff writer

The death toll of patients injured while having their gallbladders removed with laparoscopes has risen to six in New York, and at least 122 other people have been injured because of surgeons' errors, according to the state Health Department.

That represents two deaths and eight injuries added to the state's list of botched laparoscopic cholecystectomy operations since Feb. 1, when *The Times Union* first reported on a rash of complications associated with this procedure. The operation has become popular in the last two years.

"I felt I was dying. I was so sick and in such agony I was screaming at the nurses"

— Patricia Bryant

also may strongly suggest that surgeons who have one complication during their first 100 procedures get further training or proctoring from a more experienced surgeon, and after a second complication, "go back to school, period," said Dr. Harvey Bernard of the state Health Department.

Department officials are taking

The two deaths added to the state's list of laparoscopic cholecystectomy incidents since Feb. 1 actually occurred before that date, Anderman said. She did not know the specifics of the two deaths.

None of the six deaths occurred at Capital District hospitals, although there have been serious injuries at several area hospitals, she said.

"I am frustrated by the process. The incident reporting isn't just supposed to be a surveillance system to say, 'Gotcha,'" she said. "Hospitals are on the front line of providing care, and we aren't getting any feedback."

According to spokeswoman Jeanie Cross, starting in February 1991 HANYS conducted seminars and drew up written recommendations for credentialing surgeons.

"It is a little surprising to find out after we have been doing this for more than a year ... that all of a sudden the Health Department is doing it, too," she said.

If done properly, removing the

Tighter rules urged on new gallbladder surgery

By Harris Meyer
AMN STAFF

JUNE 1, 1992

Spurred by mounting reports of serious patient injury, New York state health officials are recommending strict curbs on who can perform laparoscopic cholecystectomy.

An unpublished state health department memo, obtained by *AMN*, outlines a rigorous, unprecedented hospital credentialing process for surgeons who want to perform the increasingly popular procedure.

The draft memo also urges hospital boards to make sure they don't aggravate quality problems by credentialing too many surgeons for their institutions' case volume.

The voluntary recommendations, which were circulated to hospitals for

have raised doubts about the adequacy of surgery's self-regulated system for introducing new laparoscopic procedures (*AMN*, May 4). Leading surgeons charge that too many of their colleagues rushed to perform laparoscopic cholecystectomy without adequate training and experience, and that hospitals hungry for patients failed to control them.

In the last two years, laparoscopy has eclipsed the conventional open procedure to become the preferred way of doing the nation's 500,000 or more cholecystectomies annually.

The overall complication rate is similar for the two procedures. But the laparoscopic complications being seen are rarely found in open surgery, and studies indicate that surgeons doing

ment had found six deaths and a total of 158 injuries — 24 of them permanent or life-threatening — in 85 hospitals over the last 18 months. It estimated that half the complications were injuries to the common bile duct. Many of the rest were punctures to the aorta, inferior vena cava, hepatic artery, intestines, stomach and liver.

The department has cited at least five hospitals for deficiencies. It al

See *GALLBLADDER*, page .

NEWS

515 North State
Chicago, Ill. 60610

“...raised doubts about the adequacy of surgery's self-regulated system for introducing new laparoscopic procedures.”

“Those who cannot remember
the past are condemned to
repeat it”
-George Santayana

Laparoscopic Surgery

“What a Long, Strange Trip It’s Been”

□ Laparoscopic cholecystectomy:

- Pioneers 1985-1987-1988
- Widespread adoption 1990-92
- Prospective, randomized trials 1992 to the present

□ Other laparoscopic procedures:

‘Cowboy’ advances, 1990 on

LAPAROSCOPIC OLYMPICS



J. Ponsky

Laparoscopic Procedures

Accepted

- Cholecystectomy
- Antireflux Surgery
- Adrenalectomy
- Splenectomy
- Nephrectomy
- Ventral Hernia Repair
- Heller Myotomy
- Donor Nephrectomy
- Gastric Bypass
- Colectomy
- Appendectomy*
- Inguinal Hernia Repair*

Laparoscopic Procedures

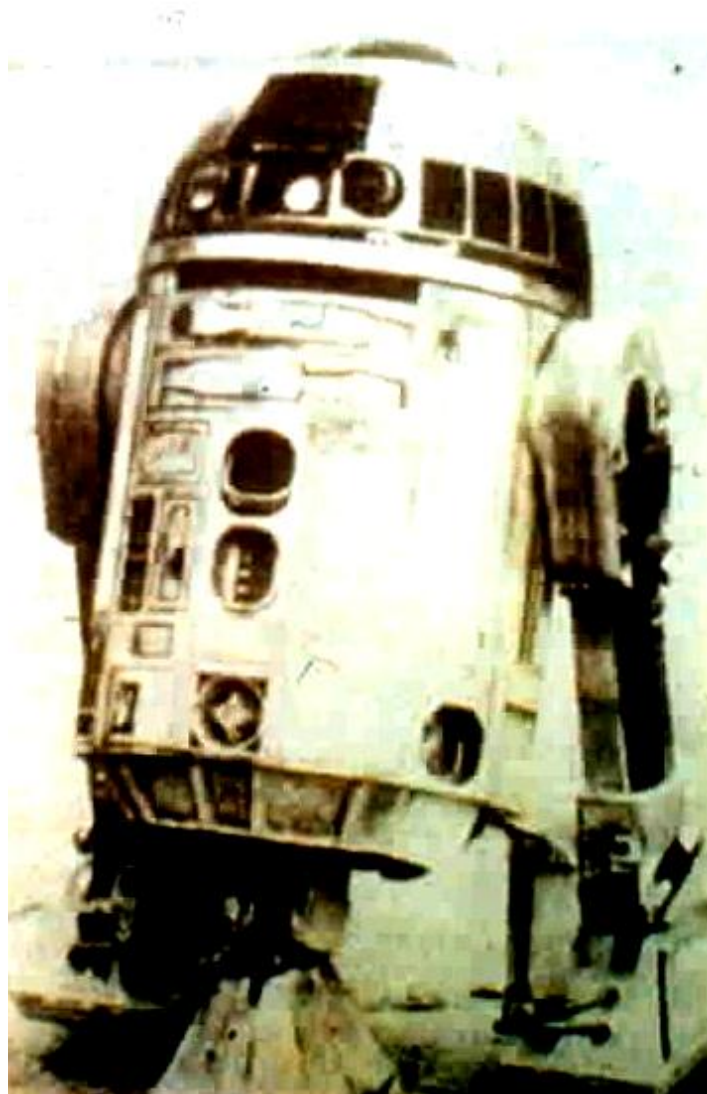
Early and/or Limited Application

- CBD Exploration
- Gastrectomy
- Liver resection
- Hepatic tumor ablation

Laparoscopic Procedures

New(er) Operations

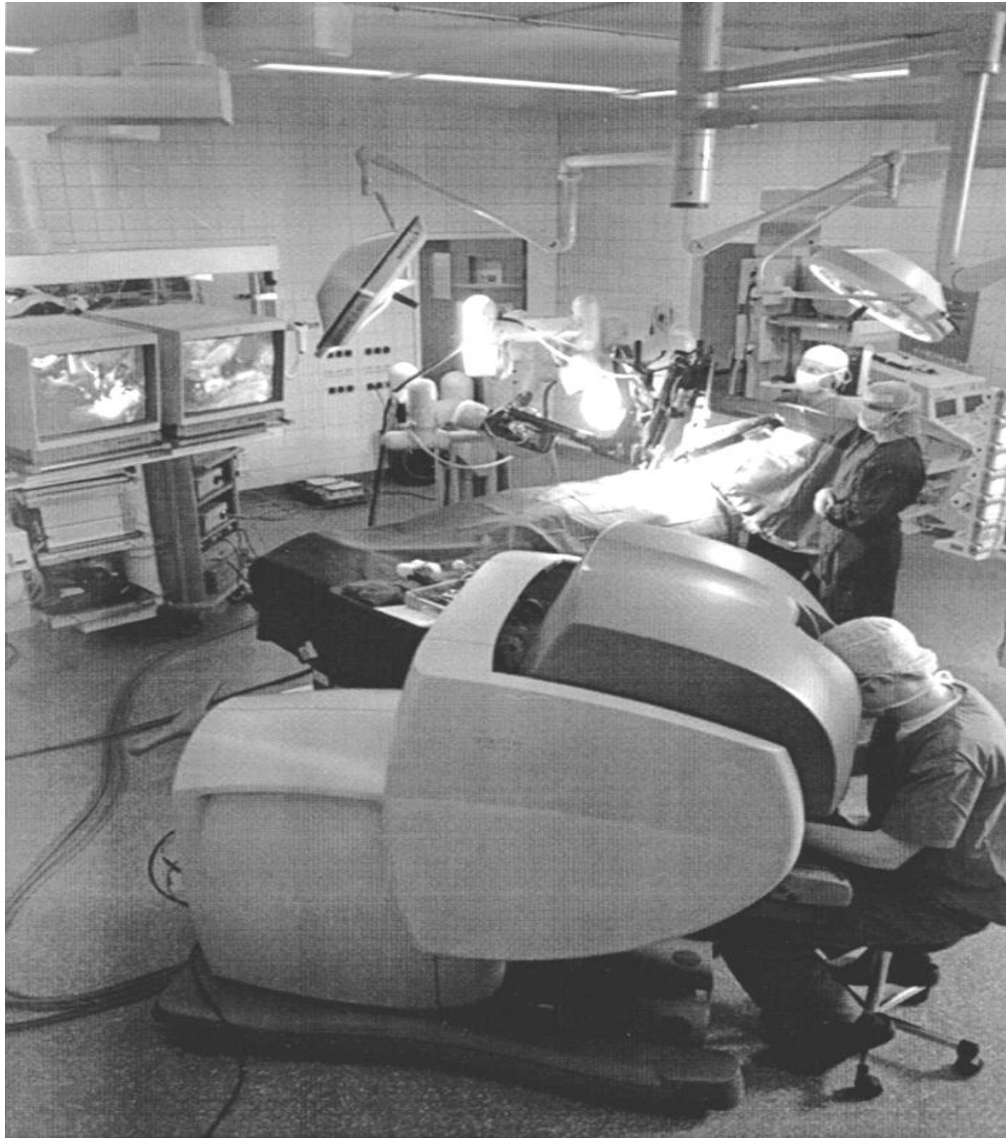
- Esophagectomy
- Esophageal Lengthening Procedures
- Rectal resection
- Pancreatic resection

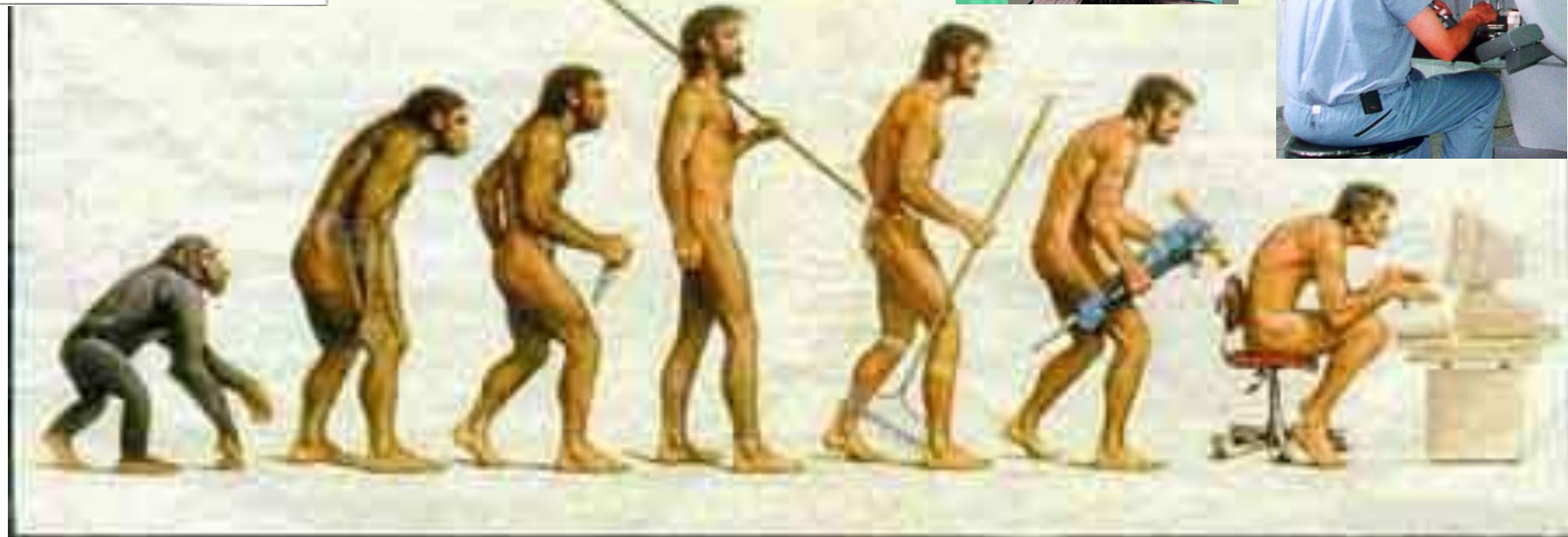
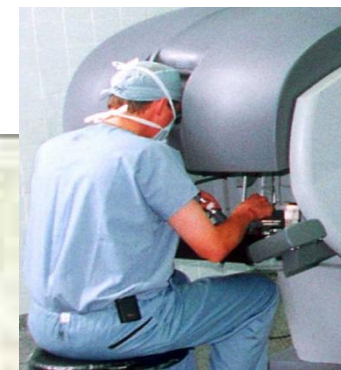
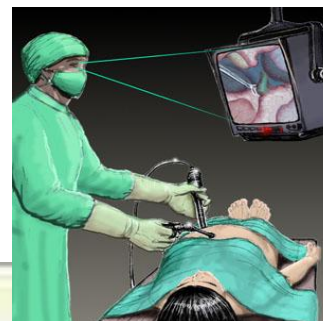


“Surgical Robotics” as currently practiced = computer interface between surgeon and patient

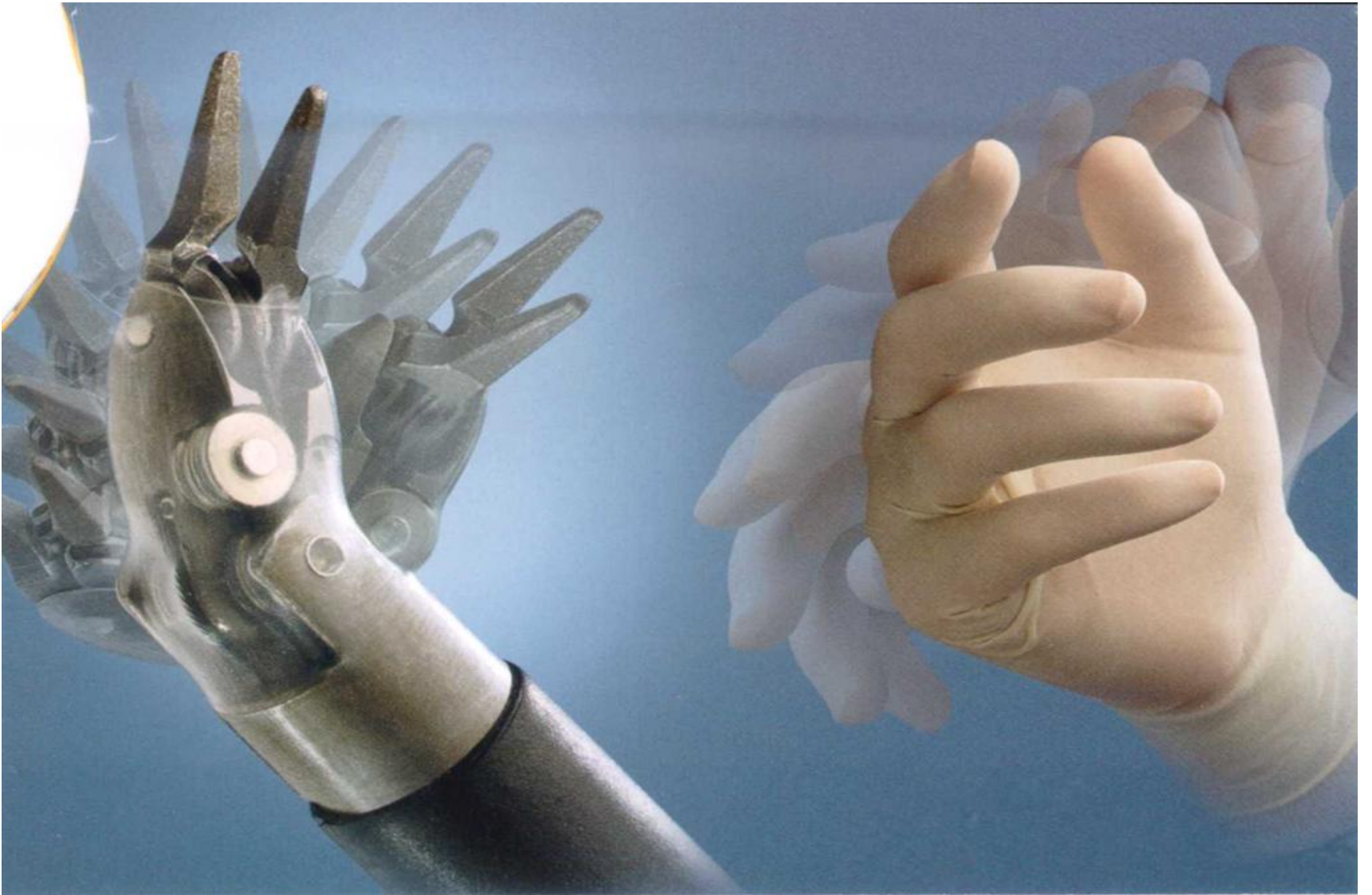
Computer-assisted (“Robotic”) Surgery

- Intuitive (DaVinci)
 - FDA approved for Gen Surg
 - Monopoly on market
 - Immersive 3-D, “wrist” articulation
 - Bulky, large ports
 - \$\$\$ (>2.5M USD purchase + FTE + disposables)





From T. Ponsky



Potential Advantages of Robotics in Surgery

- Improved dexterity
 - Tremor elimination
 - Motion scaling
 - ‘True’ motion of instruments
 - Articulation
- Better visualization
 - Surgeon directed optics
 - Stable visual field
 - 3-D vs 2-D visualization
- Enhanced ergonomics for the surgeon
- Telesurgery applications

Current Disadvantages to use of Robotics

- Absence of haptic (“tactile”) feedback
- Expense
 - Initial equipment expense
 - Per case disposables
 - Upkeep, personnel
- Complex, bulky equipment/few end effectors
- Steep learning curve
- Training and safety concerns
- Relative lack of General Surgical applications

Robotic Abdominal Surgery


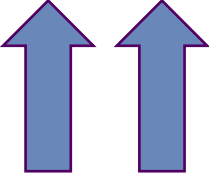
Current applications

- Esophageal myotomy/esophagectomy
- Gastric bypass in superobese
- Biliary and pancreatic reconstructive procedures
- Rectal resections
- Vascular bypasses
- Tubal reanastomosis
- Gyn-Onc resections*
- Radical prostatectomy***
- Partial nephrectomy

Clinical Experience With Robotic General Surgery

- ❑ Case series of computer-assisted surgery for laparoscopic Heller myotomy, fundoplication, cholecystectomy, donor nephrectomy, adrenalectomy, esophagectomy, etc.
- ❑ No evidence of improved outcomes
- ❑ Trans-continental laparoscopic cholecystectomy--Jacques Marescaux, M.D. in NYC, patient in Strasbourg, France
- ❑ Telesurgery to remote areas of Canada (M. Anvari)

Current Value of Robotic Surgery

Value = Quality 
Cost 
=unjustifiable for most general
surgery applications



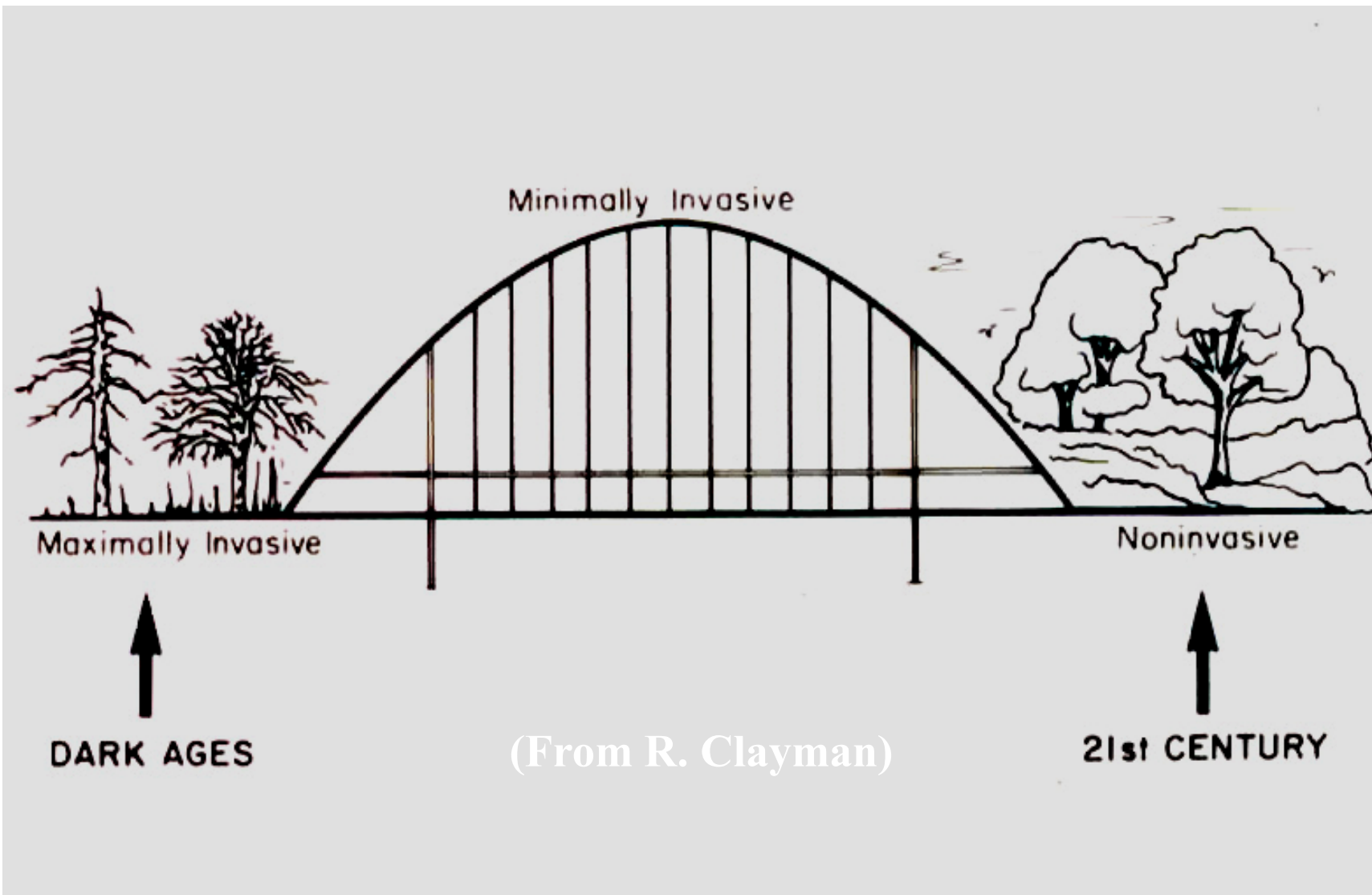
Robotics in General Surgery

Conclusions

- ❑ We are witnessing the infancy of this field; currently few documented advantages for GI surgical applications
- ❑ Numerous technical and financial impediments limit widespread application
- ❑ The potential advantages of robotic surgery compel further evaluation and application of computer-assisted technology in the O.R.
- ❑ Mini-robots may play a role in the future



A wireless endolumenal mobile robot like this could one day be used to assist in natural orifice procedures.



Surgery 'On the Cusp'

- Procedures via natural orifices
- Reduced port laparoscopy
- Other image-guided therapies

Endolumenal Procedures

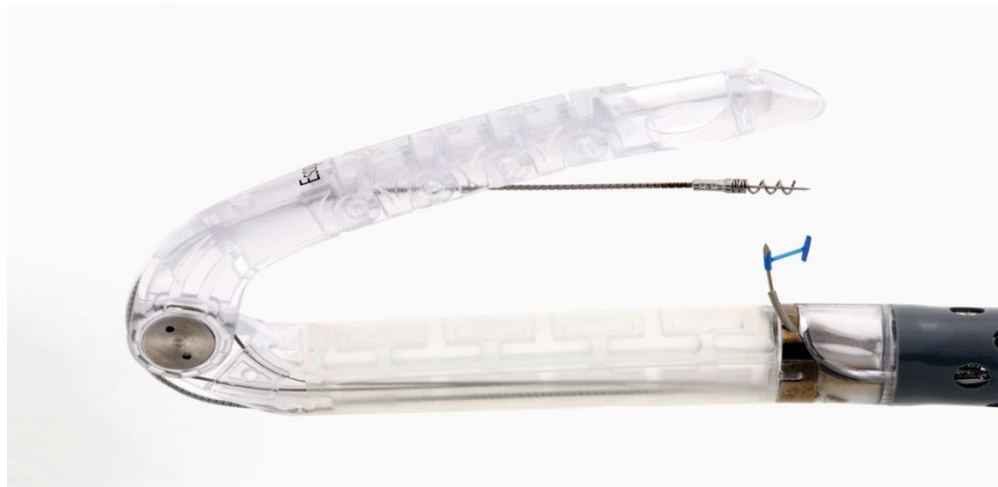
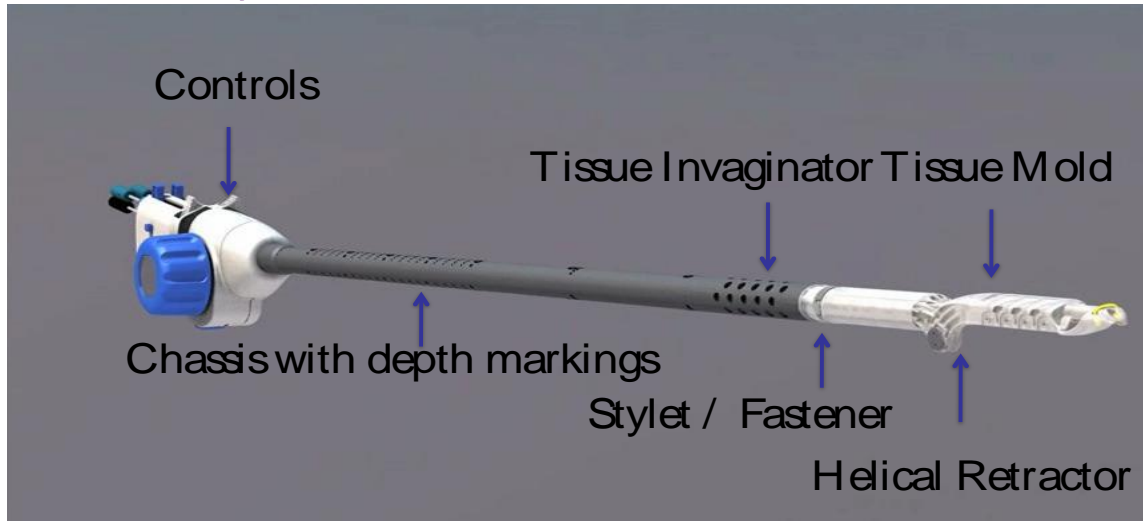
Antireflux Therapies:

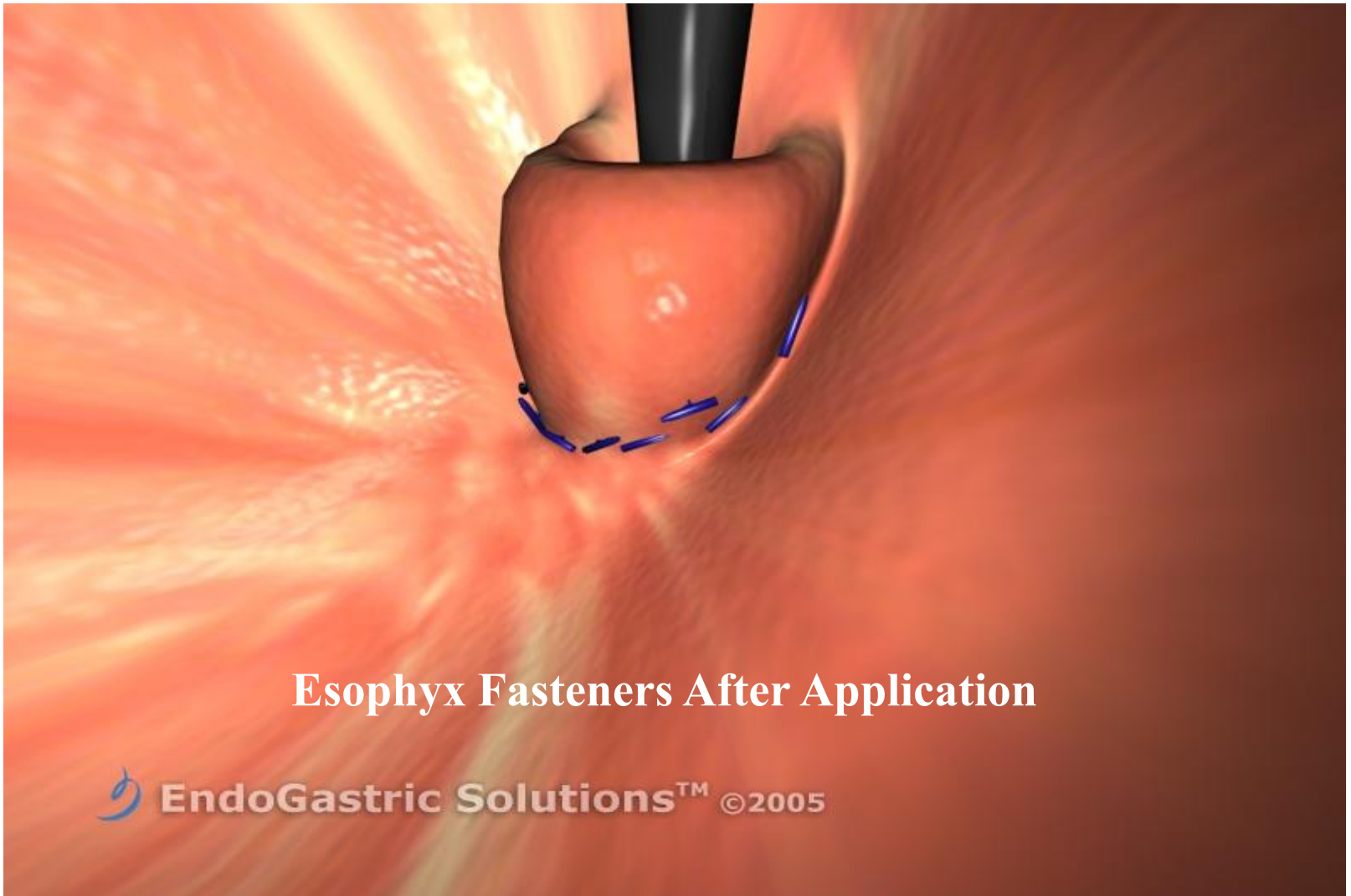
- FDA Approved
 - Stretta--submucosal RF heating--Bankrupt
 - Bard--sutured gastroplasty—Doesn't work
 - Enteryx--intramuscular injection of biopolymer--Withdrawn
 - NDO Plicator--full-thickness plication of GEJ
- Minimal clinical use--Bankrupt
 - Esophyx—trial at NU

EsophyX^R Transoral Incisionless Fundoplication (TIF)

- Endolumenal fundoplication
- Restores angle of His, creates full-thickness valve with polypropylene fasteners
- Phase II clinical trial in Europe
- Released by FDA 9/07
- Limited experience in U.S.—sham-controlled trial in progress

TIF—Esophyx Device





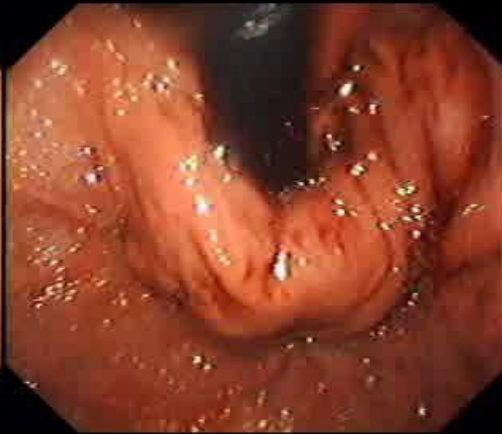
Esophyx Fasteners After Application

 EndoGastric Solutions™ ©2005

Endoluminal Fundoplication (ELF)



Pre-ELF



Post-ELF



4 week Post-ELF

Endolumenal Therapy (cont)

Upper GI

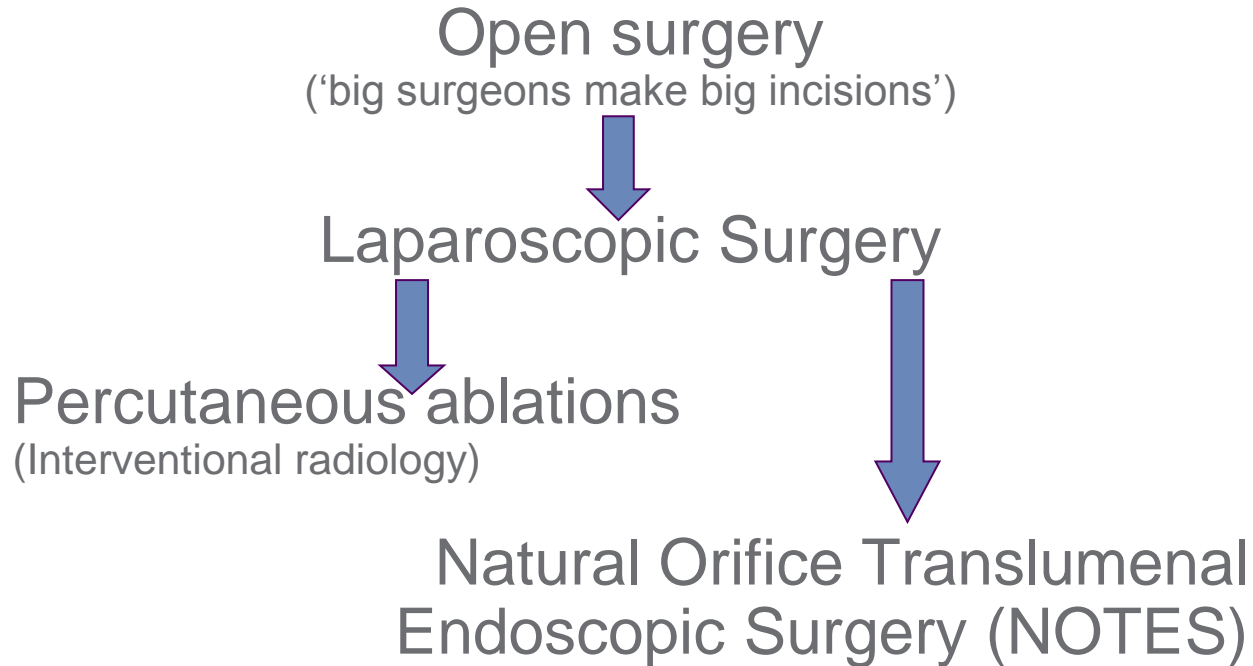
- Mucosal resections—now, full-thickness
- Ablative techniques for Barrett's**
- Endolumenal bariatric applications
- Endoscopic stapling/suturing

Trans-rectal

- TEM
- Endoscopic stapling

Natural Orifice Transluminal Endoscopic Surgery (NOTES)

Abdominal Surgery



HERMAN[®]



**“He took out my appendix and
I don’t even have a scar.”**

The NOTES Concept

- Enter body through natural orifice (mouth, anus, vagina, etc) with endoscope
- Exit mucosa of viscera
- Perform extra-luminal procedure
- Pull back into viscus and close visceral wall securely
- Remove scope from orifice

Trans-gastric NOTES

Kaloo 2004 – “Flexible transgastric peritoneoscopy: a novel approach to diagnostic and therapeutic interventions in the peritoneal cavity”

– Gastrointest Endosc 60(1): 114-7

Trans-vaginal Cholecystectomy

Tsin 2003 – “Culdolaparoscopy....can be used for exploration and operation in the abdominal cavity....(and) feasibility of a cholecystectomy..”

Tsin DA, Sequeria RL, Giannikas G. Culdolaparoscopic cholecystectomy during vaginal hysterectomy. *JSLs* 7(2): 171-2.

Why NOTES?

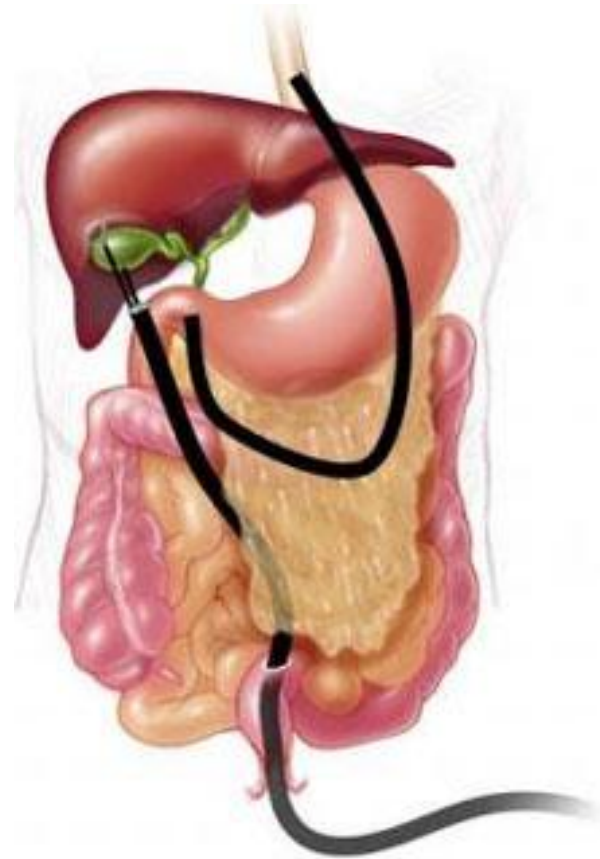
- Less invasive (?)
- Less pain
- Less tissue trauma
- Outpatient procedures—disruptive technology (?)
- Cosmesis
- Anticipated public demand for “incisionless” surgery

Possible Procedures--???

- Staging for cancer or pain
- Appendectomy
- Bowel resection
- Bariatrics
- GYN procedures
- Adhesiolysis
- Diaphragm pacing
- Cholecystectomy***
- Per-oral endoscopic myotomy (POEM)***

Natural Orifice Access Routes

- Trans-nasal
- Trans-aural
- Trans-oral**
 - Trans-esophageal
 - Trans-gastric (TG)
- Trans-vaginal (TV)**
- Trans-vesical
- Trans-anal*



NOTES Cholecystectomy

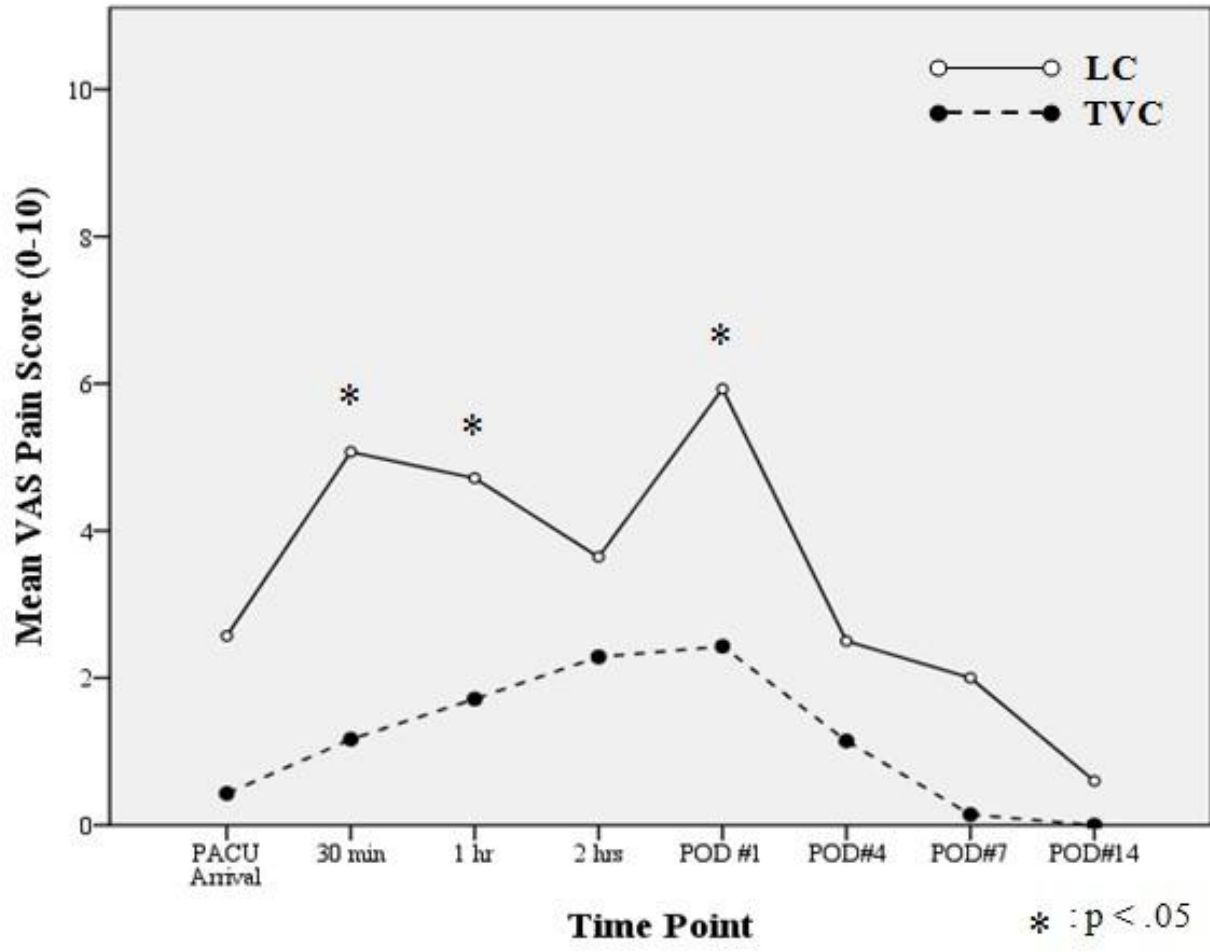
- Trans-gastric (TG)
 - Gastrotomy/closure
 - Retroflexed view
 - Remove GB/stones via esophagus
 - All 'hybrid' (lap-assisted) procedures to date
- Trans-vaginal (TV)
 - Vaginotomy/closure
 - Direct (in-line) view
 - Can use rigid and/or flexible instruments
 - Limited experience as true NOTES procedures
 - Only applicable to women

NU Hybrid NOTES™ Cholecystectomies: TG (4) vs TV (9)

- Operative time, 323 vs. 140 min*
- Access closure time, 63 vs 7 min*
- Length of stay, 52 vs 9 hrs*
- Pain pills, 4.5 vs. 0.3
- Complications, 1 vs 0

Standard LC vs. T-V Hybrid Chol'y

- ❑ 7 matched patients in each group, collected prospectively
- ❑ 4-port LC vs. T-V chol'y using single 5 mm umbilical port and flexible instruments
- ❑ OR time 68 vs. 162 min ($p < 0.05$); 6/7 in each group outpatient; no major complications
- ❑ VAS pain and narcotic use significantly less during first 24 hr. in T-V group
- Teitelbaum et al, Surg Endosc, in press



NOTES Results

- Largely unknown
- NOSCAR registry not widely used
- Many small published series, primary transvaginal
- Transgastric operations double or triple OR time; transvaginal procedures ~1.5 X
- Complications reported: gastrotomy bleeding, peritonitis, esophageal perforation, injury to bladder and rectum, inability to extract GB through esophagus*
 - 36% GBs unable to be pulled through standard overtube (Auyang, et al, Surg Endosc 2011)
- Most centers have stopped trials

They took out your gallbladder ... how?

'Natural orifice' surgery
has tongues wagging

Story by Rita Rubin, USA TODAY

Surgeons taking out gall bladders via mouth



Albert Pagliuca talks with Dr. Eric Hungness, who performed the operation with two other doctors. | THOMAS DELANY JR./SUN-TIMES

NORTHWESTERN | Aim is to reduce pain, eliminate scars

BY JIM RITTER
Health Reporter/
jritter@suntimes.com

Northwestern Memorial Hospital surgeons used an unusual new technique to remove Albert Pagliuca's gall bladder: They pulled it out through his mouth.

Surgeons inserted thin surgical instruments down Pagliuca's throat to his stomach, then cut through the stomach wall to reach his gall bladder.

Pagliuca, 44, went home the next day.

He said he felt some abdominal discomfort, "but nothing like I thought it would be." After two days, he stopped taking pain pills.

Northwestern is among several hospitals pioneering surgery through the mouth, vagina or anus to reach the gall bladder and perhaps other internal organs.

The goal is to eliminate incisions and scars, reduce pain and speed recovery.

Pagliuca is among the 700,000 Americans who have gall bladders removed each year because of gallstones. The organ is shaped like a pear, but smaller.

Surgeons typically use minimally invasive laparoscopic techniques to remove gall bladders. While these techniques are less painful than traditional open surgery, they still cut through abdominal muscles and leave several small scars.

Using the natural-opening technique, Northwestern surgeons reached Pagliuca's abdominal cavity by cutting a one-inch hole in his stomach wall.

Doctors hope this surgery will hurt less because the stomach has few pain nerves.

But if surgeons don't properly close the hole, stomach

juices could leak out, causing a life-threatening inflammation.

"We're all acutely aware of the potential downsides of these operations," said Dr. Nathaniel Soper, who performed Pagliuca's operation along with Dr. Eric Hungness and Dr. John Martin.

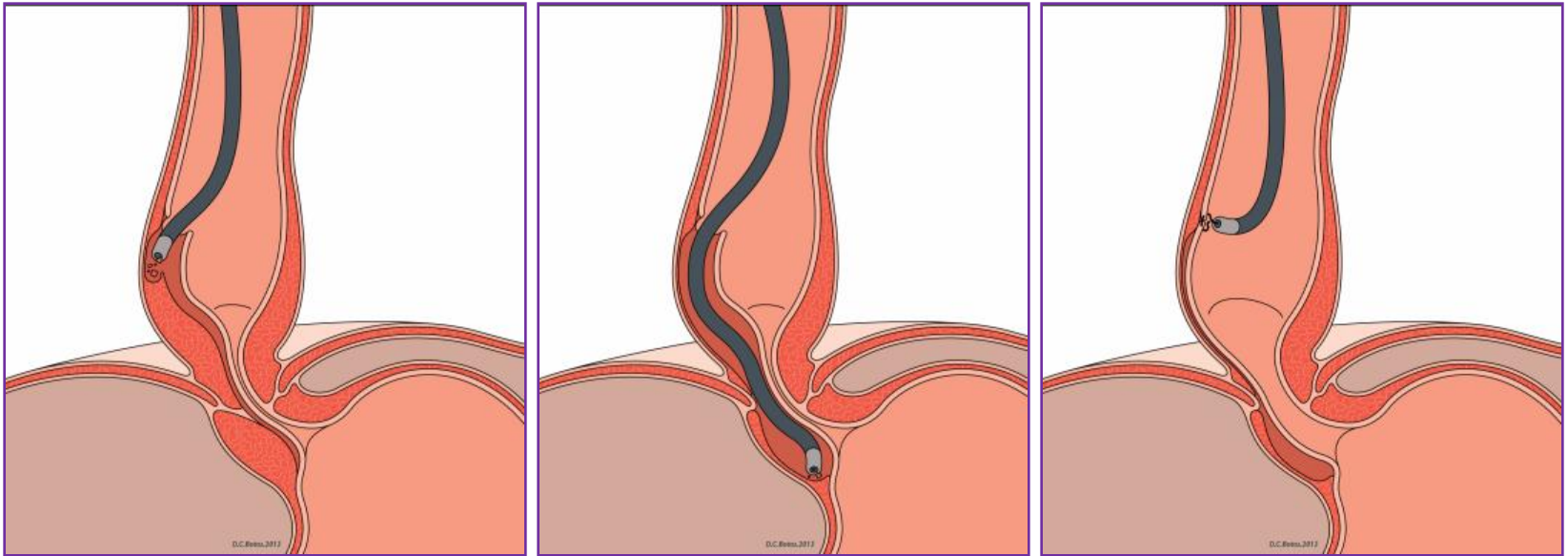
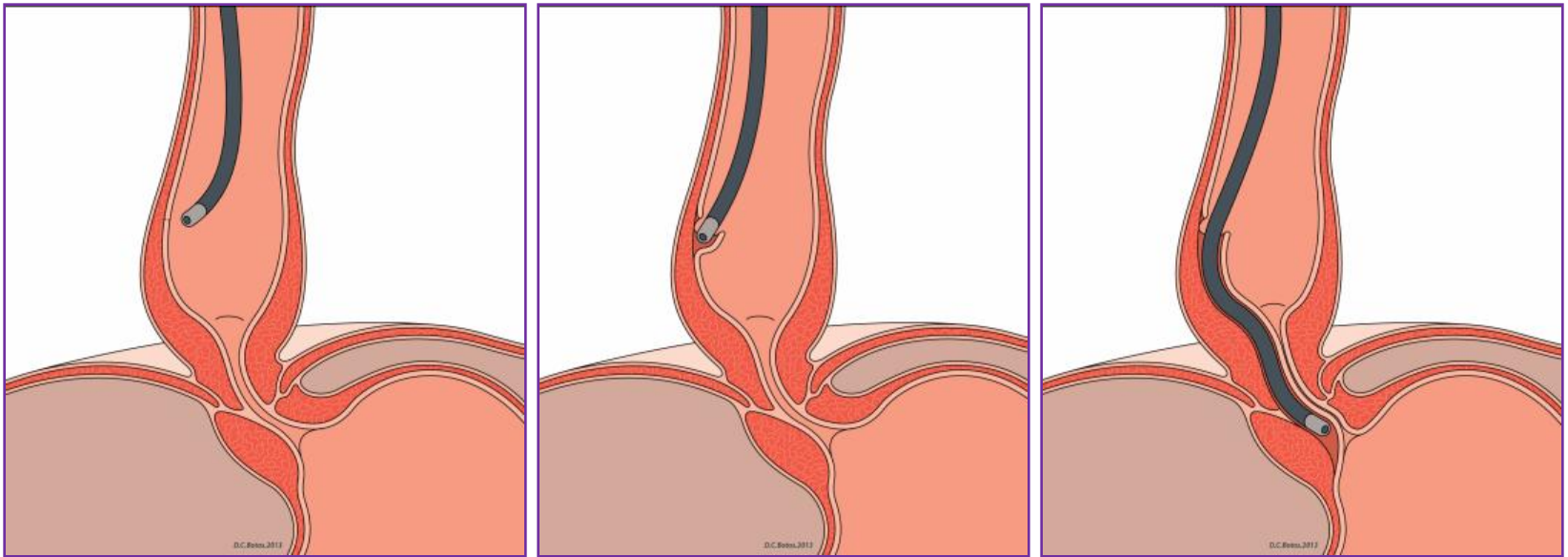
Using a different natural opening, Columbia University surgeons removed a woman's gall bladder by entering her vagina and then cutting through the vaginal wall.

A third technique is to go through the anus and cut through the colon wall. Northwestern is testing this method on pigs and cadavers.

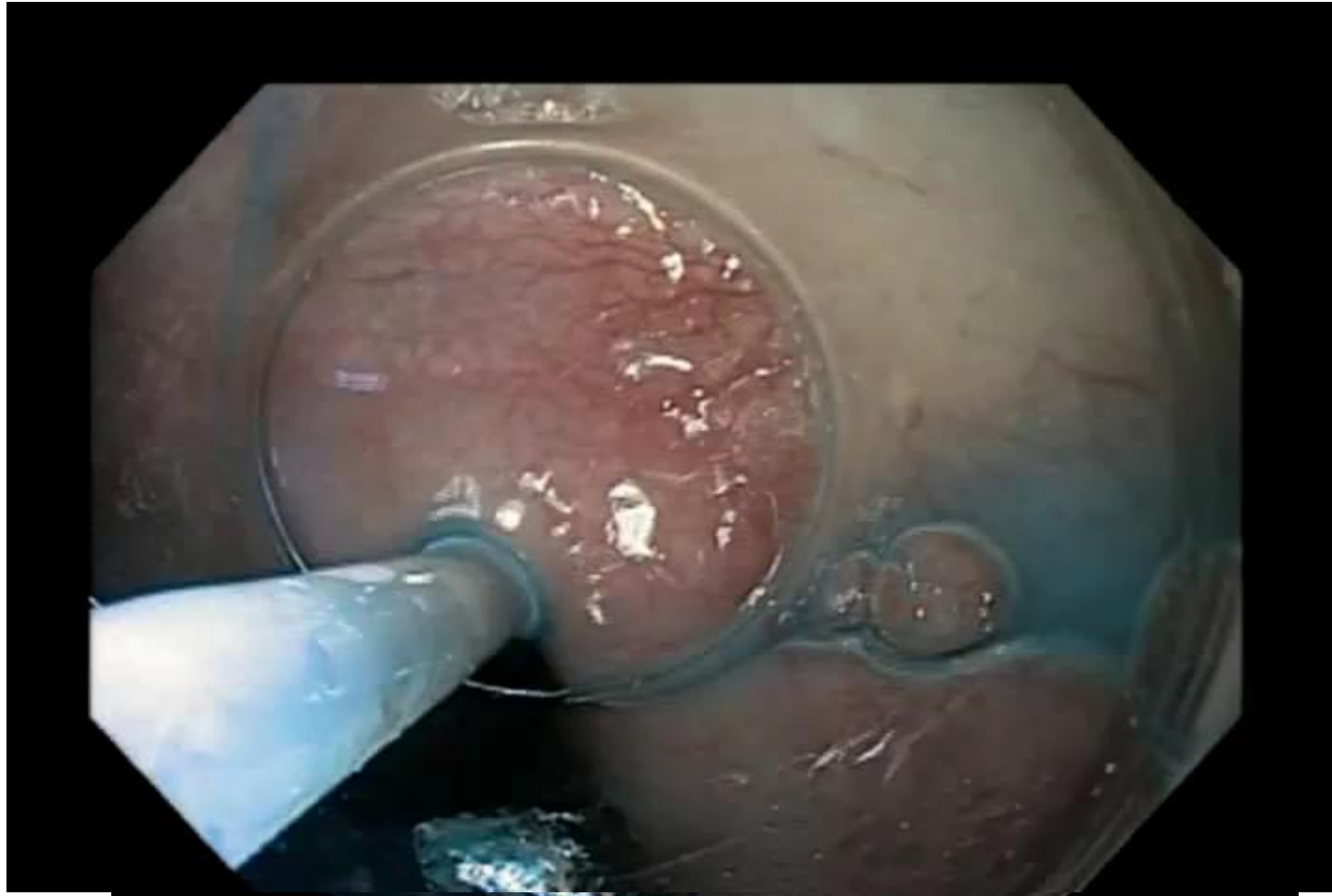
In a recent survey of about 250 patients at Northwestern and the Oregon Clinic, about 60 percent said they would prefer natural-opening surgery to current techniques.

Chicago Sun-Times 9/07

Northwestern Medicine™



POEM video



POEM Results

Thousands performed in Shanghai, Yokohama, etc.

>130 performed at NM

Publications on learning curve, perioperative results, one-year outcomes

Equivalent perioperative outcomes to Heller myotomy

~4% failure rate at one year (learning curve)

~30% rate of GERD at one year

Most patients coming to our center now demand
POEM

Hungness, Teitelbaum, Soper, et al, multiple publications

Hindrances to NOTES' Expansion

- Cost/payment considerations
- Potential issues with FDA— 'off-label use of endoscopic equipment'
- Patient safety concerns
- Lack of 'buy-in' by patients and referring physicians
- Need for better instrumentation

It's a kinder cut for patients

Surgery offers less scarring

By Rita Rubin
USA TODAY

"No-scar" abdominal surgery is one of the hottest topics of discussion when surgeons or gastroenterologists meet these days.

Instead of entering the abdomen through an incision in the skin, doctors who perform this type of operation enter the body through one of its natural openings — usually the mouth — and then make an incision internally to reach their destination.

The procedure is a cross between

endoscopy and surgery.

To reach the abdomen by way of the mouth, for example, doctors must snake an endoscope, or lighted tube, down the esophagus and into the stomach.

Working through the endoscope, doctors then make a small incision in the stomach so they can get out to other organs in the abdominal cavity.

Proponents say this "natural orifice" approach, still in its infancy, could revolutionize surgery, the way laparoscopic or "keyhole" surgery did 20 years ago. Besides leaving no visible scar, they say, the technique promises to reduce pain and recovery time.

But they express concern that some ill-prepared doctors and hospitals might embrace the technique for marketing purposes rather than for medical reasons.

They point to the rush to perform laparoscopic surgery, which led to scores of injuries and at least seven deaths in New York alone in the early 1990s. That led the state's health department to take the unprecedented step of setting criteria for surgeons to meet before allowing them to perform the procedure unsupervised.

"It's a little bit alarming to see how many courses are cropping up" for no-scar surgery, says surgeon Lee Swanstrom of the Oregon Clinic in Portland.

Swanstrom, who in May became the first U.S. doctor to remove a patient's gallbladder through her mouth, says he has been invited to speak at eight courses in the next six months.

He says he was upset to learn that an Italian doctor and a Greek doctor who attended a course in Europe recently

began operating on humans with minimal practice on animals beforehand.

So far, Swanstrom estimates, only dozens of patients worldwide have had no-scar surgery.

Three of the patients were his, all of them women whose gallbladders were removed through their mouths, while two others in New York had theirs taken out through their vaginas.

"The progress has been astonishing," says David Rattner, a Massachusetts General Hospital surgeon in Boston who has performed no-scar surgery only in pigs.

At an international conference in March 2006, Rattner says, attendees figured they were three years away from trying the approach in patients.

Still, Rattner says, "we just don't want people to go and do this on a whim."

On the Road to Transluminal Misadventure: NOTES



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It is safe to say that most of the readership of *General Surgery News* has successfully weathered the revolutionary changes brought about by minimal-access surgery through the use of laparoscopic instrumentation in the abdomen and thoracoscopic applications in the chest. Since the mid- to late 1980s, laparoscopy has completely revamped our thoughts regarding surgical approaches and has, to a degree, limited the opportunities for "traditional" open surgery that many initially experienced and perfected in their training. The important issue throughout the laparoscopic revolution has been the introduction and application of new technologies and operations utilizing the same principles of wound care and surgical management traditionally followed for decades during the "open" era.

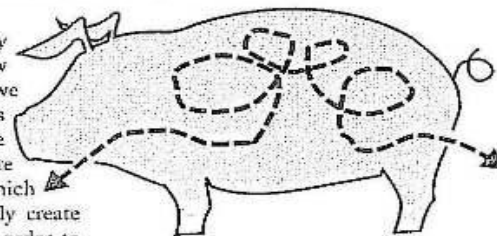
The same excitement that accompanied developments in laparoscopy appears evident in the recent interest and

various dialogues concerning natural orifice transluminal endoscopic surgery (NOTES). The use of the flexible endoscope to accomplish certain abdominal and thoracic interventions by transgressing the walls of various organs has led to a greater awareness and understanding of the importance of flexible endoscopy in surgical practice. For this I am grateful because throughout my career I have encouraged the concept that surgeons must stay involved in surgical endoscopy, and that we must mandate adequate training of flexible gastrointestinal (GI) endoscopic procedures in our residency programs. The Residency Review Committee for Surgery and the American Board of Surgery have certainly embraced this concept and for that we should be thankful. Endoscopic evaluations of the GI tract began with surgeons, and should continue to be strongly advocated in the surgical community.

Although I should be extremely pleased that the concept of NOTES creates more opportunities for surgical use of the flexible endoscope, I am quite concerned about the apparent disregard of basic surgical principles these techniques engender. Each day in our open and laparoscopic approaches we judi-

ciously attempt to avoid injury to the GI tract or other hollow viscera. Certainly, as surgeons, we recognize the dire consequences that even small leaks will create in our patients. It seems absolute folly to embrace concepts in which flexible endoscopes intentionally create perforations in the GI tract in order to remove diseased organs that can be safely extirpated through transabdominal approaches using minimal incisions. Should we launch upon this concept merely to avoid an incision (no matter how small) in the abdominal wall?

Although I am pleased that the concept of NOTES has created a greater bonding between the gastroenterologists and surgeons who see this as a potential "team sport," I fear that rogue gastroenterologists will interpret the NOTES philosophy as a "green light" to unilaterally undertake transluminal cholecystectomy, appendectomy and who knows what! In the early phase of the laparoscopic era we were challenged by a group of gastroenterologists, versed in laparoscopic diagnostic techniques, who were determined to remove gallbladders. Early privileging and credentialing strategies appropriately suggested that only those who can take



It seems absolute folly to embrace concepts in which flexible endoscopes intentionally create perforations in the GI tract in order to remove diseased organs that can be safely extirpated through transabdominal approaches using minimal incisions.

care of the complications created during laparoscopic procedures, and who had appropriate surgical training should

▶ see NOTES, page 4

Summary: NOTES 2015

- Limited clinical experience—majority ‘hybrid’
- Most centers have discontinued NOTES cholecystectomies
- Increasing interest in trans-anal procedures
- POEM procedure promising and may be the primary result of the NOTES investigations

Spin-offs

- Single incision laparoscopic surgery
 - SILS, SPA, OPUS, etc., etc.
 - In-line dissection; many instruments expensive; concern re: injuries occurring as a result of novel dissection and retraction techniques*
 - *Joseph, et al, Ann Surg 2012



Other 'Spin-Offs'

- ❑ Microlaparoscopy
- ❑ Advanced endolumenal techniques
- ❑ TEM, transrectal procedures

Future Prognostication



“We don’t like their sound, and guitar music is on the way out.”

- Decca Recording Co. executive, on rejecting the Beatles, 1962

MIS: What's Ahead

- Single incision laparoscopy—coupled with robotics?
- Return of 'needle-oscopy'
- Simulators for skill acquisition and improvement
- Computerized preoperative planning with intraoperative image registration to allow focused therapy (CT, MR, U/S, etc)
- Endoluminal procedures (bariatrics)

MIS: What's Ahead

Advanced technology application

- Purpose-built robotic systems that are smaller and cheaper
- ? Use of micro-robots
- Sense-enhancement (haptics, etc.)
- Ability to overlay alternative 'views' over visual field (scintigraphic, infrared, etc)
- Widespread telematics applications--
intraoperative consultations, etc.

MIS: What's Ahead

No-incision surgery

- Improved endolumenal techniques
- Blurring of intraluminal/extraluminal abdominal procedures
- New training paradigms for 'GI Interventionists'—GI surgeons clearly need to embrace flexible endoscopy!
- Further development and clinical application of NOTES
- Widespread application of “trackless” ablative procedures

“We can anticipate a day when
surgery can be done without a
knife or a hole”

-John Hunter, 1790

“Surgery is moving from knife, to
cannula, to needle.....
to nothing.”

--Ralph V. Clayman, 2000