

Women's Health, Session II: Building/Marketing Efficient Networks for Minimally Invasive Surgical Procedures

Thursday, April 22, 2010

1:00 p.m. – 2:00 p.m. ET

Dial in: 888-872-2155, participant 182018#

Press *6 to mute and unmute your phone line for questions and comments.

Welcome and Introductions

Presenters:

- Dr. Gerald Scallion, Medical Director at Aetna
- Steven D. Schwaitzberg, MD FACS, Chief of Surgery, Cambridge Health Alliance
- Frank Loffer, MD Medical Director of the American Association of Gynecologic Laparoscopy

FLS Sets Competency Criteria

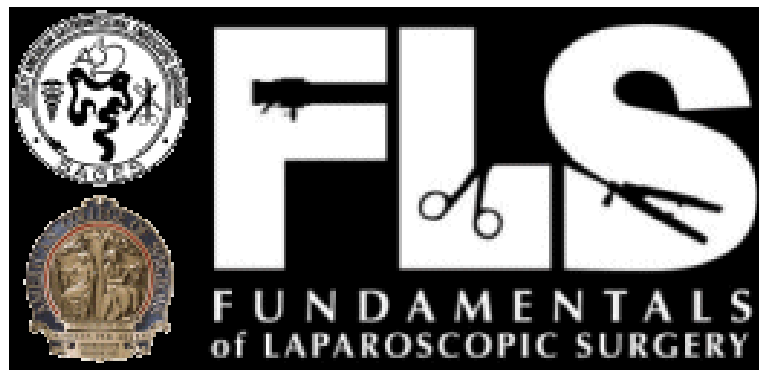
S D Schwartzberg, MD FACS

Chief of Surgery

Cambridge Health Alliance

Associate Professor

Harvard Medical School



What was (is) the case for FLS?

- 1990s
 - Void to be filled
 - Inconsistent training pathway for most surgeons
 - Limited residency curriculum “hit or miss”
 - Unique anatomic, physiologic and skills germane to laparoscopic surgery
 - Little or no standardized skills training

Top Gun

- Brainchild of James “Butch Rosser”
- Data set with over 5000 surgeons
 - Extending into lay public/kids
- Resident competitions
- Fundamental skills designed to prepare surgeons to suture in MIS
 - Pea drop
 - Cobra rope
 - Terrible triangles



Ahead of its time

- The first Top Gun Laparoscopic Skill and Suturing Program was held in 1992 on the island of Aruba, sponsored by the Academic Medical Center in Amsterdam, Holland. The 20 participants representing 8 countries could not tie an intracorporeal knot within 10 minutes at the beginning of the course, and all could perform the task in less than 2 minutes at the end of the course.

The real start

- Summer 1997
 - Working Group –
 - Hunter, Peters, Swanstrom, Schwaitzberg, Soper Ponsky, Schirmer and others
 - Mission, Vision
 - Standard “ATLS-like”
 - Cognitive and psychomotor skills
 - Measurable & validated
 - High stakes exam
 - Surgeon exam
 - FLS was born

Refinement by FLS Taskforce

- The overall goal of the FLS program was to “teach a standard set of cognitive and psychomotor skills to practitioners of laparoscopic surgery” in the belief that knowledge and application of these fundamentals would help “ensure a minimal standard of care for all patients undergoing laparoscopic surgery.” Peters et al 2004
- Comprehensive coverage of the of basic laparoscopy
 - cognitive (declarative knowledge);
 - psychomotor (procedural skill).

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Refinement by FLS Taskforce

- Educational material unique to laparoscopy and not on material normally encountered during open surgical training.
- Content specific to a particular anatomic location or to a specific laparoscopic procedure was to be avoided.
- Mechanisms for assessment as well as for didactic instruction.
 - Cognitive exam
 - Skills testing
 - FLS courses

Process

- How did ATLS become the de facto competency standard in trauma beginning in the 1980s?

Choices

- The ACS organized a working group and developed ATLS
- A few guys in Iowa cooked this up and sold the idea to the ACS
- The ATLS developed it and partnered with the much larger ACS to market it.

First steps: Chapter Creation

Chapter material was created by:

George Berci
Desmond Burkett
David Easter
David Edelman
Dennis Fowler
Paul Hansen
William Laycock
Tamara Newman
David Rattner
Jonathan Sackier
Bruce Schirmer
Steve Schweitzberg
Nathaniel Soper
Lee Swanstrom
Zoltan Szabo
Thaddeus Trus

with a goal to make it as generic fundamental as possible

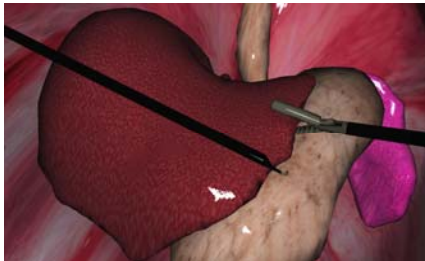
We were definitely Rookies

- Chapters were written
 - This was the easiest part!!!!!!!
- We had no idea how hard it would be to write a *good* high stakes exam

We engaged a Professional Educator: Kaaren Hoffman, PhD who led item writing sessions all over the country

Meanwhile back at the Ranch

- Psychomotor Assessment
- “Simulator Fair” At 2002 SAGES meeting
 - VR?
 - Box?
 - What skills?
 - How costly?



In the End

- VR was too expensive and procedure oriented
- Carl Wescott, MD had created a simple trainer with self contained light source and Inexpensive video camera.



What Skills?

- 1996 Gerry Fried (McGill) Developed a set of training tasks for a laparoscopic simulator
- Funding by then US Surgical (AutoSuture Canada)
- Selected by FLS Committee
- Agreements with McGill and Autosuture made

MISTELS Trainer

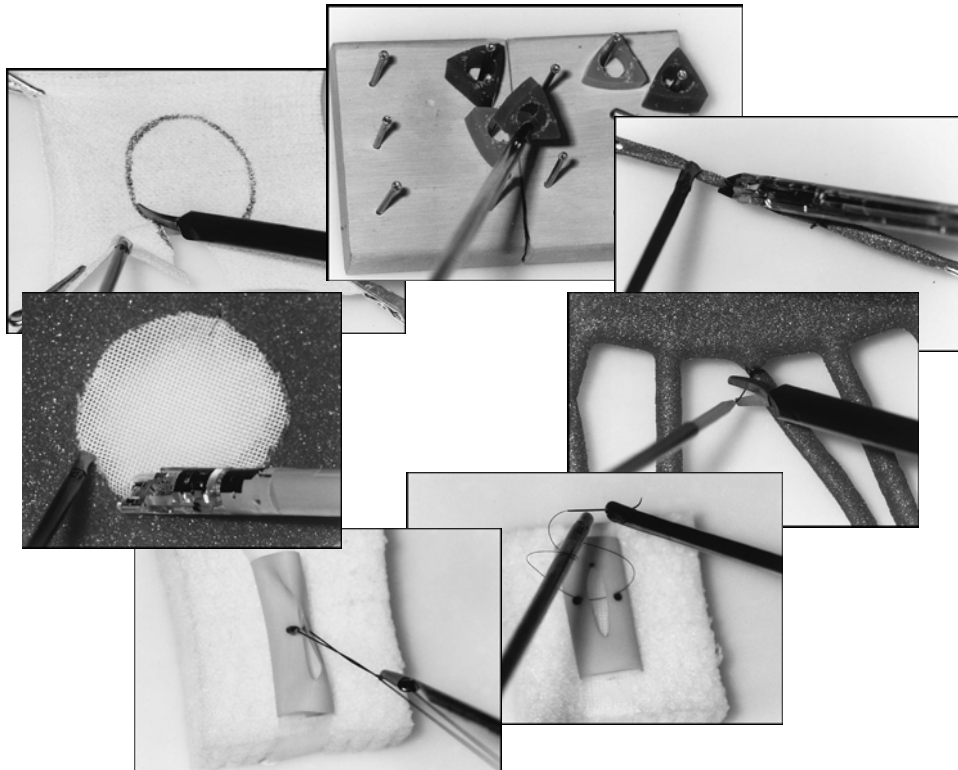
McGill Inanimate System for Training and Evaluation of Laparoscopic Skills

Scores were based on

- Time (speed)
- Errors (precision)

7Tasks

- ❖ Pegboard patterns
- ❖ Pattern Cutting
- ❖ Clip Application
- ❖ Place Ligating Loop
- ❖ Mesh Placement
- ❖ Intracorporeal knot
- ❖ Extracorporeal Knot



What did the initial studies show?

LAPAROSCOPY

Development of a Model for Training and Evaluation of Laparoscopic Skills

Anna M. Derossis, MD, Gerald M. Fried, MD, Michal Abrahamowicz, PhD, Harvey H. Sigman, MD, Jeffrey S. Barkun, MD, Jonathan L. Meakins, MD, *Montreal, Quebec, Canada*

BACKGROUND: Interest in the training and evaluation of laparoscopic skills is extending beyond the realm of the operating room to the use of laparoscopic simulators. The purpose of this study was to develop a series of structured tasks to objectively measure laparoscopic skills. This model was then used to test for the effects of level of training and practice on performance.

METHODS: Forty-two subjects (6 each of surgical residents PGY1 to PGY5, 6 surgeons who practice laparoscopy and 6 who do not) were evalu-

nificant difference in performance scores between laparoscopic and nonlaparoscopic surgeons was seen for tasks 1, 2, and 6.

CONCLUSIONS: A model was developed to evaluate laparoscopic skills. Construct validity was demonstrated by measuring significant improvement in performance with increasing residency training, and with practice. Further validation will require correlation of performance in the model with skill in vivo. *Am J Surg.* 1998;175:482-487. © 1998 by Excerpta Medica, Inc.

- Predictors of Performance

- PGY level $p=.002$
- Repetition $p<.0001$
- PGY level +training $p=.006$

Comparison of laparoscopic performance in vivo with performance measured in a laparoscopic simulator

G. M. Fried,¹ A. M. Derossis,² J. Bothwell,² H. H. Sigman²

¹Division of General Surgery, Montreal General Hospital, 1650 Cedar Avenue, Room L 9-412, Montreal, Quebec H3G 1A4, Canada

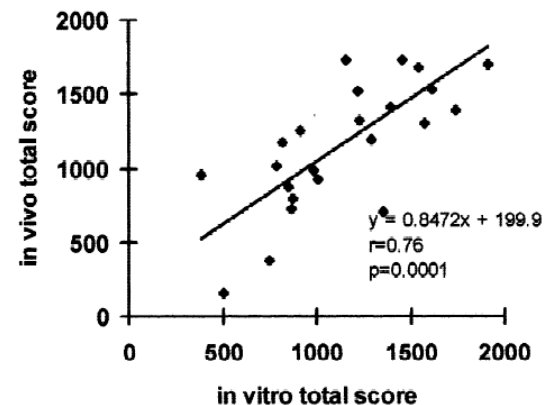
²Division of General Surgery, McGill University, Montreal, Quebec, Canada

- 12 PGY 3
- Baseline MISTELS and in vivo studies
- Tasks similar
- 2 Groups Practice vs No practice



Results

**Performance Improved with Repetition (Group A)
In vivo score correlated MISTELS SCORE**





and Other Interventional Techniques

Evaluating laparoscopic skills

Setting the pass/fail score for the MISTELS system

S. A. Fraser, D. R. Klassen, L. S. Feldman, G. A. Ghitulescu, D. Stanbridge, G. M. Fried

Steinberg-Bernstein Centre for Minimally Invasive Surgery, McGill University, Montreal, Canada

Received: 18 November 2002/Accepted: 21 November 2002/Online publication: 28 March 2003

165 surgeons divided in three groups

83 novices (noncompetent group)

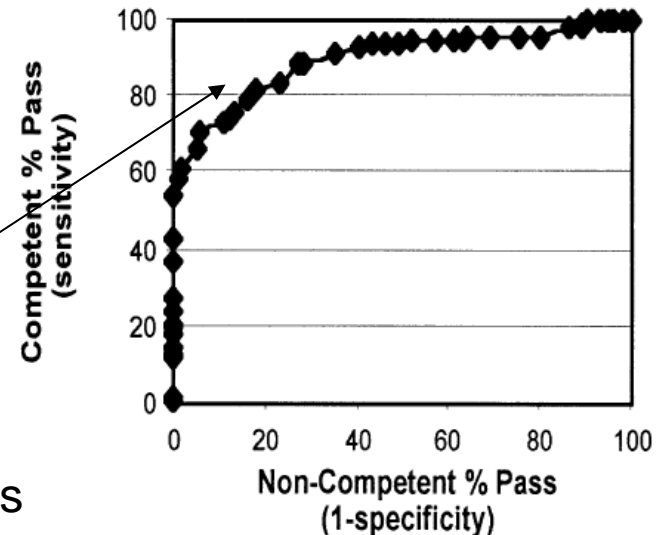
82 Chief Residents/Fellows/laparoscopists

7 tasks reduced to 5 with highest correlation
eliminate Clipping/Mesh Placement
high equipment requirement

Score = 270

18% of NC Pass

82 % of Competent Pass



MISTELS

- Selected because
 - Scores Improve with Repetition
 - Correlates with Training
 - Correlates with In vivo Scores
 - Pass/ Fail Score validated

- Construct Validity -the degree to which a test measures what it claims, or purports, to be measuring"

Next few years

- Prototype Trainer Boxes
- Three years item writing
- Beta Site testing



Beta Test Results of a New System Assessing Competence in Laparoscopic Surgery

Lee L Swanstrom, MD, FACS, Gerald M Fried, MD, FRCS, FACS, Kaaren I Hoffman, PhD,
Nathaniel J Soper, MD, FACS

-
- BACKGROUND:** There is currently a need for objective measures of surgical competence. Such measures should assess knowledge, judgment, and manual skills. The Fundamentals of Laparoscopic Surgery (FLS) program was developed by the Society of American Gastrointestinal and Endoscopic Surgeons to meet these criteria. The FLS assessment includes a multiple-choice cognitive test and a manual skills test. We present the results of validation studies of this novel assessment tool.
- STUDY DESIGN:** Beta testing of the FLS examination was undertaken at 7 sites by 70 surgeons representing 4 levels of experience and training. Surgeons provided information about their prior experience and indicated a self-assessment of their laparoscopic competence. Results were assessed by ANOVA followed by orthogonal contrasts.
- RESULTS:** Cognitive performance by training level: There was no difference between fellows and staff in

70 participants
4 levels of experience
PGY 2, PGY 5 Fellows, Staff
Cognitive/Skills Testing
Cognitive Test 2 Forms

Training Levels

Training level	Cognitive (n = 65)			Manual skills (n = 58)		
	n	Mean	SD	n	Mean	SD
2nd Year	28	65.12	7.74	24	45.50	25.01
5th Year	18	73.98	10.01	16	70.00	10.28
Laparoscopic fellows	6	83.91	3.46	7	78.71	14.47
Laparoscopic surgeons (staff)	13	81.25	11.48	11	68.91	15.68
Fellows and surgeons*	19	82.09	9.63	18	72.72	15.58

Experience Levels

Experience quartiles	Cognitive skills			Manual skills		
	n	Mean	SD	n	Mean	SD
First	15	64.19	7.32	11	36.64	27.13
Second	12	71.49	9.80	13	57.77	17.38
Third	14	75.81	7.43	10	74.10	9.65
Fourth	13	85.98	5.54	14	74.57	12.97

Beta Test Results

- Significant Differences
- Jr residents vs Sr/Fellows/Staff $p < .01$
- Lowest 2 vs high 2 quartiles $p < .0001$
experience
- Face validity
- Construct Validity demonstrated

FLS Assessment of Competency Using Simulated Laparoscopic Tasks

Gerald M. Fried

Abstract Fundamentals of Laparoscopic Surgery (FLS) is a program of SAGES and the American College of Surgeons designed to teach and evaluate the knowledge, judgment, and skills fundamental to laparoscopic surgery independent of the

- Reliable – inter-rater reliability .998
- Content & face validity – questionnaires of experts
- Construct validity – demonstrated difference between truly differing groups
- Criterion Validity predicted performance during in vivo performance



- Partnership established with ACS
- Only validated cognitive & psychomotor program in surgery with high stakes examination
- Beta testing in Urology and Gynecology

Recent Accomplishments

- CRICO/RMF launches landmark SAGES/ACS Fundamentals of Laparoscopic Surgery Patient Safety Incentive Program
- The Association of Program Directors in Surgery (APDS) recently came on board to support FLS Committee to improve resident education. "What Surgical Educators Need to Know: Laparoscopic Skills Training Using FLS and the National Skills Curriculum" on Tuesday, April 15, 2008.
- The National Capital Area Medical Simulation Center of the Uniformed Services University of the Health Sciences (USUHS) is embarking on a project to improve skills, communication and patient safety in minimally invasive surgery by introducing the FLS curriculum to all military hospitals with surgical training programs
- Adopted by Royal College of Surgeons in Australia
- American Board of Surgery REQUIRES FLS before sitting for exam
- FLS 2.0 coming soon.....

Advancing Minimally Invasive Gynecology



Franklin D. Loffer, M.D.

Associate Clinical Professor - University of Arizona

Executive Vice President/Medical Director-

AAGL *Advancing Minimally Invasive Gynecology Worldwide*



Benefits of Minimally Invasive Gynecology (MIG)

- Efficacy is equal to open procedures
- Alternatives to more complex procedures
- Decreased or no hospitalization
- Less pain
- Faster recovery
- Economic benefits



Everyone Has Difficulties Identifying Providers

- Patients
- Doctors
- Payers



Problems in Identifying Gynecologists Interested in MIG

- **Residency training is inadequate**
- **FLS –basics for cognitive & skills but does not test for procedures**
- **Number of cases do not necessarily correlate with results**



Downside of Using Only the Number of Cases

- The severity of cases
- Appropriateness of surgery



What are Surrogate Markers for Outcomes?

- **Complication rates**
- **Re-admission rates**
- **Surgery time**



Why Surgical Times Are A Surrogate Marker

Shorter times suggest:

- **Surgeon's increased confidence**
- **Increased familiarity with procedure**
- **Better understanding of anatomical variations**



What Do Number of Cases Mean in LAVH ?

With increasing numbers

- Surgery time decreases $p < 0.02$
- Surgery time unchanged w/wo trainee $p > 0.05$



What Do Number of Cases Mean in Hysteroscopic Myomectomy?

High volume vs. low volume surgeons:

- Shorter surgery time $p = 0.018$
- More tissue obtained $p = 0.01$

Betjes HE et al., J Reprod Med 2009 Jul;54(7): 425-8.



What Do Number of Cases Mean in LSH?

Comparing the first 30 cases to the second 30 cases

“After gaining experience in performing 30 cases, the operating time is significantly reduced. The operation can be performed safely during the learning period.”



Identifying MIG Gynecologists

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Patient Care Statements



The Board of Trustees of the AAGL has approved the following statements. These statements are meant to be of help to our members and their institutions in providing quality care to our patients. They are not absolute standards. It should be noted that since the date of their adoption new information may have become available which could influence their content. The AAGL is currently undertaking a review of these statements and exploring other ways it can be supportive of quality patient care.

[Endorsement Statement](#)

[Identifying Gynecologists Who Practice Minimally Invasive Gynecology \(MIG\)](#)

[Credentialing Guidelines for Operative Endoscopy](#)

[Operative Laparoscopy Training](#)

[Hysteroscopic Fluid Management Guidelines](#)

[Hysteroscopic Training Guidelines](#)



AAGL Ability to Identify Gynecologists Practicing MIG

- **AAGL members**
- **Fellows (AAGL and SRS)**
- **Faculty**
- **Areas of interest**
- **CGE**



Council of Gynecologic Endoscopy

- A Professional Interest Partner of the AAGL
- > 1000 physicians earned designation
- Peer reviewed
- Identifies surgeons who are providing MIG



Process for Inclusion in the Council of Gynecologic Endoscopy

- Evidence of CME
- Board Certification
- Review of National Data Bank
- Submission of verified cases
- Random review of operative and pathology reports



CGE Laparoscopic Practice Levels of Care

Level A - sterilizations, ectopics, etc.

**Level B - hysterectomies, myomectomies,
etc.**

Level C - difficult general

- fertility enhancing**
- urogynecology**
- oncology**



AAGL/CGE

Center of Excellence

in Minimally Invasive Gynecology

- **Provide support for MIG**
- **Track outcomes** - by procedure
 - by surgeon



AAGL's Position Paper on Route for Hysterectomies

- TAH - most commonly done
- TAH has downsides
- VH and LH are proven alternatives
- TAH should be justified
- Inability to provide MIG is not an excuse



AAGL's Challenge to PPO's

- Educate your PCP's
- Educate your subscribers
- Question all TAHs





AAGL Office – Cypress, CA

Thank You For Your Attention



WEBINAR CONFERENCE ONLINE
AAPPO Webinar

Q&A

Next Women's Health Webinar

→ [May 27, 2010, 1pm, EST](#)

**Women's Health, Session III: Making the Switch -
Strategies for Moving to More Efficient Surgical Procedures**