
FACULTY
Pedro F. Escobar, MD & Kevin J.E. Stepp, MD

MODERATOR
Robert T. O’Shea, MD

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Professional Education Information

Target Audience
Educational activities are developed to meet the needs of surgical gynecologists in practice and in training, as well as, other allied healthcare professionals in the field of gynecology.

Accreditation
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Surgical Tutorial 3:
Laparoendoscopic Single-Site Surgery and Micro-Laparoscopy:
Why LESS Is More

Faculty: Pedro F. Escobar and Kevin J.E. Stepp
Moderator: Robert T. O'Shea

Course Description

This course provides a comprehensive review of several of the most significant emerging technologies in minimally invasive surgery, including laparoendoscopic single-site surgery (LESS) and micro-laparoscopy. The current state of these surgical approaches and outcomes data is reviewed and the technologies are appraised. Practical tips and tricks and procedural videos will be emphasized, and a compelling argument for incorporating LESS and micro-laparoscopy in gynecologic practice will be provided. Finally, the rationale and merger of robotics technology and LESS will be reviewed.

Learning Objectives

At the conclusion of this course, the participant will be able to: 1) Appraise emerging minimally invasive technologies, including laparoendoscopic single-site surgery (LESS) and micro-laparoscopy, and their utility in gynecologic surgery; 2) review practical tips and tricks and procedural videos of LESS and micro-laparoscopic gynecologic surgery; 3) discuss the learning curve and outcomes data to support adoption of these surgical approaches in practice; and 4) evaluate the future of LESS surgery, including reduced port robotic surgery.
PLANNER DISCLOSURE
The following members of AAGL have been involved in the educational planning of this workshop and have no conflict of interest to disclose (in alphabetical order by last name).
Art Arellano, Professional Education Manager, AAGL*
Viviane F. Connor
Consultant: Conceptus Incorporated
Frank D. Loffer, Executive Vice President/Medical Director, AAGL*
Linda Michels, Executive Director, AAGL*
Jonathan Solnik
Other: Lecturer - Olympus, Lecturer - Karl Storz Endoscopy-America

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Consultant: Covidien, CareFusion, TransEnterix
Stock Shareholder: TransEnterix
Speaker’s Bureau: Covidien, Abbott Laboratories
Other: Proctor - Intuitive Surgical

FACULTY DISCLOSURE
The following have agreed to provide verbal disclosure of their relationships prior to their presentations. They have also agreed to support their presentations and clinical recommendations with the “best available evidence” from medical literature (in alphabetical order by last name).
Pedro F. Escobar*
Kevin J.E. Stepp
Consultant: Covidien, Stryker Endoscopy
Stock Shareholder: Titan Medical
Speaker’s Bureau: Covidien, Stryker Endoscopy
Robert T. O’Shea*
Asterisk (*) denotes no financial relationships to disclose.
Laparoendoscopic Single-Site Surgery and Micro-Laparoscopy: Why LESS is More

Pedro F. Escobar, M.D., FACOG, FACS
Associate Professor of Surgery
Director of Laparoscopy and Robotic Surgery
Department of OB/GYN and Women's Institute
Cleveland Clinic

I have no financial relationships to disclose.

OBJECTIVE

• Analyze and interpret data for single incision in gynecology
• Review appropriate pre-operative assessment
• Identify important considerations to be made prior to proceeding with surgery

Acknowledged Worldwide Efforts!
If I did not mentioned you or your group please does not mean an offense, insult or otherwise!!

Expansion of Minimally Invasive Gynecologic Surgery

The Levels of evidence used for original research articles in Obstetrics & Gynecology:

I: A randomized, controlled trial
II: A cohort or case-controlled study
III: Case series

Single-Port Laparoscopy Studies

Feasibility
Case Report
Case/Control Studies
Prospective Trials

The Levels of evidence used for original research articles in Obstetrics & Gynecology:

I: A randomized, controlled trial
II: A cohort or case-controlled study
III: Case series
Laparoendoscopic single-site surgery in gynaecology: A new frontier in minimally invasive surgery

Fader, Levinson, Gunderson, Winder, Escobar

JMAS October-December 2010 | Volume 6 | Issue 4


Laparoendoscopic single-site versus traditional laparoscopic surgery in patients with cholecystectomy


• Seven RCTs involving 611 patients
• The cosmetic score of the LESSC group was significantly higher at 1 week, 2 week and 1 month (p<0.001)
• LESSC showed a lesser physical quality of life! (p<0.001)
• LESSC is associated with a higher cosmetic score and a lesser short-term PQOL score compared with TLC.

Laparoendoscopic Single-Site Nephrectomy Compared with Conventional Laparoscopic Nephrectomy: A Systematic Review and Meta-analysis of Comparative Studies


• Two RCTs and 25 retrospective studies including a total of 1094 cases
• LESS-N offers a safe and efficient alternative to CL-N with less pain, shorter recovery time, and better cosmetic outcome

<table>
<thead>
<tr>
<th>Year, Author</th>
<th>Type of Study</th>
<th>Type of Surgery</th>
<th>No. of Patients</th>
<th>Incision Size (cm)</th>
<th>Access Port Used</th>
<th>Operating Time (min)</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pelosi et al. 1992</td>
<td>Case Series</td>
<td>LAVH</td>
<td>4</td>
<td>Operative laparoscope</td>
<td>N/A</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Kosumi et al. 2001</td>
<td>Case Report</td>
<td>Ovarian cystectomy</td>
<td>1</td>
<td>Operative laparoscope</td>
<td>N/A</td>
<td>None</td>
<td></td>
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<tr>
<td>Ghezzi et al. 2005</td>
<td>Case Series</td>
<td>Salpingectomy for treatment of tubal pregnancy</td>
<td>10</td>
<td>Operative laparoscope and percutaneous sutures</td>
<td>27 min (15-37)</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Lim et al. 2009</td>
<td>Case Series</td>
<td>Adnexal surgery</td>
<td>12</td>
<td>Wound retractor and surgical glove</td>
<td>73 min (25-110)</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Fader &amp; Escobar 2009</td>
<td>Case Series</td>
<td>TLH, BSO, Radical hysterey</td>
<td>13</td>
<td>2-3 SILS port (Covidien) and GelPort (Applied Medical)</td>
<td>65 min (35-178)</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

Gynecology

A cohort or case-controlled study

RCTs
Laparo-endoscopic single-site surgery in gynecology
A review of the literature and available technology
Uppal, Frumovitz, Escobar, Ramirez JMG 2010 In Press

<table>
<thead>
<tr>
<th>Year, Author</th>
<th>Publication</th>
<th>Type of Surgery</th>
<th>No. of Patients</th>
<th>Incision Size (cm)</th>
<th>Access Port Used/Equipment</th>
<th>Operating Time (min)</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fagotti et al. 2009</td>
<td>Case Series</td>
<td>Ovarian cystectomy</td>
<td>32</td>
<td>TriPort (Advanced Surgical Concepts) and 5mm EndoEYE (Olympus)</td>
<td>79  (79-100)</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Kim et al. 2009</td>
<td>Case Series</td>
<td>Adnexal surgery</td>
<td>24</td>
<td>Surgical retractor, surgical glove, 5-mm laparoscope, flexible instruments (Cambridge)</td>
<td>70  (40-120)</td>
<td>Additional trocar needed in 1 case</td>
<td></td>
</tr>
<tr>
<td>Yoon et al. 2010</td>
<td>Case Series</td>
<td>Salpingectomy- Ectopic pregnancy</td>
<td>20</td>
<td>Surgical glove-wound retractor-30 degree scope</td>
<td>55  (25-85)</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Escobar et al. 2010</td>
<td>Case Series</td>
<td>Endometriosis and complex adnexal disease</td>
<td>9</td>
<td>SILS port and 5mm Endo Eye (Olympus)</td>
<td>45  (30-110)</td>
<td>Additional trocar needed in 1 case</td>
<td></td>
</tr>
</tbody>
</table>

RCT’s??

Single-Port Compared With Conventional Laparoscopic-Assisted Vaginal Hysterectomy: A Randomized Controlled Trial

Table 4. Complications in the Study Population

<table>
<thead>
<tr>
<th>Complications</th>
<th>Single-Port Laparoscopic-Assisted Vaginal Hysterectomy (n=8)</th>
<th>Conventionally Laparoscopic-Assisted Vaginal Hysterectomy (n=8)</th>
<th>p-Value</th>
<th>Relative Risk (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>10</td>
<td>12</td>
<td>0.389</td>
<td>0.360-1.000 (0.050-0.790)</td>
</tr>
<tr>
<td>Respiratory tract</td>
<td>0</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asymptomatic bowel dilation</td>
<td>0</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal cuff tears</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data are n, % unless otherwise specified.
Fisher exact test is relative risk 95% confidence interval.
A randomized prospective study of single-port and four-port approaches for hysterectomy in terms of postoperative pain


Compared with four-port TLH, SPLS-TLH is a feasible approach
Reduction of postoperative pain is not evident with SPLS-TLH!

Postoperative pain after conventional laparoscopy and laparoendoscopic single site surgery (LESS) for benign adnexal disease: a randomized trial


The Problems?

- Ergonomics
- Steep learning curve!!
- Poor adaptation
- Equipment
**How about Robotics?**

- 3 surgeon-controlled arms
- Triangulated retraction
- Wrist articulation
- Advanced instrumentation
  - Bipolar
  - Harmonic
  - Suction irrigation

**Why Robotics? How the modalities compare?**

- **Comparison of single-port laparoscopy, standard laparoscopy, and robotic surgery in patients with endometrial cancer**

- **Perioperative outcomes of total laparoendoscopic single-site hysterectomy versus total robotic hysterectomy in endometrial cancer patients: a multicentre study.**

- **The LESS and robotic approaches both appear reasonable and each may have benefits and limitations depending upon the patient population**

- **Our findings suggest SPL surgery for endometrial carcinoma is feasible with similar operating times, hospital length of stay, complication rates, and estimated blood loss when compared with laparoscopy and robotics.**

**Additional Applications**

Combining Multi-Port and Single-Site Technology

**da Vinci® single-site platform: anthropometrical, docking and suturing considerations for hysterectomy in the cadaver model**


- **Technical requirements, limitations, anthropometrical, docking and suturing considerations on the performance of robotic hysterectomy using the da Vinci® Single-Site Platform in the cadaver model**

- **The planned surgical procedure was successfully completed with single-port robotics in 87.5% of cases**

- **High BMI was correlated with difficulty docking the robot, correlation coefficient 0.98.**
Clinical Trials

- In progress

Conclusions

- Single-Site and Reduce-Port Laparoscopy are concepts in current evolution and progress

- Although data is promising adoption is low in USA, better in China, Asia, Korea, Japan

- Robotics is perhaps the future for Single-Site, and micro laparoscopy
Illustrate basic techniques for performing LESS and Micro-Laparoscopy.
Demonstrate proper instrument positioning during gynecologic single port procedures.
Discuss some of the challenges associated with getting started with single incision laparoscopy. Provide strategies for overcoming these challenges.
Instrument Positioning
Using Straight Instruments
Ensuring Uterosacral Support
LESS TLH - Large Fibroids
LESS - Cuff Closure

Exposure Tricks
with Single Incision Laparoscopic Surgery
Suturing with LESS

Micro-laparoscopy

2 weeks post-op

Carolina Medical Center
Advanced Surgical Specialties for Women
CULTURAL AND LINGUISTIC COMPETENCY

Governor Arnold Schwarzenegger signed into law AB 1195 (eff. 7/1/06) requiring local CME providers, such as the AAGL, to assist in enhancing the cultural and linguistic competency of California’s physicians (researchers and doctors without patient contact are exempt). This mandate follows the federal Civil Rights Act of 1964, Executive Order 13166 (2000) and the Dymally-Alatorre Bilingual Services Act (1973), all of which recognize, as confirmed by the US Census Bureau, that substantial numbers of patients possess limited English proficiency (LEP).

California Business & Professions Code §2190.1(c)(3) requires a review and explanation of the laws identified above so as to fulfill AAGL’s obligations pursuant to California law. Additional guidance is provided by the Institute for Medical Quality at http://www.imq.org

Title VI of the Civil Rights Act of 1964 prohibits recipients of federal financial assistance from discriminating against or otherwise excluding individuals on the basis of race, color, or national origin in any of their activities. In 1974, the US Supreme Court recognized LEP individuals as potential victims of national origin discrimination. In all situations, federal agencies are required to assess the number or proportion of LEP individuals in the eligible service population, the frequency with which they come into contact with the program, the importance of the services, and the resources available to the recipient, including the mix of oral and written language services. Additional details may be found in the Department of Justice Policy Guidance Document: Enforcement of Title VI of the Civil Rights Act of 1964 http://www.usdoj.gov/crt/cor/pubs.htm.

Executive Order 13166, “Improving Access to Services for Persons with Limited English Proficiency”, signed by the President on August 11, 2000 http://www.usdoj.gov/crt/cor/13166.htm was the genesis of the Guidance Document mentioned above. The Executive Order requires all federal agencies, including those which provide federal financial assistance, to examine the services they provide, identify any need for services to LEP individuals, and develop and implement a system to provide those services so LEP persons can have meaningful access.

Dymally-Alatorre Bilingual Services Act (California Government Code §7290 et seq.) requires every California state agency which either provides information to, or has contact with, the public to provide bilingual interpreters as well as translated materials explaining those services whenever the local agency serves LEP members of a group whose numbers exceed 5% of the general population.

If you add staff to assist with LEP patients, confirm their translation skills, not just their language skills. A 2007 Northern California study from Sutter Health confirmed that being bilingual does not guarantee competence as a medical interpreter. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2078538.