Single Port Laparoscopic Surgery, Mini Laparoscopy and Robotics – Safe and Appropriate Adoption into Your Practice

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Professional Education Information

Target Audience
This educational activity is developed to meet the needs of residents, fellows and new minimally invasive specialists in the field of gynecology.

Accreditation
AAGL is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The AAGL designates this live activity for a maximum of 1.0 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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This course is designed to help you navigate the growing field of reduced port surgery. Single port surgery, mini laparoscopy and robotics all have something to offer as we move forward in laparoscopic gynecology.

We will demonstrate surgical procedures, from routine oophorectomy and hysterectomies to radical gynecologic oncologic surgery, using these new techniques and video presentations.

Advantages and disadvantages of the various platforms, instruments and techniques available will be presented.

Learning Objectives: At the conclusion of this course, the participant will be able to: 1) Explain the advantages and disadvantages of the various platforms available for single port laparoscopic surgery; 2) use the learning process to communicate effectively to patients and OR staff the appropriate use of reduced port surgical platforms; and 3) integrate the reduced port surgical platforms into their surgical practices.
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).
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Consultant: Conceptus Incorporated
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LindaMichels, Executive Director, AAGL*
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Stephanie A. King
Speakers Bureau: Karl Storz
Consultant: Spouse: Merck, Olympus
Speakers Bureau: Spouse: Karl Storz
Anthony Siow*

Asterisk (*) denotes no financial relationships to disclose.
Single Port Laparoscopic Surgery, Mini Laparoscopy and Robotics – Safe and Appropriate Adoption into Your Practice

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No financial relationships to disclose

- Learn advantages and disadvantages of the various platform available for single port laparoscopic surgery
- Use the learning process to communicate effectively to patients and OR staff the appropriate use of reduced port surgical platforms
- Integrate the reduced port surgical platforms into surgical practices

LESS OPERATING ROOM

ROBOTICS
M-LPS/3 mm
LPS

LESS
S-LPS

45°
Moving beyond simple procedures

Moving Beyond Simple Procedures: more than 200 LESS procedures over 3 yrs

LESS procedures in GYO

<table>
<thead>
<tr>
<th>Disease</th>
<th>Key LESS procedure/completion</th>
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<tbody>
<tr>
<td>Ovarian cancer</td>
<td>Border-line Ovarian Tumor staging and prophylactic adnexectomy</td>
</tr>
<tr>
<td>Endometrial cancer</td>
<td>Simple hysterectomy (+/- lymphadenectomy)</td>
</tr>
<tr>
<td>Cervical cancer</td>
<td>Simple and radical hysterectomy (+/- lymphadenectomy)</td>
</tr>
</tbody>
</table>
LESS experience on adnexal surgery at UCSC-Rome

2009
2010
2011
2012
3 YEAR EXPERIENCE

Case-Control

2010
2011

RCT

Laparoscopic Single-Site Surgery (LESS) for Treatment of Benign Adnexal Disease: Single-Center Experience Over 3 Years

Lenzi Ferraretti, MD; Maria Cristina Resta, MD; Giuseppe Viventi, MD; Giuseppe Scambia, MD; and Anna Fagotti, MD.

JMIG, 2012

Cystectomy (%) 42 (33.6)
Adnexectomy (%) 79 (63.2)
Staging BOT (%) 4 (3.2)

Reply to: “Some criticism about LESS in gynecological surgery for benign and malignant diseases”.

Respect of patient’s body image in case of:
- BRCA-positive women
- any woman with cancer who needs ovarian tissue for freezing, before undergoing RT/CT
- models, whose physicality is their means of financial support
- pediatric patients
- patients asking for reassignment of sex

Fagotti et al. F&S 2011

Tumor
Ovarian cancer
Endometrial cancer
Cervical cancer

LESS procedures in GYO

<table>
<thead>
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<th>LESS procedure</th>
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Laparoscopic Single-Site Surgery for Fertility-sparing Surgery of Border Line Ovarian Tumors: Initial Experience

Francesco Marzocchi, MD; Francesco Fudani, MD; Cristiano Resta, MD; Fabrizio Galleria, MD; Giovanni Scambia, MD; and Anna Fagotti, MD.

JMIG, 2012

Table 1. Patient Clinical and Demographic Characteristics

- Age (years): Mean ± SD
- Menopause: Pre, Post-M, Menopause
- Tumor stage: IA, IB, IC, ID, IE, II
- BOT: Border-line Ovarian Tumor
- Infertility: Yes, No
- Initial Surgery: Laparoscopic, Robotic, Vaginal, Open
- Ovarian tissue for freezing: Yes, No
- Genitourinary series: Yes, No
- Radiation therapy: Yes, No
- Chemotherapy: Yes, No

LESS experience on hysterectomy at UCSC-Rome

2009
2010
2011
2012
2013

Case Report

PROSPECTIVE OBSERVATIONAL 3-mm/3-LSLESS, LESS

LESS-RH

MULTICENTRIC

PILOT

2010
2011
2012
2013

LESS procedures in GYO

<table>
<thead>
<tr>
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<th>LESS procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ovarian cancer</td>
<td>Border-line Ovarian Tumor staging and prophylactic adnexectomy</td>
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</tr>
<tr>
<td>Cervical cancer</td>
<td>Simple and radical hysterectomy (+/- lymphadenectomy)</td>
</tr>
</tbody>
</table>

- **LESS RH:** the first report on LESS type III hysterectomy involves a woman with cervical cancer.  
  *Boruta DM, AJOG, 2012*

- **LESS RH for the treatment of early stage cervical cancer.**
  *Fader AN, Gyn Onc 2013*
**THE ERA OF COMPARISON**

A comparison between LESS and ROBOTICS surgery highlights the benefits of LESS surgery, especially in minimizing incisions and reducing recovery time.

### LESS vs. ROBOTICS

**Comparative Study**

- **Table 1:**
  - **Variable:** Laparoscopic versus LESS surgery outcomes.
  - **LESS Robotic Surgery:**
    - Total operative time: 90.3 min
    - Estimated blood loss: 50 mL
    - Length of hospital stay: 2 days
  - **LESS Robotic Surgery:**
    - Total operative time: 80.2 min
    - Estimated blood loss: 40 mL
    - Length of hospital stay: 1 day

**Conclusion:** LESS surgery offers significant advantages over traditional laparoscopic surgery in terms of reduced operative time, blood loss, and hospital stay.

### Minimally Invasive Surgery

LESS vs. ROBOTICS

**LESS-Robotics**

- **LESS Robotic Surgery:**
  - Total operative time: 85 min
  - Estimated blood loss: 30 mL
  - Length of hospital stay: 1 day

**LESS vs. RSS**

- **RSS Robotic Surgery:**
  - Total operative time: 95 min
  - Estimated blood loss: 50 mL
  - Length of hospital stay: 2 days

**Conclusion:** LESS surgery provides comparable outcomes to RSS surgery with reduced complications and faster recovery.

**References:**

2. JMIC, 2013.
LESS HYSTERECTOMY IN OBESE PATIENTS: DOES THE BMI INFLUENCE THE SUCCESSFUL RATE? A MULTICENTRIC EVALUATION

Rome, Boston, Baltimore

< 30
30 - 35
> 35

Fanfani et al., submitted

REFERENCES


**Disclosure**

- **Consultant:** Merck, Olympus
- **Speakers Bureau:** Karl Storz

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**Reduced Port Surgery**

  - Wheelees Single Incision BTL
  - Pelosi Single Incision TAH BSO, Appy
- **General Surgery** (1997)
  - Navarra, Cuesta Single Incision Cholecystectomy
- **Working together** (April 2007)
  - Urology and General Surgery (together)
    - Rao and Rao One Port Umbilical Cholecystectomy
  - Gynecology and General Surgery (together)
    - Curtillo & King Single Port Access Surgery

---

**Reduced Port Surgery**

- **Single Port Access (SPA)**
  - Initial Camera (5mm) Trocar Site
  - Camera Trocar Site
  - Lateral 5 mm Trocar Site
  - Umbilical Incision (1.5cm)

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**At the conclusion of this course, the participant will be able to:**

- Explain the advantages and disadvantages of the various platforms available for single port laparoscopic surgery
- Use the learning process to communicate effectively to patients and OR staff the appropriate use of reduced port surgical platforms, their risks and benefits
- Integrate the reduced port surgical platforms into their surgical practices safely and cost effectively
**Single Port Surgery**

- Cholecystectomy
- Gastric
- Liver
- Pancreas
- Small Bowel
- Meckel's
- Spleen
- Adrenal
- Ventral Hernia Repair
- Hysterectomy
- Oophorectomy
- Bladder
- Kidney
- Prostate
- General Surgery
- Gynecology
- Pediatric Surgery
- Urology
- Veterinary Surgery
- Plastic Surgery

**Reduced Port Surgery**

**Access**
- Simple
- Allow easy instrument exchanges
- Cost Effective
- Reasonable incision size
- Minimize hand/instrument/trocar clashing
- Minimize air leaks
- Allow smoke evacuation
- Allow easy specimen extraction/anastomosis

**Current Status**

- Cosmetic
- Shorter Stay
- Less Pain
- Faster Recovery

- Safety – so far, so good ??

**Two Platforms**

- Multi Trocar Techniques
  - Single Port Access (SPA)
  - Multiple trocars through one skin incision, separate fascial defects
  - Minilaparoscopy
  - Needle Laparoscopy
  - Standard Instrumentation
  - Transvaginal

- Single Port Device Techniques
  - SILS™, LESS, SSL, S‐Portal (Device driven)
  - Multiple instruments through one fascial defect
  - Articulating, bent or curved instruments

**SINGLE PORT DEVICE TECHNIQUES**

**Adverse Events**

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>4PLC</th>
<th>SILC</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound Complications (total)*</td>
<td>2.5%</td>
<td>8.4%</td>
<td>0.13</td>
</tr>
<tr>
<td>Erythema</td>
<td>0%</td>
<td>3.4%</td>
<td>0.15</td>
</tr>
<tr>
<td>Cellulitis</td>
<td>0%</td>
<td>1.7%</td>
<td>0.52</td>
</tr>
<tr>
<td>Postoperative wound infection</td>
<td>2.5%</td>
<td>1.7%</td>
<td>1.00</td>
</tr>
<tr>
<td>Suture-related complication</td>
<td>0%</td>
<td>1.7%</td>
<td>0.52</td>
</tr>
<tr>
<td>Seroma</td>
<td>0%</td>
<td>0.4%</td>
<td>1.00</td>
</tr>
<tr>
<td>Postoperative Hernia Incidence</td>
<td>1.2%</td>
<td>8.4%</td>
<td>0.05</td>
</tr>
<tr>
<td>Retained Choledocholithiasis</td>
<td>1.3%</td>
<td>0.8%</td>
<td>1.00</td>
</tr>
<tr>
<td>Bile Duct Injury or Bile Leak</td>
<td>0%</td>
<td>0%</td>
<td>1.00</td>
</tr>
</tbody>
</table>

ACS 2011 total adverse event p=0.46

- Homero Rivas

University Hospita Case Medical Center, Cleveland, Ohio

University of Tennessee, Knoxville, Tennessee
**Reduced Port Surgery**

Trocar Size and Hernia Formation

- 5mm < 10mm < 15mm
- Puncture < Hassan (open)

**Reduced Port Surgery**

Trocar Site and Hernia Formation

- Para-umbilical > Lateral
- Umbilicus is a weakened area
- Lateral - Multiple muscle layers

**Reduced Port Surgery Two Platforms**

Multi Trocar Techniques
- Single Port Access (SPA)
- Multiple trocars through one skin incision, separate fascial defects
- Minilaparoscopy
- Needle Laparoscopy
- Standard Instrumentation
- Transvaginal

- No new Instruments
- No Crossing
- No Endowrist/Articulating
- Decreased COSTS
- Disadvantages ??
  - Training
  - Stepwise
  - Adaptable
  - Adaptable

**Decision Time**

Every Minimally Invasive Procedure ....

Starts out as Single Port

**Single Port Access**

- Reduction in pain
- Reduction in recovery time
- Reduction in port/entry sites size and number
- Reduction in instrument exchange
- Reduction in errors/complications
- Reduction in Costs (Economic and Ecologic)

This is where Single Port Needs to take us ....
**Reduced Port Surgery**

- Reduction in the number of trocars ...
  - Single Port Access
  - Two trocar procedures
- ...or the size of the Trocars
  - Needlelesscopic / Minilaparoscopy
  - Thinner “5mm” trocars - When is 5mm not 5mm?
- Single Port Rescue - Safety

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**“Single” Port Access Surgery**

The Future ???

- A “hidden” port site ?
- A “smaller” port site ?
- A “second” or “third” port site ?

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**Reduced Port Surgery**

*Safety*

When is Single Port not “Single Port?”

*When it doesn’t make sense and is safer*

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**Reduced Port Surgery**

“Evolving Together”

- Access
  - Need “versatile answer”
    - Don’t make the decision before the operation
    - Make it after you see what your up against
  - Reduced Heads
  - Reduced Footprint (when is 5mm not 5mm ?)
  - Increase Versatility
  - Economic/Ecologic

---

**Reduced Port Surgery**

Single Port Access

- Separate very low profile trocars or “sleeves”
- Single Skin Incision
- Separate fascial incisions
- ~ $85 / case
**Reduced Port Surgery**

**Single Port Access**

“Sleeves”

- Smaller Head Design (< 1.8cm)
- Longer Shaft
- Reduced Footprint (Steel)
- Re-usable
- Single Port, Minilaparoscopy, Transvaginal Access

**Single Port Access** “2012”

- Triangulation: 7-8cm spread internally

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**Reduced Port Surgery**

**Instrumentation**

- Mini Laparoscopy – Safer and More Versatile than Needles/Sutures

**Reduced Port Surgery**

ASH (Access Site Hernia)

- Single Port Access Surgery – Results
  - Closing Fascial Defects and Hernia Formation
    - General Surgery Procedures (PGC n = 222)
      - Closed
      - 2 Hernias in Colon Patients
    - Gynecology Procedures (SAK n = 212)
      - Not Closed
      - No Access Site Hernias

King, Podolsky, Curcillo – submitted 2011

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**Reduced Port Surgery**

“Evolving Together”

- Costs
  - Reusable vs Disposable?
  - Economic
  - Ecologic

**Single Port Surgery**

- Costs
  - MPL $180
  - Single Port Access < $80
  - Single Port Device $ > 400
**Single Port Access Surgery Development**

- Progressive reduction of port sites
  - 4 to 3 to 2 to 1
- Transition to 3mm instruments when appropriate

**The development of Single Port Surgery...**

... challenges us to improve outcomes...
... leads us to question what we do...
... pushes us to stop being “extremists”...

**Reduced Port Surgery**

- How to develop a Safe Procedure
  - Maintain Safe Standards
  - Dissection
  - Maintain Safe Outcomes
  - Port Sites and Hernias
  - Maintain Costs
  - Economic and Ecologic
  - Safe Training Platform

**Reduced Port Surgery “Evolving Together”**

- The Benefits
  - None proven except cosmetics
  - Is this any better?

**The Vehicle(s) of Change ??**

Change needs Maturation

- Single Port Access
- Mini Laparoscopy
- NOTES

A New Platform ??
Is this better then multiport ??

The bigger picture –
- evolution and improvement

Please —
 instruments don’t cause injuries —

Be Safe
Be Cautious

Single Port Rescue
Another Port Site
Mini Laparoscopy

"ALL GOOD THINGS NEED TO DEVELOP AND MATURE;
START THEM FOR THE WRONG REASONS,
RUSH INTO THEM
AND THEY NEVER REACH THEIR FULLEST POTENTIAL"

PGC@curcillo.com

References:

King SA, Atogho A, Podolsky E, Curcillo, PG.
Single Port Access (SPA) Bilateral Oopherectomy and Hysterectomy.
Laparoscopy Today, Volume 7/Number 2, Fall 2008

Podolsky ER, Rottman SJ, Poblete H, King SA, Curcillo PG.

Podolsky ER, Curcillo PG.


XU J, Delvadia D, Curcillo PG, King SA, Kotlar E:
Single Port Access (SPA) Laparoscopic Tubal Occlusion.
Journal of Gynecologic Surgery – Accepted May 2010

Curcillo PG, Wu A, King SA:
Reduced Port Surgery: Developing a URF Pathway in Single Port Access Surgery.
Endoscopy, 2009; 41(Suppl 2):175-177

Curcillo PG, Wu A, King SA.
The Road to Reduced Port Surgery: From Single Big Incisions to Single Small Incisions, and Beyond.

"The evolution of Reduced Port Surgery....
... will let us realize we can do whatever comes next"

PGC@curcillo.com

"Its not just about the Incision..."
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 Dymanly-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.

Dynamly-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.