4th Annual Workshop on Video Assisted Laparoscopy & Robotic Hysterectomy with Intensive Hands-on Laparoscopic Suturing

December 6-7, 2012 New York, New York

Educational Grant
AAGL Acknowledges that it has received support in part by educational grants and equipment (in-kind) from the following companies: 3-Dmed, CareFusion, Covidien, Inc., Ethicon Endo-Surgery, Inc., Ethicon Women’s Health & Urology, Intuitive Surgical, Mimic Technologies, Karl Storz Endoscopy-America, Inc., Teleflex
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
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 19.50 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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As a provider accredited by the Accreditation Council for Continuing Medical Education, AAGL must ensure balance, independence, and objectivity in all CME activities to promote improvements in health care and not proprietary interests of a commercial interest. The provider controls all decisions related to identification of CME needs, determination of educational objectives, selection and presentation of content, selection of all persons and organizations that will be in a position to control the content, selection of educational methods, and evaluation of the activity. Course chairs, planning committee members, presenters, authors, moderators, panel members, and others in a position to control the content of this activity are required to disclose relevant financial relationships with commercial interests related to the subject matter of this educational activity. Learners are able to assess the potential for commercial bias in information when complete disclosure, resolution of conflicts of interest, and acknowledgment of commercial support are provided prior to the activity. Informed learners are the final safeguards in assuring that a CME activity is independent from commercial support. We believe this mechanism contributes to the transparency and accountability of CME.
# Table of Contents

Course Description ........................................................................................................................................ 1

Disclosure ...................................................................................................................................................... 7

Why and How to Use Different Sutures, Including Barbed Sutures, for Laparoscopic and Robotic Surgery. Trocar Placement and Set-up for Video-Laparoscopy and Robotic Platform: The Secret to Success  
F.R. Nezhat ................................................................. 9

Tips and Tricks in Suturing  
J.L. Hudgens ............................................................... 17

How to Start Robotic Surgery: Tips and Tricks  
V.V. Morozov ............................................................. 20

Different Types of Laparoscopic Hysterectomy and Why: Robotic-assisted vs Video-assisted Laparoscopy  
C.H. Nezhat ................................................................. 23

Video-assisted and Robotic-assisted Laparoscopic Hysterectomy for Endometriosis, Adhesions, and Patients with Previous C-sections  
C.R. Nezhat ................................................................. 29

Supracervical Hysterectomy: Different Tricks to Avoid Injuring Ureter and the Bladder During Robotic-assisted vs Video-assisted Laparoscopy  
R.K. Zurawin .............................................................. 35

Robotic-assisted, Supracervical Hysterectomy and Sacrocolposuspension  
P.S. Finamore ............................................................. 38

Robotic-assisted vs Video-assisted Laparoscopy for Retroperitoneal Dissection and Lymphadenectomy  
M.M. Leitao ................................................................. 45

Perils and Pitfalls of Morcellation: Myomectomy and Hysterectomy – How to Shrink a Large Uterus Intraoperatively  
T. Tulandi ................................................................. 51

Alternative to Hysterectomy – Myomectomy: Robotic-assisted vs Video-assisted Laparoscopy  
S.F. Palter ................................................................. Unavailable at the time of print

Step-by-Step Approach to the Straight-Forward and Difficult Vaginal Hysterectomy  
P.S. Finamore ............................................................. 54

How to Restore Normal Anatomy as You Face Total Confusion During Completely Abnormal and/or Rare Anatomy  
C.R. Nezhat ................................................................. 59
<table>
<thead>
<tr>
<th>Title</th>
<th>Author(s)</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tips and Tricks for Approaching Retroperitoneal Structures</td>
<td>F.R. Nezhat</td>
<td>61</td>
</tr>
<tr>
<td>Management of Endometriosis</td>
<td>T. Tulandi</td>
<td>64</td>
</tr>
<tr>
<td>Minimally Invasive Alternatives to Hysterectomy: Endometrial Ablation and Myomectomy, Uterine Fibroid Embolization, HIFU, and Myolysis</td>
<td>R.K. Zurawin</td>
<td>73</td>
</tr>
<tr>
<td>Safe and Effective Use of Power Sources in Minimally Invasive Surgery</td>
<td>J.L. Moritz</td>
<td>84</td>
</tr>
<tr>
<td>Bladder and Ureter Injury, Prevention and Management: How to Perform Cystoscopy and Place Ureteral Catheter</td>
<td>P.T. Soliman</td>
<td>105</td>
</tr>
<tr>
<td>Keynote Address: Evidence-based Medicine vs Real-Life Evidence in OBGYN</td>
<td>A.M. Vintzileos</td>
<td>110</td>
</tr>
<tr>
<td>Laparoscopic Management of Vascular Injury: Clip Application, Suturing Repair and Hemostatic Agents</td>
<td>C.H. Nezhat</td>
<td>118</td>
</tr>
<tr>
<td>Robotic and Laparoscopic Technique: Tips and Tricks in Obese Patients – How to Close Vaginal Cuff to Avoid Dehiscence</td>
<td>P.T. Soliman</td>
<td>127</td>
</tr>
<tr>
<td>Anesthesia for Operative and Robotic Surgery: How to Convince an Anesthesiologist to Place Obese or Non-obese Patient in Steep Trendelenburg</td>
<td>S. Littwin</td>
<td>130</td>
</tr>
<tr>
<td>Cultural and Linguistic Competency</td>
<td></td>
<td>138</td>
</tr>
</tbody>
</table>
4th Annual Workshop on Video Assisted Laparoscopy & Robotic Hysterectomy with Intensive Hands-on Laparoscopic Suturing

General Chair: Farr R. Nezhat, MD
Scientific Program Chair: Camran R. Nezhat, MD, Ceana H. Nezhat, MD
Session Chair: Linus T. Chuang, MD, Tamer A. Seckin MD, Radha Syed, MD, Patrick F. Vetere, MD

Faculty:
Peter S. Finamore, MD, Fabio Ghezzi, MD, Joseph (Jay) L. Hudgens, MD, Mario M. Leitao, MD, Sanford M. Littwin, MD, Jacques L. Moritz, MD, Vadim V. Morozov, MD, Steven F. Palter, MD, Michael C. Pitter, MD, Pamela T. Soliman, MD, MPH, Togas Tulandi, MD, Anthony M. Vintzileos, MD, Robert K. Zurawin, MD

Lab Faculty:
Uchenna C. Acholonu, Jr., MD, Adrian Balica, MD, Shan Biscette, MD, Douglas N. Brown, MD, PhD, E. Cristian Campian, MD, Jennifer Eun Sun Cho, MD, Moushumi S. Datta, MD, Erica C. Dun, MD, Lena El Hachem, MD, Tamara N. Finger, MD, Gabrielle Gossner, MD, Kathy Huang, MD, Valentin Kolev, MD, Michael L. Lewis, MD, Connie S. Liu, MD, Nimesh P. Nagarseth, MD, Azadeh A. Nezhat, MD, Linda M. Nicoll, MD, Iris K. Orbuch, MD, Laurence Orbuch, MD, Jason A. Sternchos, MD, Michael Wenof, MD, Jyoti Yadav, MD

Description

This two-day workshop and hands-on course is designed to educate attendees in the art and science of laparoscopic suturing and knot-tying, as well as provide step by step techniques for performing video-assisted laparoscopic and robotic-assisted hysterectomy. The curriculum of this course is a continuum of didactics followed by hands-on training sessions in a repetitive and increased fashion, reaffirming and maximizing technical skill development. The hands-on session will include instruction and performance of extracorporeal knots, intracorporeal knots, slip knots, and the use of barbed sutures. Lectures will be evidence-based and will include extensive surgical videos of video-assisted laparoscopic and robotic-assisted hysterectomy and myomectomy, supracervical hysterectomy, and retroperitoneal dissection from expert faculty. The course will also include interactive live surgeries of mini video laparoscopy and robotic-assisted hysterectomy which will reinforce the knowledge and skills acquired from the earlier didactic sessions. Additional topics will include laparoscopic, robotic and hysteroscopic myomectomy, endometrial ablation, treatment of endometriosis, pelvic reconstruction, normal and abnormal anatomy and complications.

Course Objectives

At the conclusion of this course, the clinician will be able to:
1. Assess the treatment options for patients presenting for minimally invasive approach for hysterectomy;
2. Distinguish between video-assisted laparoscopic and robotic-assisted hysterectomy;
3. Describe effective room set-up for video-assisted laparoscopy and robotic platform;
4. Describe patient positioning and trocar-placement for video-assisted laparoscopic and robotic-assisted hysterectomy;
5. Identify different docking and selection of proper instrumentation for robotic platform;
6. Apply the skills necessary to perform video-assisted laparoscopic and robotic-assisted hysterectomy, myomectomy and pelvic reconstructive surgery while minimizing conversions;
7. Identify proper intra-operative techniques for performing video-assisted laparoscopic and robotic-assisted hysterectomy for complex pathologies;
8. Predict, manage and prevent complications, including ureter, bladder and bowel injuries in laparoscopic and robotic-assisted surgery;
9. Compare minimally invasive alternatives to hysterectomy, including endometrial ablation and myomectomy;
10. Describe step by step approach to a straightforward and difficult vaginal hysterectomy;
11. Evaluate new indications and techniques of the new energy sources— their actions and their complications;
12. Estimate and manage anesthetic implications of steep trendelenberg and pneumoperitoneum;
13. Determine the fundamental techniques in laparoscopic suturing;
14. Identify applications of interrupted and continuous laparoscopic suturing;
15. Demonstrate optimal bite placement and knot tying technique during laparoscopic tissue approximation; and
16. Apply a surgeon's knot using laparoscopic needle holders

Course Outline

THURSDAY, DECEMBER 6, 2012
6:30 Registration and Continental Breakfast; Exhibit Hall Visit

7:30 Introduction and Opening Remarks  F.R. Nezhat

Session I  Session Chair: C.R. Nezhat

7:45 Why and How to Use Different Sutures, Including Barbed Sutures, for Laparoscopic and Robotic Surgery. Trocar Placement and Set-up for Video-Laparoscopy and Robotic Platform: The Secret to Success  F.R. Nezhat
- Vaginal Cuff Repair
- Myomectomy
- Bladder
- Bowl
- Ureter
Suturing will be demonstrated using both technologies: Robotic-assisted and Video-assisted Laparoscopy

8:15 Tips and Tricks in Suturing  J.L. Hudgens

8:25 How to Start Robotic Surgery: Tips and Tricks  V.V. Morozov
Different Types of Laparoscopic Hysterectomy and Why: Robotic-assisted vs Video-assisted Laparoscopy

8:35 C.H. Nezhat

9:00 Question & Answers

9:15 Break; Exhibit Hall Visit

9:30 LAB SESSION I: Pelvic Trainers / Suture Lab / Robot Lab / Simulation Lab with Preceptors (Maximum 3 participants per trainer) Faculty

Session II

C.H. Nezhat

11:00 Video-assisted and Robotic-assisted Laparoscopic Hysterectomy for Endometriosis, Adhesions, and Patients with Previous C-sections

11:25 Supracervical Hysterectomy: Different Tricks to Avoid Injuring Ureter and the Bladder During Robotic-assisted vs Video-assisted Laparoscopy

11:50 Question & Answers

12:00 Lunch; Exhibit Hall Visit

Video Live Surgery from Varese, Italy: Mini Video Laparoscopy F. Ghezzi

This course provides a live surgical demonstration of a Minilaparoscopic Total Hysterectomy (mTLH). This technique holds the advantage of eliciting a reduced level of wound pain compared with conventional laparoscopy, with better cosmetic results. This course demonstrates the technique of mTLH, discusses appropriate candidates for this procedure, and will show tips and tricks to overcome the difficulties related to the reduced instruments diameter.

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

1) Implement the use of minilaparoscopic instruments for total laparoscopic hysterectomy;
2) demonstrate how to ensure vessels sealing with mini laparoscopic instruments;
3) discuss the advantages of minilaparoscopy over conventional laparoscopy for hysterectomy.

Session III

T.A. Seckin

1:00 Robotic-assisted, Supracervical Hysterectomy and Sacrocolposuspension P.S. Finamore

1:20 Robotic-assisted vs Video-assisted Laparoscopy for Retroperitoneal Dissection and Lymphadenectomy M.M. Leitao

1:40 Perils and Pitfalls of Morcellation: Myomectomy and Hysterectomy – How to Shrink a Large Uterus Intraoperatively T. Tulandi

2:00 Question & Answers

2:15 Break; Exhibit Hall Visit
2:30  **LAB SESSION II**: Pelvic Trainers / Suture Lab / Robot Lab / Simulation Lab with Preceptors (Maximum 3 participants per trainer)  
Faculty

**Session IV**  
Session Chair: R. Syed

4:00  Alternative to Hysterectomy – Myomectomy: Robotic-assisted vs Video-assisted Laparoscopy  
S.F. Palter

4:20  Step-by-Step Approach to the Straight-Forward and Difficult Vaginal Hysterectomy  
P.S. Finamore

4:40  How to Restore Normal Anatomy as You Face Total Confusion during Completely Abnormal and/or Rare Anatomy  
C.R. Nezhat

5:00  Question & Answers

5:15  **LAB SESSION III**: Pelvic Trainers / Suture Lab / Robot Lab / Simulation Lab with Preceptors (Maximum 3 participants per trainer)  
Faculty

7:00  Adjourn  
Lab Session will be open until midnight  
(CME credit will not be available from 7:00 p.m. until midnight)

**FRIDAY, DECEMBER 7, 2012**

7:00  Continental Breakfast  
Open Practice on Pelvic Trainers; Exhibit Hall Visit

**Session V**  
Session Chair: L.T. Chuang

8:00  Tips and Tricks for Approaching Retroperitoneal Structures  
F.R. Nezhat

8:20  Management of Endometriosis  
T. Tulandi

8:40  Minimally Invasive Alternatives to Hysterectomy: Endometrial Ablation and Myomectomy, Uterine Fibroid Embolization, HIFU, and Myolysis  
R.K. Zurawin

9:00  Question & Answers

9:15  Break; Exhibit Hall Visit

9:30  **LAB SESSION IV**: Pelvic Trainers / Suture Lab / Robot Lab / Simulation Lab with Preceptors (Maximum 3 participants per trainer)  
Faculty

**Session VI**  
Session Chair: P.F. Vetere

10:50  Safe and Effective Use of Power Sources in Minimally Invasive Surgery  
J.L. Moritz

11:10  Bladder and Ureter Injury, Prevention and Management: How to Perform Cystoscopy and Place Ureteral Catheter  
P.T. Soliman

11:30  **Mimic Simulation Competition**
11:50  Question & Answers

12:00  Lunch; Exhibit Hall Visit

**Video Live Surgery** from Newark, New Jersey:
Robotic-assisted Hysterectomy  M.C. Pitter

This course provides a live surgical demonstration of a robotic myomectomy. This minimally invasive surgical approach is a fundamental skill that most gynecologists that conservatively treat uterine leiomyomas should be comfortable performing. This course demonstrates the technique, discusses appropriate candidates for this procedure, and will show techniques for enucleating myomas while minimizing thermal damage to the surrounding myometrium and multilayered closure of the hysterotomy incision. A review of the benefits of robotic surgery versus laparoscopic or open techniques will be included.

**Learning Objectives:** At the conclusion of this course, the participant will be able to:
1) Apply skills learned to perform robotic myomectomy; 2) identify the appropriate dissection plane for enucleation of myomas; 3) discuss the advantages of robotic over laparoscopic or open abdominal myomectomy; and 4) discuss the method for a multilayered closure of the myometrium.

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**Session VII**

Session Chair: F.R. Nezhat

- **1:00**  **Keynote Address:** Evidence-based Medicine vs Real-life Evidence in OBGYN  A.M. Vintzileos
- **1:30**  Laparoscopic Management of Vascular Injury: Clip Application, Suturing Repair and Hemostatic Agents  C.H. Nezhat
- **1:50**  Robotic and Laparoscopic Technique: Tips and Tricks in Obese Patients – How to Close Vaginal Cuff to Avoid Dehiscence  P.T. Soliman
- **2:10**  Question & Answers
- **2:25**  Break; Exhibit Hall Visit
- **2:40**  **LAB SESSION V:** Pelvic Trainers / Suture Lab / Robot Lab / Simulation Lab with Preceptors (Maximum 3 participants per trainer)  Faculty

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**Session VIII**

Session Chair: C.R. Nezhat

- **4:30**  Anesthesia for Operative and Robotic Surgery: How to Convince an Anesthesiologist to Place Obese or Non-obese Patient in Steep Trendelenburg  S.M. Littwin
- **4:45**  SURGICAL VIDEO: Tips for Avoiding Complications  F.R. Nezhat
- **5:10**  Question & Answers
- **5:25**  **LAB SESSION VI:** Pelvic Trainers / Suture Lab / Robot Lab / Simulation Lab with Preceptors (Maximum 3 participants per trainer)  Faculty
7:00  Adjourn
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

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).
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Shan Biscette*
Douglas N. Brown*
E. Cristian Campian
Grants/Research Support: Coloplast
Consultant: American Medical Systems
Jennifer Eun Sun Cho*
Linus T. Chuang*
Moushumi S. Datta*
Erica C. Dun*
Lena El Hachem*
Peter S. Finamore
Consultant: Boston Scientific Corp., Intuitive Surgical
Tamara N. Finger*
Fabio Ghezzi*
Gabrielle Goossner*
Jian Qun (Kathy) Huang
Speaker’s Bureau: Intuitive Surgical
Joseph (Jay) L. Hudgens
Consultant: Karl Storz Endoscopy-America
Valentin Kolev*
Mario M. Leitao
Consultant: Intuitive Surgical
Other: Proctor - Intuitive Surgical
Michael L. Lewis*
Sanford M. Littwin*
Connie S. Liu*
Jacques L. Moritz*
Vadim V. Morozov
Other: Proctor - Intuitive Surgical
Stock/Shareholder: Titan Medical
Nimesh P. Nagarsheth*
Azadeh A. Nezhat*
Camran R. Nezhat*
Ceana H. Nezhat
Consultant: Intuitive Surgical, Lumenis, Karl Storz Endoscopy-America
Speaker’s Bureau: Conceptus Inc., Ethicon Women’s Health & Urology
Farr R. Nezhat
Consultant: Genzyme, Plasma Surgical
Linda M. Nicoll*
Iris K. Orbuch*
Laurence Orbuch*
Steven F. Palter*
Michael C. Pitter
Speaker’s Bureau: Intuitive Surgical
Tamer A. Seckin*
Pamela T. Soliman*
Jason A. Sternchos*
Radha Syed
Consultant: Myriad Genetics Lab, Neosurgical
Other: Abbott Laboratories - Back up site for a study
Togas Tulandi*
Patrick F. Vetere*
Anthony M. Vintzileos
Speaker’s Bureau: Hologic
Michael Wenof*
Jyoti Yadav*
Robert K. Zurawin
Consultant: Ethicon Endo-Surgery, Ethicon Women’s Health & Urology, Conceptus Inc., CONMED Corp., UpToDate

Asterisk (*) denotes no financial relationships to disclose.
Why and How to Use Different Sutures, Including Barbed Sutures, for Laparoscopic and Robotic Surgery. Trocar Placement and Set-up for Video-Laparoscopy and Robotic Platform: The Secret to Success

Farr R. Nezhat, MD, FACOG, FACS
Professor of Obstetrics and Gynecology
Columbia University Medical Center
Chief, Gynecologic Robotic, Minimally Invasive Surgery Fellowship
Division of Gynecologic Oncology
Department of Obstetrics and Gynecology
St. Luke's-Roosevelt Hospital Center
New York, NY

December 6–7, 2012

Objectives

• Identification of proper instrumentation

• Utilize the proper techniques with laparoscopic and robotic-assisted surgery

• Provide an adequate assessment of intra-operative injury

Applications of Suturing

• Oppose tissues during reconstructive procedures
  • Vaginal cuff, cervical stump
  • Myomectomy
  • Tubal reanastomosis
  • Pelvic floor repair

• Management of intraoperative complications
  • Vascular
  • GI
  • GU

Proper Instrumentation

Sutures and Needles
• Vaginal cuff – No. 0 absorbable or PDS on CT-1 needle
• Myomectomy closure – No. 0 or 2-0 absorbable for myometrium, 3-0 for serosa
• Colposuspension – No. 0 nonabsorbable on SH or CT-1
• Tubal reanastomosis – No. 6-0 or 7-0 vicryl
• Quill™ (Angiotech) PDO, V-Loc™ 180 (Covidien)

Conflict of Interest

• Consultant: Genzyme; Plasma Surgical
Technique

**Intracorporeal**
- 12-25cm length
- Cut suture to length of needle driver

**Extracorporeal**
- Cut suture 36 in / 70 cm

**Proper Instrumentation**

**Knot Pushers**
- Extracorporeal knot tying
- Open-ended
- Close-ended
  - Avoids slippage of knot pusher off suture
- Laparoties (Ethicon) – absorbable clips to fasten knots

**New Methods**
- Quill™ (Angiotech)
- V-Loc™ 180 (Covidien)
- Endo-Stitch™ (Covidien)
**Quill™**

- Bidirectional barbed suture
- Eliminates need for tying

**V-Loc™ 180**

- Unidirectional barbed suture
- Looped end
- Eliminates need for tying

---

### History of Barbed Sutures

- 1951: First presented for tendon repairs [1]
- 2004: First US FDA approval for bidirectional barbed polydioxanone suture (Quill, Quill Medical Inc.) [3]
- 2009: V-Loc 180 was FDA approved (Covidien)

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**Barbed suture products:**
- the Quill™ SRS bidirectional barbed suture product line (Angiotech Pharmaceuticals, Inc., Vancouver, BC, Canada)
- V-Loc™ Absorbable Wound Closure Device product line (Covidien, Mansfield, MA)

**Contain barbs that anchor the sutures to tissue without knots.**

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**Barbed sutures are available in both absorbable and non-absorbable monofilament materials.**

**Available bidirectional and unidirectional barbed suture materials include:**
- PDO
- Poliglecaprone 25
- Glycomer 631
- Nylon
- Polypropylene
Bidirectional Barbed Sutures (Quill™ device)

- Bidirectional barbed sutures are manufactured from monofilament fibers. [1]
- A micromachining technique that cuts barbs into the suture around the circumference in a helical pattern. [1]
- The barbs are separated from one another by a distance of 0.88 to 0.98 mm and are divided into 2 groups that face each other in opposing directions from the suture midpoint. [2]
- Needles are swaged onto both ends of the suture length.
- Barbed suture is 1 suture size greater than its conventional equivalent.
  - For example, a 2-0 barbed suture equals a 3-0 smooth suture.

PDO Configurations

PDO (polydioxanone) Monofilament

- Absorbable
- Essentially, complete in approximately 180 days
- Non-absorbable
- While suture sutures are not absorbed, progressive hydrolysis of the nylon is color change evaluation, gradual loss of the tensile strength overtime.
**Unidirectional Barbed Suture (V-Loc)**

- Manufactured from monofilament fibers, but needles are swaged onto only 1 end whereas the other end maintains a welded closed loop to facilitate initial suture anchoring.
- Unidirectional barbed suture is rated equal in strength to its USP smooth suture counterpart.
- This strength rating difference between the 2 barbed varieties is the result of labeling differences, rather than an actual material benefit. [1]

**V-Loc™ wound closure device:**
- V-Loc™ 90 absorbable wound closure device is made from synthetic polyester, Glycomer™ 631.
- Composed of glycolide, dioxanone and trimethylene carbonate.

**V-Loc Needle Types**

<table>
<thead>
<tr>
<th>Premium reverse cutting</th>
<th>Taper point</th>
</tr>
</thead>
<tbody>
<tr>
<td>P-12 3/8 CIRCLE, 19 mm</td>
<td>CV-15 3/8 CIRCLE, 17 mm</td>
</tr>
<tr>
<td>• Length: 6, 12, 18, 23 inches</td>
<td>• Length: 6 inches (15 cm)</td>
</tr>
<tr>
<td>• Size: 2-0, 3-0, 4-0</td>
<td>• Size: 4-0, 3-0</td>
</tr>
<tr>
<td>• Color: Undyed</td>
<td>• Color: violet</td>
</tr>
<tr>
<td>P-14 3/8 CIRCLE, 24 mm</td>
<td>CV-23 1/2 CIRCLE, 17 mm</td>
</tr>
<tr>
<td>• Length: 11, 15, 18, 23 inches</td>
<td>• Length: 12 inches, 18 inches</td>
</tr>
<tr>
<td>• Size: 2-0, 3-0, 4-0</td>
<td>• Size: 4-0, 3-0</td>
</tr>
<tr>
<td>• Color: Undyed</td>
<td>• Color: violet</td>
</tr>
<tr>
<td>P-11 3/8 CIRCLE, 16 mm</td>
<td>V-20 1/2 CIRCLE, 26 mm</td>
</tr>
<tr>
<td>• Length: 12, and 18 inches</td>
<td>• Length: 6 inches, 12 inches, 18 inches</td>
</tr>
<tr>
<td>• Size: 3-0, 4-0</td>
<td>• Size: 3-0, 4-0 (6, 12, and 18 inches)</td>
</tr>
<tr>
<td>• Color: undyed</td>
<td>• 2-0-18 inches</td>
</tr>
</tbody>
</table>

**Room Set-Up**

- Modified dorsal lithotomy (Allen Universal)
- Uterine manipulator (V-Care, Koh, HUMI)
- Docking (Side, Front)
- Trocar placement

**Side Docking Diagram**

3 arm  4 arm

**Uterine Manipulation**

- ZUMI®
- KOH® cups
- VCare®
- HUMI®
- RUMI®
- Vaginal probes
Robotic Instruments

Trocar Placement

Laparoscopic

Robotic

Proper Instrumentation

Suturing Devices

- Endo-Stitch™ (Covidien)
  - Needle toggles back and forth
  - Disposable

Endo-Stitch™

Suturing

- V-Loc™ 180 device
  - Absorption within 180 days
  - First available wound closure device made from polyglyconate, a copolymer of glycolic acid and trimethylene carbonate.
# V-Loc™ 180: Needle Types

<table>
<thead>
<tr>
<th>Taper point</th>
<th>Premium reverse cutting</th>
</tr>
</thead>
<tbody>
<tr>
<td>CV-23 1/2 CIRCLE, 17 mm</td>
<td>P-12 3/8 CIRCLE, 10 mm</td>
</tr>
<tr>
<td>• 0: 0, 6, 12, 18 inches</td>
<td>• 2: 0: 12, 18, 24 inches</td>
</tr>
<tr>
<td>• 4: 0: 6, 12, 18, 24 inches</td>
<td>• 3: 0: 6, 12, 18, 23 inches</td>
</tr>
<tr>
<td>• Color: green</td>
<td>• Color: clear</td>
</tr>
<tr>
<td>CV-21 1/2 CIRCLE, 17 mm</td>
<td>P-14 3/8 CIRCLE, 94 mm</td>
</tr>
<tr>
<td>• 0: 12, 18 inches</td>
<td>• 2: 0: 12, 18, 24 inches</td>
</tr>
<tr>
<td>• 3: 0: 12, 18, 23 inches</td>
<td>• Color: clear</td>
</tr>
<tr>
<td>• 4: 0: 6, 12, 18, 23 inches</td>
<td>• Color: clear</td>
</tr>
</tbody>
</table>

| GS 21 1/2 CIRCLE, 37 mm | GS 21 1/2 CIRCLE, 37 mm |
| • 0: 12, 18 inches | • 2: 0: 12, 18, 24 inches |
| • 2: 0: 6, 12, 18, 23 inches | • 3: 0: 6, 12, 18, 23 inches |
| • Color: green | • Color: clear |

| V-20 1/2 CIRCLE, 26 mm | V-20 1/2 CIRCLE, 26 mm |
| • 0: 12, 18 inches | • 2: 0: 12, 18, 24 inches |
| • 3: 0: 12, 18, 23 inches | • 4: 0: 6, 12, 18, 23 inches |
| • Color: green | • Color: clear |

## References

THANK YOU!
Tips for Efficient Laparoscopic Suturing

Jay L. Hudgens, M.D.
Center for Women’s Health
Owensboro, KY

Disclosure

Consultant: Karl Storz Endoscopy-America

Learn to Learn

Whole – Part – Whole

10. Learn Systematically

1. Set the Needle
2. Re-approximate the Tissue
3. Tie the Knot

9. “Right” Your Needle

8. Confirmation is “Key”
7. “Line up” the Tissue and “Turn” the Key

6. Pass it on

5. The Knot Pusher is a Long Finger

4. It’s all about the Loop

3. There is no place like HOME!

2. Expert’s know how to ROLL.
1. Let the Left hand do the Work

References


How to Start Robotic Surgery: Tips and Tricks
Vadim Morozov, MD
University of Maryland School of Medicine
New York City 2012

Disclosure
- Intuitive Surgical: Other: Proctor
- Titan Medical: Other: Stock Ownership

Objective:
- To help new robotic surgeons start robot-enhanced program
- To describe the steps of successful robotic work flow
- To navigate the "kinks" of complex OR setup
- To avoid "labor pains" of already established process

If you just starting, and are the first one....
- Meet with the hospital's and OR administration
- Clearly express your expectations for the robot:
  - More cases per months
  - More advanced cases
  - More minimally-invasive cases
  - Better visibility of your practice
  - Ability to keep up with new technology

Listen and Suggest to the Administration
- Higher patient volume
- Better OR utilization
- Ability to attract local and regional providers
- Better visibility of the hospital
- ULTIMATELY: better patient's outcomes and satisfaction

Robotic OR team....
- Is the ultimate success or failure factor!!!!!!!!
- Designate robotic coordinator (OR nurse with experience)
- Consistent scrub tech and first assistant
- In academic institutions – second assist is a designated person
- Establish certain rules:
  - No brakes until the case is almost over
  - The same instruments used in every case
  - OR coordinator speaks with you directly about EVERYTHING
Consistent OR for robotic cases

- Easier to use with many ESU boxes and wires
- Don’t have to move the robot from room to room
  - Less chance to damage robot
  - Less chance to damage other equipment
- Shorter turn-around time
- Overall, better satisfaction with the case

Easier to use with many ESU boxes and wires

Instrumentation

- Have all available and extra instruments outside the OR
- KNOW your instruments
- Make sure the first-assist/scrub tech test them BEFORE start
- Have a back up plan: what if PK bipolar doesn’t work....

Recording and Documenting

- Make sure all cases (at least in the beginning) are recorded
- Educate your circulator how to use, record, and burn video
- Ensure that you can easily switch between different screens and cameras
- Have pictures printed at the end of EVERY case
  - Recent AAGL blog discussion, x-ray vs. laparoscopy
- Watch and review your first 10 cases – you learn a lot!!!

Driving and docking the robot

- No way is better than the other
- Don’t let Intuitive rep to dock the robot:
  - It must be your circulator, she/he needs to learn
- Mark the floor for bed position and robot position
- Think ahead – is the manipulation of the uterus more important than dexterity of the arms?

Ending the case

- If you have another robotic case
  - Ask the circulator to undrape the robot while you are finishing
  - If possible – get a second person to help (always good for beginning and end)
  - Make sure next case cart is outside the door
  - Communicate with PACU, anesthesia, pre-op area

Follow up is important

- Meet with your robotic team REGULARLY
- Tell them they are doing a great job
- Listen to them !!!!
- Meet with robotic coordinator separately
- Discuss problems, issues, make suggestions
Position yourself

- Try to become a member of the Robotic Committee
- Offer to be a "physician in-charge" of robotics
- Don’t be afraid to express your concerns with administration
- Don’t be annoying...have concrete ideas rather than complaints

Thank you
Different Types of Laparoscopic Hysterectomy and Why: Robotic-assisted vs Video-assisted Laparoscopy

Ceana Nezhat, MD
Atlanta Center for Special Pelvic Surgery and Reproductive Medicine
Atlanta, Georgia, USA

Disclosure

- Consultant: Intuitive Surgical, Lumenis, Karl Storz Endoscopy-America
- Speaker’s Bureau: Conceptus Incorporated, Ethicon Women’s Health & Urology, Hologic
- Other: Medical Advisor - Plasma Surgical, Scientific Advisory Board – SurgiQuest

Background

The first LAVH was reported in 1989


First Laparoscopic Radical Hysterectomy with Para-aortic and Pelvic Node Dissection

1989


Background

- Among the more than 600,000 hysterectomies done in the US, 65% are done by laparotomy
- Only about 10% of all hysterectomies are performed laparoscopically

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Number</th>
<th>Abdominal (TAH &amp; SCH, %)</th>
<th>Laparoscopic (LA VH &amp; LH, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>536,580</td>
<td>352,943 (65.9)</td>
<td>31,568 (10.7)</td>
</tr>
<tr>
<td>1991</td>
<td>532,390</td>
<td>344,251 (64.8)</td>
<td>27,637 (5.2)</td>
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<td>1992</td>
<td>540,870</td>
<td>344,251 (64.3)</td>
<td>29,336 (5.4)</td>
</tr>
<tr>
<td>1993</td>
<td>540,870</td>
<td>344,251 (64.3)</td>
<td>29,336 (5.4)</td>
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<td>1997</td>
<td>540,870</td>
<td>344,251 (64.3)</td>
<td>29,336 (5.4)</td>
</tr>
<tr>
<td>1998</td>
<td>540,870</td>
<td>344,251 (64.3)</td>
<td>29,336 (5.4)</td>
</tr>
<tr>
<td>1999</td>
<td>540,870</td>
<td>344,251 (64.3)</td>
<td>29,336 (5.4)</td>
</tr>
</tbody>
</table>

GAP in DATA

2000 | 620,000 | 423,460 (68.3) | 138,465 (22.3) | 58,075 (9.4) |
2001 | 637,000 | 424,242 (66.6) | 139,580 (21.9) | 71,904 (11.3) |
2002 | 659,000 | 454,051 (68.9) | 135,881 (20.6) | 69,068 (10.5) |
2003 | 606,000 | 411,474 (67.9) | 130,332 (21.5) | 64,194 (10.6) |
2004 | 610,000 | 413,580 (67.8) | 135,163 (22.2) | 61,867 (10.1) |

Background

The inherent difficulties of laparoscopic surgery

- The concern for patient’s safety
- Steep learning curve of laparoscopy
- Ability to operate off the remote screen with no perception of depth
- Limited time allowed for laparoscopic training in most educational programs

Background

Most of the present laparoscopic instruments are derived from laparotomy instruments

Introduction and use of computer-enhanced robotic systems

- Provide immersive “laparotomy-like” environment
- Ease the major difficulties that are encountered by the laparoscopic surgeon
- Facilitate the learning process while preserving the minimally invasive approach

Vessel/Tissue Sealing Devices

EnSeal, Ligasure, ACM Gyrus

Advantages of Robotic Technology

- Opportunity to bridge the gap between laparotomy & laparoscopy
- Improved dexterity
- Tremor filtration
- 3-D vision offering an immersive environment
- Intraabdominal articulation using laparoscopic instruments
**Robot: The Console**
- Positioned remotely from the patient
- Has controls for 3 dimensional viewing
- Ability to choose 0 or 30° laparoscope
- Motion scaling: reducing tremor

**The Surgical Cart**
- Supports either 3 or 4 robotic arms
- Central arm holds the 12mm camera
- 8mm or 5mm instruments are attached to the arms through an adapter

**Video Cart**
- 2 Video Camera Control Boxes
- 2 light sources

**The Masters**
Finger “masters” controls which convert human movements into electrical signals that direct the robot instruments

**Dexterity and the Robot**
- Large Yellow Arrows
  - 4 movements allowed in traditional laparoscopy
- Red Arrows
  - Endocorporeal movements by Endowrist technology
- Small Yellow Arrow
  - Grip

**da Vinci® Robot**
Vaginal Cuff Closure

Materials and Methods

- Prospective database and retrospective analysis of 97 patients
- None of the patients were candidates for vaginal hysterectomy due to the nature and complexity of the cases
- Patients with history of peritonitis, massive intra-abdominal adhesions, and bowel surgery were excluded

Materials and Methods

- Vascular pedicles were desiccated and transected using various vessel sealing electrosurgical devices during LAH and RALH
- In LAH cases, a 5- or 12mm umbilical canula and three 5mm accessory ports were used

Materials and Methods

- da Vinci® system was utilized for all RALH cases, mostly for suturing
- One 12mm intra-umbilical port and two 8mm lateral ports were used for placement of 3 robotic arms
- The unpaired t-test with a two-tailed P value (P < 0.05, CI 95%) was used for analysis

Results

<table>
<thead>
<tr>
<th></th>
<th>LAH</th>
<th>RALH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of procedures</td>
<td>55</td>
<td>42</td>
</tr>
<tr>
<td>Age (years)</td>
<td>47 ± 1.3</td>
<td>49 ± 1.3</td>
</tr>
<tr>
<td>Parity</td>
<td>1.5 ± 0.15</td>
<td>2.0 ± 0.27</td>
</tr>
<tr>
<td>Previous laparoscopy (%)</td>
<td>0.38 ± 0.08 (28.7)</td>
<td>0.55 ± 0.91 (50.0)</td>
</tr>
<tr>
<td>Previous laparotomy (%)</td>
<td>0.75 ± 0.13 (47.4)</td>
<td>0.50 ± 0.085 (47.7)</td>
</tr>
</tbody>
</table>

Values expressed as Mean ± SER, unless otherwise specified

Results

<table>
<thead>
<tr>
<th></th>
<th>LAH</th>
<th>RALH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uterine weight, g</td>
<td>190 ± 24</td>
<td>160 ± 120</td>
</tr>
<tr>
<td>EBL, ml</td>
<td>67 ± 7.5</td>
<td>65 ± 13</td>
</tr>
<tr>
<td>Intra-op complications</td>
<td>0.016 ± 0.013</td>
<td>0.023 ± 0.024</td>
</tr>
<tr>
<td>Post-op complications</td>
<td>0.016 ± 0.013</td>
<td>0.048 ± 0.033</td>
</tr>
<tr>
<td>Short-term post-op pain</td>
<td>0.091 ± 0.039</td>
<td>0.20 ± 0.064</td>
</tr>
<tr>
<td>Long-term post-op pain* (pain before surgery, %)</td>
<td>0.091 ± 0.29* (60.0)</td>
<td>0 (N/A)</td>
</tr>
</tbody>
</table>

Values expressed as Mean ± SER, unless otherwise specified

*Defined as postoperative pain shorter than 6 weeks

*P-value < 0.05, CI - 95%
Complications

<table>
<thead>
<tr>
<th></th>
<th>LAH</th>
<th>RALH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-operative</td>
<td>1 Uretotomy</td>
<td>1 Cystotomy</td>
</tr>
<tr>
<td>complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 Ureteroperitoneal fistula*</td>
<td>1 Leakage of urine – fistula suspected, not confirmed* (treated with bladder rest for 2 weeks)</td>
</tr>
<tr>
<td>Postoperative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>complications</td>
<td>1 Vaginal cuff bleeding, required suturing</td>
<td></td>
</tr>
</tbody>
</table>

\* - repaired laparoscopically
\* - patient with severe bladder endometriosis

Conclusion

- For experienced laparoscopic surgeons, LAH is superior to RALH, specifically with severe pelvic pathology
- The robot offers the surgeon ergonomic, tremorless, 3D capabilities
- The cost and additional training requirement for OR staff and surgeon may limit its widespread use

Conclusion

- Robotic procedures is a useful teaching tool and facilitator for transition from open abdominal to a laparoscopic approach
- Robot may bridge the gap between laparotomy and laparoscopy, which is limited by a steep learning curve

Thank you
Video assisted and Robotic assisted Laparoscopic Hysterectomy for Endometriosis, Adhesions and Patients with Previous Cesarean Sections

Camran Nezhat, MD
Clinical Professor Department of OB/GYN UCSF
Adjunct Clinical Professor Department of OB/GYN & Surgery Stanford University Medical Center
Center for Special Minimally Invasive and Robotic Surgery
Palo Alto, CA
www.Nezhat.org

Disclosure

- I have No financial relationships to disclose

Objectives

- Describe techniques for safe laparoscopic access
- Describe techniques used in difficult hysterectomies
- Describe techniques used to address difficult adhesions during laparoscopy

Learning Objective

- To be able to restore normal anatomy

Communicate with your Anesthesiologist

- Describe your anticipated procedure
- Estimated blood loss
- Estimated duration
- Preoperative antibiotics

HOW CAN WE REDUCE RISK OF COMPLICATION?

Test your equipment prior to the patient entering the operating room
- Review normal anatomy
- How to develop retroperitoneal dissection
- Discuss preoperative planning
- Examine proper instrumentation and techniques for dissection
- Review possible complications and management

**Step 1 – Know the Anatomy**

- Abdominal wall
- Ligaments
- Avascular spaces
  - Para-vesical space
  - Vesico-vaginal space
  - Vesico-uterine space
  - Recto-vaginal space
- Vascular structures

- The course of inferior epigastric vessels
- Posterior aspect of anterior abdominal wall
- The vesicouterine and vesicovaginal spaces
- The obturator internus muscle
- Right paravesical space and its structures
The rectovaginal space is completely developed. The appearance of space A) in a non-hysterectomized patients, and B) in a hysterectomized patient.

Intraperitoneal view of the sacral promontory and the location of the bifurcation of Aorta (*).

Anatomic relationships of the bifurcation of the Aorta, inferior vena cava and sacral promontory.

The relationship of bladder, ureters and rectum after a radical hysterectomy.

The ureter crosses over the common iliac artery.
Step 2 - Patient Positioning

- The patient is in supine position.
- The thighs are not flexed so that the suprapubic and lateral trocars may be maneuvered.
- Nasogastric tube is placed before procedure.

Ensure the patient is completely relaxed.
Step 3 – Palpation of aorta

The aorta and sacral promontory are palpated.


Step 4 – Insertion of Veress needle

Veress needle is grasped by the shaft and directed posteriorly at a 90° angle. Inset shows elevation of skin and subcutaneous tissue by towel clips.


Accessory Trocars

- Standard laparoscopy
  - Two to three 5 mm ports
  - 2 lateral
  - 1 supr-pubic
- Robotic
  - Three to four 5-8 mm ports
  - Similar configuration
  - Configuration may be altered depending on surgery
Continuation.....

- Before positioning the robotic cart, pressure points must be carefully padded.
- In the case of an airway emergency or cardiac arrest, resuscitating the patient requires disengaging the robotic instruments before backing the cart away from the OR table.
- Avoid head docking and use side or between legs docking when possible.

Thank You!

References

Supracervical Hysterectomy: Different Tricks to Avoid Injuring Ureter and the Bladder During Robotic-assisted vs. Video-assisted Laparoscopy

Robert K. Zurawin, MD
Chief, Section of Minimally Invasive Gynecologic Surgery
Baylor College of Medicine
Houston, Texas

Disclosure
- Consultant: Conceptus Incorporated; CONMED Corporation; Ethicon Endo-Surgery; Ethicon Women's Health & Urology; Hologic; UpToDate

Objective
- At the conclusion of this activity, the participant will be able to:
  - Identify the anatomic structures of the pelvis and their relationship to the course of the ureter
  - Develop their surgical technique to minimize injury to the ureter during laparoscopic hysterectomy

Avoiding Complications

Review of Laparoscopic Pelvic Anatomy
Pararectal Space
Paravaginal Space

Pelvic Sidewall – 3 Surgical Layers

Lateral Pelvic Sidewall

Laparoscopic Dissection of the Pelvic Sidewall and Ureter

Identifying the Ureter Before Coagulating the Uterine Artery

Importance of the Uterine Manipulator
Elevation of Ureters

Ureteral injury

Ureter tied off

Ureteral thermal injury - Robotic

Excision of ureteral endometriosis

Vaginal Cuff Closure and the Ureter
Robotic Supracervical Hysterectomy and Sacrocolposuspension

Peter S. Finamore, MD, MA, FACOG
Associate Director of the Division of Urogynecology and Pelvic Reconstructive Surgery
Winthrop University Hospital
Assistant Professor Obstetrics and Gynecology
Stony Brook University School of Medicine

Disclosures
• Consultant: Boston Scientific Corp. Inc.; Intuitive Surgical

Objectives
• Pelvic Organ Prolapse and Levels of Pelvic Organ Support
• Current Surgical Techniques to treat POP
• Docking for a Sacrocolpopexy
• Videos of Robotic Sacrocolpopexy
• Tips and Tricks

Normal Pelvic Floor Anatomy

Delancey’s Three Levels of Support

Level I Support – Apical Compartment
Upper vagina and cervix suspended from lateral pelvic walls via the uterai-sacral and cardinal ligament complex
The fibers pull the top of the vagina, the cervix, & the lower uterine segment posteriorly towards the sacrum on the levator plate away from the genital hiatus.
Level II Support – Mid Vagina – Anterior and Posterior Compartment

Mid vagina anteriorly, pubocervical fascia is attached to arcus tendineus fascia pelvis (a.k.a. white line) and the superior fascia of levator ani muscle.

Mid vagina posteriorly, recto-vaginal septum attached to levator fascia on each side, ‘posterior white line’.

Level III Support – Distal Vagina

Perineal membrane and perineal body support the lower 1/3 of vagina, urethral and anal canal.

The perineal body joins together fascial coverings and muscular components of the superficial and deep perineal compartments.

Compartment Defects

- Loss of Level I support leads to apical prolapse i.e. uterine or vaginal vault prolapse and enterocele.

Level I Support Defect

Loss of Level II support leads to paravaginal defect as well as anterior compartment (cystocele) and/or posterior compartment (rectocele) defects.

Level III Support Defects

- Major component of pelvic support – Perineocele – attenuated perineal body.
**Prolapse Facts**

- 50% of women age 50-79 will have some form of prolapse.
- Lifetime risk of undergoing surgery for prolapse and incontinence is 11%.
- 300,000 women undergo surgery per year for this condition.
- Risk factors: Age, Obesity, Multiparity, Hysterectomy, Genetic Component, Smoking, Chronic coughing, Constipation/straining.

**Prolapse Treatment Options**

- Observation
- Pessary Management
- Vaginal Reconstructive Surgery
  - Decreased morbidity compared to abdominal surgery.
  - Long-term success rates are lower than abdominal approaches.
- Vaginal Mesh – Controversial.
- Sacrocolpopexy with Mesh Augmentation
  - Open (abdominal) or laparoscopic.
  - Advantages:
    1. Preserves normal axis of vagina.
    2. Attains maximal vaginal depth.
    3. Provides long-lasting support for compromised tissues.
    4. Represents the gold standard for surgical repair - 50 years experience.

**Sacrocolpopexy**

- Open (abdominal)
  - Excellent long-term results: 93-100% success rates with durable repair.
  - Increased morbidity: invasive mid-line incision leading to prolonged recovery time (2-4 hospital days).
  - Limited patient candidates.
- Laparoscopic
  - Reproduce open approach minimally invasively.
  - Technically difficult learning curve due to complex suturing and dissection.
- Now Robotic...

**Da Vinci® Sacrocolpopexy for Vaginal Vault or Uterine Prolapse - APICAL REPAIR**

- Represents a state-of-the-art minimally invasive approach to surgical correction of vaginal vault or uterine prolapse by supporting the vagina to the sacrum using a polypropylene mesh.
- The da Vinci System’s high-resolution 3D visualization, wristed instrumentation and intuitive movement allow reconstructive pelvic surgeons to perform the most precise, complete and durable minimally invasive approach to advanced pelvic organ prolapse.

29.5% Underwent Concomitant Hysterectomy

Pre-op POP-Q Exam: C point*

Open (Abdominal) Sacrocolpopexy: N=105

Robotic Sacrocolpopexy: N=73

P Value

Total Operative Time (min)

da Vinci Sacrocolpopexy: Proven Results

2.7 1.3

Length of Stay (days)

255 103

EBL (ml)

-8 -9

Post-op POP-Q Exam: C point*

<0.001

<0.001

<0.001

<0.001

-0.008

73 consecutive robotic sacrocolpopexy patients compared with historical cohort of 105 consecutive abdominal patients

Dramatically decreased blood loss and length of stay in the robotic group with no loss of efficacy: C point suspension superior to open cohort results

Subsequent study looking at 1 year outcome reported 100% anatomical cure for the apex and significant improvement in pelvic floor function

Surgical Steps

Summary

1. Anterior Bladder Dissection

- Locate vesico-uterine peritoneum, tent up and infer (bladder flap)
- Dissed the bladder of the lower uterine segment, cervix and anterior vaginal wall
- Correct plane is avascular
- Bedside assistant can provide counter traction from the vagina or with 3rd robotic arm tenaculum can pull up on fundus of cervical stump
- Take approx 8 cm down of wall

Instruments:

- da Vinci™ (Intuitive Surgical, Sunnyvale, CA)
- Hot Shears™ (Monopolar Curved Scissors)
- Maryland Bipolar Forceps
- Fenestrated Bipolar Forceps
- 30° Scope (Da Vinci)

Scope:

1. Hysterectomy +/- BSO
   - Subtotal hysterectomy:
     - Leave the uterus in situ for later morcellation
   - Total hysterectomy:
     - Perform vaginotomy and remove the uterus
2. Develop the bladder flap anteriorly
3. Develop the rectovaginal septum
4. Develop the presacral space and expose the anterior longitudinal ligament
5. Attach mesh to the anterior vaginal wall
6. Attach mesh to the posterior vaginal wall
7. Adjust mesh tension
8. Attach mesh to the sacrum
9. Close the peritoneum

Switch to the 30° scope:

10. Develop the presacral space

Switch to the 5° scope:

11. Morcellate the uterus if necessary

12. Use the camera to close the fascia if using a fascial closure device

Switch back to the 5° scope:

13. Leave the uterus in situ for later morcellation

Hysterectomy:

- Leave the uterus in situ for later morcellation
- Vaginal cuff closure

da Vinci SACROCOLOPPEXY: Proven Results

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Robotic</th>
<th>Open (Abdominal)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-op POP-Q Exam: C point*</td>
<td>29.5%</td>
<td>47.9%</td>
<td>0.02</td>
</tr>
<tr>
<td>Pre-op POP-Q Exam: C point*</td>
<td>47.9%</td>
<td>21.5%</td>
<td>0.02</td>
</tr>
<tr>
<td>Total Operative Time (min)</td>
<td>128</td>
<td>225</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Post-op POP-Q Exam: C point*</td>
<td>0.008</td>
<td>2.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Length of Stay (days)</td>
<td>103</td>
<td>205</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
2. Rectovaginal Dissection
- Locate recto-uterine peritoneum, tent and enter
- Use tenaculum or assistant to create counter traction
- Able to dissect to perineal body
- Beware of the rectum
- Correct plane is avascular
- Dissect 6-10 cm of the posterior vaginal wall.

3. Presacral Dissection
- Retract the sigmoid to the left (using the 3rd instrument arm or assistant port), anterior about 3cm to the right
- Tent the peritoneum overlying the sacral promontory
- Dissect presacral fat, beware of middle sacral vessels along the anterior longitudinal ligament
- Open or tunnel peritoneum between posterior and sacral dissection to cover mesh

4. Posterior Mesh Attachment
- Attach posterior arm of Y mesh first
- Able to take down to perineal body to cover entire posterior compartment
- Secure with multiple sutures to recto-vaginal connective tissue, avoid full thickness blies into vagina
- Place the distal (corner) sutures first and work way up the posterior wall to the cervix

5. Anterior Mesh Attachment
- Flip anterior leaf of Y mesh over and secure to the pubocervical connective tissue with multiple sutures, again avoid suture through and through the vaginal wall
- Place the distal and lateral (corner) sutures first, working down towards cervix
- Trim excess mesh

6. Sacral Mesh Attachment
- Have bedside assistant push on vaginal apex to determine where to secure mesh to ligament
- Avoid middle sacral vessels or presacral venous plexus by locating an avascular area of the anterior longitudinal ligament
- Additional sutures (2-3) are placed superiorly to allow for adequate visualization
- Trim the excess mesh

7. Close Peritoneum
- Retropereitonealize the mesh to help prevent bowel adherence to the mesh
- Use a running stitch to close the peritoneum overlying the mesh
- This step is facilitated by the earlier opening of the peritoneum from the sacrum to the vagina or tunneling
- This process also obliterates cul de sac
8. Cystoscopy

- Confirms bilateral ureteral patency and no trauma/damage during the dissection.
- Use the intravenous indigo carmine.

Tips & Tricks

Managing Presacral Hemorrhage

- Remain calm
- Communicate with the patient-side team
- Apply pressure with an available da Vinci instrument.
- Use the Ray-Tec™ X-Ray Detectable 4” x 4” Sponge to apply pressure.
- Consider attempting to control bleeding with the Maryland Bipolar Forceps
  – May require switching instruments
- Consider using FloSeal™
- “Emergency” undock as a last resort
  – Release da Vinci instruments from tissue.
  – Remove instruments and trocars all in one step by depressing the set-up joint button.
  – Keep the assistant port holding pressure.

General Operating Tips & Tricks

- Keep the instrument tips in view at ALL TIMES.
- Ensure that the patient-side assistant has access to the ports after instrument arms are in place.
- Anticipate potential external interferences.
- Lower the patient bed prior to docking.
- COMMUNICATE with the bedside team.
- Move insufflation from the endoscope to the assistant port to reduce fogging.
- Manually lifting up the abdominal wall when docking (a.k.a. burping) allows for lower insufflation pressure.

Suturing Tips & Tricks

- Practice in the lab.
- Consider placing two surgeons knots (one right on top of the other) followed by two half hitches when tying the CV-2 Gore-Tex® suture.
- Use a sliding knot on the first (most inferior/distal) sacral suture to prevent the 1st intracorporeal knot from slipping.
- Do not grasp the suture too close to the knot when tying.
- Keep your loops loose but your knots tight.

da Vinci Sacrocolpopexy Tips & Tricks

- Retract the small bowel and omentum; identify the sacrum BEFORE docking the patient cart.
- The thick black band, indicating the remote center, should be just visible at the level of the peritoneum.
- Begin with the 0° scope to place ports, hysterectomy +/- BSO and dissection.
- Use the 30° down scope for presacral dissection.
- Extend the presacral peritoneal dissection inferiorly to the vagina.
- Use the wide-weave polypropylene mesh (Y-configuration).
- Attach the posterior mesh first.
- Loosely tie the anterior leaf of mesh to sacral end to keep it out of field of view.
- Confirm the appropriate tension before suturing the mesh.
Summary

da Vinci® Sacrocolpopexy for Pelvic Organ Prolapse
- Minimally invasive surgery
- Surgical times can be longer than open laparotomy
- Faster recovery/Less post op pain
- 2 weeks for robotic surgery, 3-4 weeks for vaginal and 6 weeks for abdominal
- Most patients are back to work in 2 weeks
- State of the art technology - changing the way traditional surgery has been performed

Post Test

Where is the best location of the camera during a Robotic sacrocolpopexy?
1) At the level of the umbilicus
2) Left upper quadrant
3) Right upper quadrant
4) Above the umbilicus
5) It does not matter because the camera is moved to different sites during the case
Robotic-assisted vs video-assisted laparoscopy for retroperitoneal dissection and lymphadenectomy

Mario M. Leitao, Jr., MD
Associate Professor, Weill Cornell Medical College
Associate Member, Gynecology Service
Co-Director, Robotic Surgery Program
Department of Surgery
Memorial Sloan-Kettering Cancer Center

Objectives

- To provide the available evidence supporting laparoscopic/MIS approaches for endometrial cancer
- To describe the technical differences for laparoscopic lymphadenectomy with and without the use of the robotic platform
- To describe the available literature comparing standard laparoscopy with robotically-assisted laparoscopy

Disclosure

Intuitive Surgical: Surgical Proctor

Natural Evolution of Technology

Konrad Zuse’s Z1 (1938)
First binary computer
Mechanical calculator

UNIVAC I – UNIVersal Automatic Computer (1951)
First commercial computer
U.S. Census Bureau
Original price: $150,000
Ultimate price: $1.5 million
46 systems built and sold

IBM 701 – (1953)
First commercial IBM computer
$15,000/month rental fee
Only 19 systems built and sold

Demand for Improved Technology

For Operating on People

For the Ballgame at Home
Evolution of Technology

First personal computer
Kit that user had to put together, make it work, and write software
256 Byte RAM
$400

IBM 5100 – First IBM PC (1975)
50 pounds
Programming language (APL or BASIC)
64K storage version
$19,975
($86,000 – 2012)

Where's the RCT?

Versus

What's the difference?

Natural Evolution of MIS
Integration of computer technology in the operative field

NOT Anti-Laparoscopy!

Summary of RCTs
Laparoscopy is standard

<table>
<thead>
<tr>
<th>Year</th>
<th>From</th>
<th>Zorlu</th>
<th>Zullo</th>
<th>Tozzi</th>
<th>Torea</th>
<th>Drente</th>
<th>OGEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>NO</td>
<td>SAME</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>2005</td>
<td>YES</td>
<td>SAME</td>
<td>SAME</td>
<td>SAME</td>
<td>SAME</td>
<td>SAME</td>
<td>SAME</td>
</tr>
<tr>
<td>2010</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>2011</td>
<td>YES</td>
<td>SAME</td>
<td>SAME</td>
<td>SAME</td>
<td>SAME</td>
<td>SAME</td>
<td>SAME</td>
</tr>
</tbody>
</table>

Total # of cases: 61 | 52 | 78 | 122 | 279 | 332 | 2616

OP time: NO SAME NO NO NO NO

EBL: YES YES YES YES YES NO

LN counts: SAME SAME SAME SAME SAME SAME

LOS: YES YES YES YES YES YES YES

Complications: SAME SAME SAME SAME SAME SAME

QOL: SAME SAME SAME SAME SAME SAME

Cost-effective: SAME SAME SAME SAME SAME SAME

Survival: SAME SAME SAME SAME SAME SAME

Minimally Invasive Surgery
Benign hysterectomy in the US 2003

**Robotics**

**Why?**
- Provides significant improvements
- 3-D imaging
- Wrist-like motion of instruments
- Comfortable operating environment for surgeon
- Easier to adapt to minimally invasive approach from an open approach
- Easier to suture
- Instrument movements complementary to surgeon’s
- Radical procedures much easier
- Much easier to operate in obese
  - Integration of computer technology into surgery

**Laparoscopy +/- RBT**

**Patient positioning**

**RBT LND**

**Trocar placement – to IMA**
- Minimum distances

**RBT LND**

**Trocar placement – To renal vessels**
- Minimum distances

**RBT Para-aortic LND to renals**

**Alternate trocar placement**
- Minimum distances

**Robotic Platform**

**General thoughts**
- A tool
- Not new surgery or procedure
- Very rare to have “robotic” complication if used properly
- Surgeon who’s using the robot has a complication as with any other tool

**Robotics Platform**

**Robotic Platform**

**General thoughts**
- A tool
- Not new surgery or procedure
- Very rare to have “robotic” complication if used properly
- Surgeon who’s using the robot has a complication as with any other tool
**Standard Trocar Placement for Operative Laparoscopy**

**Pelvic LND**
*With and without RBT*

**Para-aortic LND**
*With and without RBT*

**Incorporation of Platform**
*Uterine cancer*

**Completely Cases**

**Uterine cancer**
*Perioperative outcomes*

---

<table>
<thead>
<tr>
<th>Variable</th>
<th>LRE (n=292)</th>
<th>RBT (n=307)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age (years)</td>
<td>62 (25-85)</td>
<td>60 (27-85)</td>
<td>0.2</td>
</tr>
<tr>
<td>Median BMI (kg/m2)</td>
<td>28.1 (16.9-57.2)</td>
<td>28.7 (16.6-66)</td>
<td>0.1</td>
</tr>
<tr>
<td>BMI ≥ 40 kg/m2</td>
<td>29 (10%)</td>
<td>51 (15%)</td>
<td>0.049</td>
</tr>
<tr>
<td>Conversions</td>
<td>39 (13%)</td>
<td>37 (11%)</td>
<td>0.4</td>
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**Completed Cases**

**Variable**

<table>
<thead>
<tr>
<th>Variable</th>
<th>LRE (n=263)</th>
<th>RBT (n=310)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAVH</td>
<td>229 (87%)</td>
<td>-</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TLH</td>
<td>33 (13%)</td>
<td>137 (100%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Other</td>
<td>1 (0.4%)</td>
<td>5 (1.6%)</td>
<td></td>
</tr>
<tr>
<td>Hysterectomy only</td>
<td>24 (9%)</td>
<td>32 (10%)</td>
<td>0.6</td>
</tr>
<tr>
<td>Hyst + PLND</td>
<td>120 (46%)</td>
<td>150 (48%)</td>
<td>0.5</td>
</tr>
<tr>
<td>Hyst + PLND+PALND</td>
<td>119 (46%)</td>
<td>126 (41%)</td>
<td>0.3</td>
</tr>
<tr>
<td>Other</td>
<td>-</td>
<td>2 (0.7%)</td>
<td></td>
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</table>

**Uterine cancer**

**Variable**

<table>
<thead>
<tr>
<th>Variable</th>
<th>LRE (n=263)</th>
<th>RBT (n=310)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median EBL (cc)</td>
<td>100 (0-400)</td>
<td>50 (0-400)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LOS (days)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>2 (1-15)</td>
<td>1 (0-5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>0 day (same day d/c)</td>
<td>0 (0%)</td>
<td>12 (4%)</td>
<td></td>
</tr>
<tr>
<td>1 day</td>
<td>86 (32%)</td>
<td>217 (70%)</td>
<td></td>
</tr>
<tr>
<td>2 day</td>
<td>138 (53%)</td>
<td>58 (19%)</td>
<td></td>
</tr>
<tr>
<td>&gt;=3 days</td>
<td>39 (15%)</td>
<td>23 (7%)</td>
<td></td>
</tr>
<tr>
<td>Total room time (min)</td>
<td>256 (128-532)</td>
<td>298 (142-613)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total operative time (min)</td>
<td>184 (80-445)</td>
<td>213 (96-533)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

---

### Results

**Robotics learning curve**

COMPLETED Uterine cancer cases (310 RBT/263 LSC) - 5/07 - 12/31/10 (44 months)

Median total room time

LRS = 250 min


---

**Complications**

<table>
<thead>
<tr>
<th>Variable</th>
<th>LRS (n=263)</th>
<th>RBT (n=310)</th>
<th>P-value</th>
</tr>
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<tbody>
<tr>
<td>Any grade</td>
<td>33 (12%)</td>
<td>31 (10%)</td>
<td>0.1</td>
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<tr>
<td>Grade 1-2</td>
<td>32 (12%)</td>
<td>22 (7%)</td>
<td>0.04</td>
</tr>
<tr>
<td>Vaginal cuff leak/separation</td>
<td>1 (0.4%)</td>
<td>1 (0.3%)</td>
<td>0.9</td>
</tr>
<tr>
<td>Grade 3+</td>
<td>7 (3%)</td>
<td>9 (3%)</td>
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<tr>
<td>Intraoperative ureteral transection</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Intraoperative obturator n. transection</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Intraoperative IVC injury</td>
<td>1</td>
<td>2</td>
<td></td>
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<tr>
<td>Intraoperative cystotomy</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Pelvic abscess</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>E. coli empyema</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Lymphocyst</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Non-infected pelvic collection</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Trocar site herniation</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>


---

### Impact of robotics program

**Change in MIS approach**

<table>
<thead>
<tr>
<th>Year</th>
<th>LRS</th>
<th>RBT</th>
<th>P-value</th>
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<tbody>
<tr>
<td>2007</td>
<td>54%</td>
<td>12%</td>
<td>0.01</td>
</tr>
<tr>
<td>2008</td>
<td>15%</td>
<td>5%</td>
<td>0.002</td>
</tr>
<tr>
<td>2009</td>
<td>6%</td>
<td>4%</td>
<td>0.005</td>
</tr>
<tr>
<td>2010</td>
<td>4%</td>
<td>2%</td>
<td>0.006</td>
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</table>


---

### Robotics

**Impact on practice**

Role of planned laparotomy – newly diagnosed endometrial cancer

Summary

• MIS approach preferred and should be considered standard
• Patient outcomes generally excellent with or without robot
• Significant challenges with standard laparoscopy beyond the few experienced surgeons
• RBT is LAPAROSCOPY
• RBT will allow more surgeons to offer MIS and do more complex cases
• Incorporation of computer technology into surgery

THE FUTURE of minimally invasive surgery

THANK YOU!
Perils and pitfalls of morcellation

Togas Tulandi MD, MHCM
Professor and Academic Vice Chairman of Obstetrics and Gynecology
Milton Leong Chair in Reproductive Medicine
McGill University

Conflict of interests

- I have no financial relationships to disclose.

Case

- 36 years old female
- Symptomatic uterine myoma
- Laparoscopic myomectomy
- Abdominal pain and fever

Which uterus has to be morcellated?

Not evaluated: uterine mobility, vaginal width, BMI and uterine consistency

Condous, et al, JMIG 2009
Page 51
Use of morcellator

- Morcellation from medial or lateral incision?
- Use a tenaculum
- Grasp securely and not too large
- Make sure no other tissue being grasped
- Away from bowel, omentum etc.

RCT of Morcelllex and Rotocut G1 (Zullo et al, JMIG 2010)

- Handling score (VAS)
  - LASH 7.0 5.8 P: 0.003
  - Myomectomy 7.2 6.5 P: 0.045
- Excellent handling

Complications

- Parasitic myoma 0.12%
- Morcellation of malignant tissue
- Intra-abdominal injury

It appears that LPD could be due to metaplasia of mesenchymal cells of the peritoneum, and in susceptible women, leaving fragments of myoma in the abdominal cavity might contribute to the development of LPD.

Accordingly, one should avoid leaving fragments of the uterus or myoma tissue in the abdominal cavity after morcellation.
Vaginal morcellation

Favero 2012
**Step-By-Step Vaginal Hysterectomy and Difficult Vaginal Hysterectomy**

Peter S. Finamore MD, FACOG, MA
Associate Director Division of Urogynecology and Pelvic Reconstructive Surgery
Winthrop University Hospital, Mineola, NY
Assistant Professor Department of OB/GYN
State University of New York Stony Brook

---

**Objectives**

- Background
- Step-by-Step TVH
- Difficult Vaginal Hysterectomy
- Update on Mesh

---

**Background**

- Most common operation by gynecologists
- 2nd most common major surgical procedure in USA
- Rate: 6 – 9/1000 women
- 1985: 724,000
- 1998: 600,000 performed
- An average of 622,000 per year over the last decade

---

**Advantages of TVH**

- No abdominal incision
- Early ambulation
- Almost entirely retroperitoneal
  - Less chance for ileus
- Less interference with pulmonary function
- Fewer complications
- Less anesthesia
- Less postoperative analgesia
- Earlier discharge
- Tolerated by elderly / obese / those with medical conditions
- Repair of pelvic support defects

---

**Disclosure**

- Consultant: Boston Scientific Corp. Inc.; Intuitive Surgical
Step-By-Step Vaginal Hysterectomy

- Many variation on technique
  - Vasconstrictors, Foley, anterior or posterior entry, closure of cuff, closing peritoneum, suspending apex, suture, instruments, etc., etc., etc.
- Patient selection is key to making surgery go smoothly
  - Size of uterus, degree of descent, previous surgery, BMI
- Patient position — neurologically safe
- Know your anatomy
  - Bones, ligaments, muscles, connective tissue, nerves, vessels
- Good exposure/assistant
- Proper instruments

Step 1
• Locate vesico-uterine fold to identify bladder
• Be careful not to remove excess vaginal tissue as this could lead to shortening of the vagina
• Use Bovie on cut to make incision (can be done sharply as well)
• Take incision down to avascular pubo-cervical fascia (vaginal tissue ‘falls away’ from cervical tissue)

Step 2
• Dissect vagina off cervix sharply — avoid using sponge to ‘push’ tissue away — mobilize vagina anteriorly and posteriorly
• Entry into peritoneal cavity — posteriorly easier
• Tent peritoneum and entry sharply — do not push peritoneum away
• Once entered explore and place long weighted speculum — protects rectum

Step 3
• Dissect bladder off of lower uterine segment — if peritoneum identified enter anteriorly as well and place retractor to protect bladder
• Foley can help to locate bladder — feel the balloon
• Clamp, cut and suture ligate Uterosacral ligament with 1st bite — make sure to incorporate peritoneum with this bite to limit bleeding — tag and hold

Step 4
• If anterior cul de sac has not been entered yet, continue to dissect bladder and enter now
• With bladder protected anteriorly and rectum protected posteriorly clamp cardinal ligament complex — hug the uterus to prevent injury to ureters
• Clamp alternating pedicles from side to side to help improve uterine mobility

Step 5
• Next pedicle likely to includes uterine vessels – continue to make tips of clamp slide off cervix to protect ureters
• Once uterine are clamped you can pull uterus through to clamp the uterine-ovarian pedicle or continue step wise as previously — tag these
Step 6

• Once the entire specimen is out inspect ovaries or remove them as predetermined
• Inspect the pedicles between the 2 tagged pedicles (uterosacral and utero-ovarian) to ensure hemostasis

Step 7

• Closure of the peritoneum to obliterate cul de sac with a purse string suture and prevent enterocele above the ovarian pedicle
• Suspend angles of vaginal cuff to tagged uterosacral pedicles to prevent prolapse
• Close vaginal cuff with running suture

Difficult Vag Hyst

• Complete procidentia
• Elongated cervix
• Enlarged uterus
• Non-mobile or adhered uterus
• Adnexal mass
• Previous pelvic surgery

Tips

• Avoid excessive blunt dissection
• With adhesive disease or uterine immobility a finger in the rectum and or foley bulb to help delineate proper planes
• Uterine morcellation for large uterus
  – Blood supply should be controlled
  – Myomectomy if possible

Morcellation

• Bivalve uterus
• Coring – eventually turns uterus inside out
• Elliptical wedges

Bivalving
Coring

Atlas of Pelvic Anatomy and Gynecologic Surgery
Baggish and Karram

Ultimately it is usually a combination of above methods

Update on Mesh

FRIEND OR FOE?

Uses of Synthetic Mesh in Urogynecology

- Slings – for SUI
- Abdominally for Sacrocolpopexy
- Vaginally for Prolapse TVM
- General Surgery for Hernia Repairs
- Colorectal for Mesh Rectopexy

Synthetic Mesh

- Problems with early mesh
  - Material (e.g. Gortex), Pore Size, Mesh Weight etc.
- Newer Mesh
  - Type 1 Macroporous polypropylene Mesh
    - Pore size >75 microns
    - Bacteria < 1 micron
    - Macrophages 20 microns
    - WBC 15 microns
  - Light Weight
  - Hybrid Mesh
FDA notifications in Oct 2008 and July 2011

- 2008
  - High bacteria count in vagina – risk of erosion/exposure, pelvic pain, dyspareunia
  - Permanent – almost impossible to remove entire mesh once placed
  - Extensive patient counseling

- 2011
  - Increase in adverse events reported, complications should no longer be considered rare
  - New complications not reported in 2008 FDA notification
    - Vaginal narrowing and scarring – not able to treat successfully despite multiple repeat surgeries

- Recommendations
  - Conversion of FDA Device Class
    - No new TVM will be approved without efficacy and safety data, randomized comparative studies
  - Any existing product on the market has to be looked at for efficacy and safety
    - Any product that is not studied or does not prove to be safe will be pulled from the market
    - Already several producers have decided they will not put the resources into these 522 aftermarket analysis studies

- Legal Component
  - Misinformation – no longer ‘if you had a complication’, now ‘if you had a mesh’…
  - Confusion about all mesh – TVM, Slings, Abdominal Mesh for SCP
  - No RECALLS!

References
- Nieber et al Cochrane Database Syst Rev, 2009
- Advances in Reconstructive Vaginal Surgery Kovac and Zimmerman, Lippincott Williams & Wilkins, 2006

Post Test
- What is the best reason to close the peritoneum above the ovarian pedicles?
  1) To aid in support
  2) To protect the ureters
  3) To prevent intrabdominal collection from bleeding pedicle
  4) To be able to remove the ovaries more easily in future operation
  5) To prevent bowel injury

THANK YOU

QUESTIONS?
How to Restore Normal Anatomy as You Face Total Confusion During Completely Abnormal and or Rare Anatomy

Camran Nezhat, MD
Clinical Professor Department of OB/GYN UCSF
Adjunct Clinical Professor Department of OB/GYN & Surgery Stanford University Medical Center
Center for Special Minimally Invasive and Robotic Surgery Palo Alto, CA
www.Nezhat.org

Disclosure

I have No financial relationships to disclose

Objectives

Describe techniques for restoring normal anatomy during cases with completely distorted anatomy

Describe techniques used to address difficult adhesions during laparoscopy

Learning Objective

To be able to restore normal anatomy in cases with confusion picture and/or distorted anatomy

Confusing Picture

Confusing Picture
THANK YOU!
Consultant: Genzyme; Plasma Surgical

Objectives
- Review normal anatomy
- Delineate indications for sidewall dissection
- Discuss preoperative planning
- Examine proper instrumentation and techniques for dissection
- Review possible complications and management

Normal Anatomy of Retroperitoneal Space

3 Surgical Layers
1. Ureter in its parietal peritoneum
2. Internal iliac vessels w/ anterior branches
3. Psoas w/ external iliac artery, external iliac vein, obturator nerve and vessels

Sound surgical technique is based on accurate anatomic knowledge.

Course of the Ureter
- The lower half of each ureter traverses the pelvis after crossing the common iliac vessels at their bifurcation
- Lies just medial to the ovarian vessels.
- Descends into the pelvis adherent to the peritoneum of the lateral pelvic wall and the medial leaf of the broad ligament.
- Enters the bladder base anterior to the upper vagina.
- Terminates in the bladder trigone, after an oblique course.

Retroperitoneal Anatomy

Source: Berek & Novak’s Gynecology, 15th ed
Pelvic Sidewall Dissection

- Division or excision of pathologic lesions adherent to the pelvic sidewall
- Retroperitoneal dissection to confirm normal anatomy or to excise pathologic tissue

Indications

- Oophorectomy
  - Peritoneal Implants and mass
  - Endometriomas
  - Cul-de-sac Obliteration
- Ovarian Remnant
- Adhesions
- Malignancy
  - Lymphadenectomy
  - Radical Hysterectomy

Preoperative Planning

- Bowel prep
  - Mechanical
  - Antibiotic
- Ureteral Stents
- Preoperative IVP
- Cystoscopy
- Sigmoidoscopy

Planning should be individualized

Controversies in Preoperative Planning

- Kuno et al, review of 3071 major gynecologic surgeries
  - prophylactic ureteral catheters did not prevent injury
- To Prep or Not to Prep....
  - Cochrane Database 2005 review of mechanical bowel prep (MBP) data
    - 9 RCT, 1593 patients: 789 MBC, 803 no MBP
    - no convincing evidence MBP reduces post-op complications
      - when looking at anastomotic leakage, MBP was harmful

Proper Patient Counseling

"It's a very simple procedure. We slice off the top of your head, scoop out your breasts with a spoon, and saw off your ears and mouth."

Hydrodissection

Evaluate and Restoration of Anatomy

Prevention of Ovarian Remnant

- Ensure IP ligament is free and mobile prior to ligation of ovarian vessels
- Ensure that pre-tied suture or staples are well below ovarian tissue
- Electrocoagulation and ligation or clips are preferable
- If ovary is adherent to sidewall ensure:
  - Meticulous adhesiolysis
  - Retroperitoneal hydrodissection
  - Removal of contiguous peritoneum

Conclusions

- Pelvic sidewall dissection can be learned and applied safely
- Laparoscopy facilitates dissection through improved visualization and magnification
- Knowledge of anatomy remains the cornerstone of sound surgical technique

Management of Endometriosis

Togas Tulandi MD, MHCM
Professor & Academic Vice Chairman of Obstetrics and Gynecology
Milton Leong Chair in Reproductive Medicine
McGill University

Conflict of interests

- I have no financial relationships to disclose.

CASE

- 36 yrs old female
- infertility of 2 year duration
- ovarian endometrioma 4 cm

Surgery or IVF?

Endometriosis

- Chronic disease that requires long-life management plan by maximizing medical treatment and avoidance of repeated surgery (ASRM).
- Options: infertility, pelvic mass, pain?
  - Expectant
  - Medical treatment
  - Surgery
  - Combination treatments

Redefining Reproductive Surgery
(Tulandi & Marzal, J Min Inv Gynecol 2012)

REPRODUCTIVE SURGERY

1. Primary surgical treatment for infertility
2. Surgery to enhance IVF outcome
3. Surgery for Fertility Preservation
I. Reproductive Surgery as a primary treatment

Minimal and Mild Endometriosis (Endocan study vs. Gruppo Italiano per lo studio dell'endometriosi)

Meta-analysis: Odd ratio 1.66 (minimal effect)

Adhesions after endometriosis surgery

Transient Abdominal Oophoropexy
Recto-vaginal and bowel endometriosis

- 5-12% of all endometriosis

Shaving technique

1. Separate anterior rectum from vagina
2. Excision of the lesion incl. posterior vagina
3. Close the vagina

Donnez & Squifflet, 2010

- Recurrence of severe pelvic pain in women who did not conceive: 20%

Donnez & Squifflet, 2010

Endometriosis of the appendix accounts for 3% of all intestinal endometriosis.

- Removal of abnormal looking appendix leads to pain relief in 90% of cases.

<table>
<thead>
<tr>
<th>Table II: A series of 550 cases of deep endometriosis treated by the laparoscopic shaving technique without segmental resection.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laparoscopic shaving (n = 550)</td>
</tr>
<tr>
<td>Lesion size (cm)</td>
</tr>
<tr>
<td>Duration of surgery (min)</td>
</tr>
<tr>
<td>Post-operative hospitalization (days)</td>
</tr>
<tr>
<td>Complications, n (%)</td>
</tr>
<tr>
<td>Rectal perforation</td>
</tr>
<tr>
<td>Ureteral injury</td>
</tr>
<tr>
<td>Urinary retention</td>
</tr>
<tr>
<td>Blood loss &gt; 300 ml</td>
</tr>
</tbody>
</table>

The presence of ovarian endometrioma does not affect the number of collected oocytes or embryo quality.

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of antral follicle</td>
<td>7.7 ±1.0 8.5±0.9 0.3</td>
</tr>
<tr>
<td>Number of retrieved oocyte</td>
<td>6.0± 0.4 6.1 ±0.5 0.8</td>
</tr>
<tr>
<td>Number of retrieved oocyte when endometrioma size &gt; 25mm</td>
<td>5.8±1.4 6.6±1.1 0.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Good embryos (transferred)</td>
<td>65.6 ±6.8 74.5 ±7.5 0.34</td>
</tr>
<tr>
<td>The presence of ovarian endometrioma does not affect the number of collected oocytes or embryo quality.</td>
<td></td>
</tr>
</tbody>
</table>

Endometrioma, number of oocytes and embryo quality
“sharp dissection with scissors when the cyst capsule was adherent to the surrounding tissue”

Effects of surgical treatment of endometrioma on IVF outcome

No difference

Endometrioma and IVF

- Small endometrioma does not have to be removed before IVF
- Careful laparoscopic excision is superior to fenestration and coagulation
- Surgery is associated with similar IVF pregnancy rate than no surgery.

Robotic versus standard laparoscopy for the treatment of endometriosis (Nezhat et al, 2010)

<table>
<thead>
<tr>
<th>Stage of endometriosis</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robotic</td>
<td>14</td>
<td>17</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Non-Robotic</td>
<td>14</td>
<td>16</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>

Role of laparoscopic treatment of endometriosis after failed IVF

<table>
<thead>
<tr>
<th>TABLE 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison of patients with a history of prior failed IVF cycles, who underwent laparoscopic treatment of endometriosis to patients who did not undergo laparoscopic treatment.</td>
</tr>
<tr>
<td>No laparoscopy</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Number of patients (n)</td>
</tr>
<tr>
<td>Average age (y)</td>
</tr>
<tr>
<td>Average number of failed IVF cycles</td>
</tr>
<tr>
<td>Pregnancy rate</td>
</tr>
<tr>
<td>Spontaneous pregnancy rate</td>
</tr>
</tbody>
</table>

Littman et al, Fertil Steril, 2005
REPRODUCTIVE SURGERY

I. Primary surgical treatment for infertility
II. Surgery to enhance IVF outcome
III. Surgery for Fertility Preservation

Grafting cryopreserved ovarian tissue

- Orthotopic site
- Heterotopic site

CASE

- 36 yrs old female
- Infertility of 2 year duration
- Ovarian endometrioma 4 cm

Surgery or IVF?

- It depends on a variety of factors:
  - Symptoms
  - Stage of endometriosis
  - Ovarian reserve and ovarian access for IVF
  - Risk of surgery and cost
- Some women with infertility and endometriosis may benefit from a combination of assisted reproduction and surgery.
**Medical Treatment**

- Continuous OCP
- GnRHa
- Danazol?
- Progestins

**RCT of GnRHa (goserelin) vs. L-norgestrel IUS (n:40)**

Comparable results.

**L-Norgestrel IUS vs. Depo-provera**

Wong et al, 2010

**Dienogest vs. GnRHa**


<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Dienogest</th>
<th>Leuprolide acetate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>15</td>
<td>12.5</td>
<td>25</td>
</tr>
<tr>
<td>Weight gain</td>
<td>8</td>
<td>6.7</td>
<td>5</td>
</tr>
<tr>
<td>Depression</td>
<td>6</td>
<td>5.0</td>
<td>11</td>
</tr>
<tr>
<td>Decreased libido</td>
<td>5</td>
<td>4.2</td>
<td>8</td>
</tr>
<tr>
<td>Acne</td>
<td>5</td>
<td>4.1</td>
<td>6</td>
</tr>
<tr>
<td>Alopecia</td>
<td>4</td>
<td>3.3</td>
<td>7</td>
</tr>
<tr>
<td>Migraine</td>
<td>3</td>
<td>2.5</td>
<td>6</td>
</tr>
<tr>
<td>Sleep disorder</td>
<td>2</td>
<td>1.7</td>
<td>10</td>
</tr>
<tr>
<td>Vaginal dryness</td>
<td>2</td>
<td>1.7</td>
<td>9</td>
</tr>
<tr>
<td>Hot flushes</td>
<td>0</td>
<td>0.0</td>
<td>9</td>
</tr>
</tbody>
</table>

FAS, full analysis set

n=number of patients

**Change from baseline in kg (mean ± SD)**

- 12 weeks: DNG vs Placebo
- 24 weeks: DNG vs LA
- 52 weeks: Extension Study

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>Dienogest</th>
<th>Leuprolide acetate</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 weeks</td>
<td>0.4</td>
<td>0.2</td>
<td>-</td>
</tr>
<tr>
<td>24 weeks</td>
<td>0.3</td>
<td>0.2</td>
<td>0.7</td>
</tr>
<tr>
<td>52 weeks</td>
<td>1.2</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Mechanism of Progestin

1. Inhibits endometriotic tissue growth by decidualization and then atrophy.
2. Decreases pituitary gonadotropin secretion and ovarian hormone production.

Efficacy of Progestin

- RCTs: 80% women had partial or complete pain relief.
- Evidence: RCT of 274 women randomized to DMPA-SC (104 mg) or leuprolide (11.25 mg) for 6 mths.
- Significant reduction on pelvic pain, dysmenorrhea, dyspareunia, pelvic tenderness and induration at 12 mths FU.

Table 3: Results of the three RCTs investigating the efficacy of 17β-estradiol in preventing symptoms recurrence after surgery for endometriosis (secondary outcome)

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Length of Follow-up</th>
<th>Improvement in Secondary Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>Leuprolide</td>
<td>6 months</td>
<td>80% women had partial or complete pain relief</td>
</tr>
<tr>
<td>2004</td>
<td>DMPA-SC</td>
<td>12 months</td>
<td>60% women had significant reduction on pelvic pain, dysmenorrhea, dyspareunia, pelvic tenderness and induration</td>
</tr>
<tr>
<td>2005</td>
<td>DMPA-SC</td>
<td>12 months</td>
<td>60% women had significant reduction on pelvic pain, dysmenorrhea, dyspareunia, pelvic tenderness and induration</td>
</tr>
</tbody>
</table>

Progestins

- DMPA: injection every 3 mths
- L-norgestrel intrauterine system
- Eltonorgestrel subdermal implant
- MPA 30-100 mg daily p.o.
- Norethindrone acetate 5-15 mg daily p.o.
- Dienogest

Dienogest – a Unique Progestin

Dienogest (DNG) is a 19-nortestosterone derivative. The special chemical structure of DNG leads to a unique pharmacologic profile.
**Pharmacological profile of various progestins**

<table>
<thead>
<tr>
<th>Progestogenic</th>
<th>Estrogenic</th>
<th>Glucocorticoid</th>
<th>Androgenic</th>
<th>Anti- Androgenic</th>
<th>Anti-mineralocorticoid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progestosterone</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
</tr>
<tr>
<td>Dideoxyprogesterone</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
</tr>
<tr>
<td>Levonorgestrel</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
</tr>
<tr>
<td>Gestodene</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
<td>–</td>
</tr>
<tr>
<td>Norgestimate (^{b})</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
</tr>
<tr>
<td>Desogestrel (^{c})</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
</tr>
</tbody>
</table>

Drospirenone

<table>
<thead>
<tr>
<th>Progestogenic</th>
<th>Estrogenic</th>
<th>Glucocorticoid</th>
<th>Androgenic</th>
<th>Anti- Androgenic</th>
<th>Anti-mineralocorticoid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progestosterone</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
</tr>
<tr>
<td>Dideoxyprogesterone</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
</tr>
<tr>
<td>Levonorgestrel</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
</tr>
<tr>
<td>Gestodene</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
<td>–</td>
</tr>
<tr>
<td>Norgestimate (^{b})</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
</tr>
<tr>
<td>Desogestrel (^{c})</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
</tr>
</tbody>
</table>

Gestodene

<table>
<thead>
<tr>
<th>Progestogenic</th>
<th>Estrogenic</th>
<th>Glucocorticoid</th>
<th>Androgenic</th>
<th>Anti- Androgenic</th>
<th>Anti-mineralocorticoid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progestosterone</td>
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<td>–</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
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<tr>
<td>Dideoxyprogesterone</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
</tr>
<tr>
<td>Levonorgestrel</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
</tr>
<tr>
<td>Gestodene</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
<td>–</td>
</tr>
<tr>
<td>Norgestimate (^{b})</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
</tr>
<tr>
<td>Desogestrel (^{c})</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>(+)</td>
</tr>
<tr>
<td>Cyproterone acetate</td>
<td>+</td>
<td>–</td>
<td>(+)</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

Drospirenone

Effect on Symptoms

**CASE**

- 39 yrs with chronic and severe pelvic pain
- PH: Supracervical hysterectomy and BSO (stage IV endometriosis) 1 year ago
- Surgery to remove the cervix and ovarian remnant?
- Medical treatment?

**Video**

- Type I: pure RV septum, far from cervix
- Type II: Posterior fornix, behind the cervix
- Type III: hourglass lesion >3mm, posterior fornix to anterior rectal wall, infiltrating rectal muscle

Donnez & Squifflet, 2010

---

* + indicates activity; (+) indicates negligible activity at therapeutic dosages; – indicates no activity


**Reverse technique**

1. Separate lesion from cervix
2. Close the vagina
3. Excision of the lesion from the rectum

*Better space to work in deep pelvis.*

**Indications of surgery**

1. Failed medical treatment
2. Advanced disease
3. Large pelvic mass

- **Conservative surgery**
- **Definitive surgery**
- **Gold standard: laparoscopy**
Minimally Invasive Alternatives to Hysterectomy: Endometrial Ablation and Myomectomy, Uterine Fibroid Embolization, HIFU, and Myolysis

Robert K. Zurawin, MD
Associate Professor
Chief, Section of Minimally Invasive Gynecologic Surgery
Department of Obstetrics and Gynecology
Baylor College of Medicine
Houston, Texas

Objectives

Review hysterectomy rates in the US
Review the minimally invasive approaches to hysterectomy
Examine the surgical alternatives to hysterectomy
Identify the non-surgical options
- Radiologic
- Pharmacologic

Rates of Hysterectomy in the US

5.38 per 1000 women years
- Unchanged from the previous decade
  - 48.1% White
  - 11.3% African American
  - 7.0% Hispanic
  - 4.6% Asian/other

Indications for hysterectomy
- Fibroids 33%
- Menstrual disorder 17%
- Prolapse 13%
- Endometriosis 9%


Route of Hysterectomy

<table>
<thead>
<tr>
<th></th>
<th>Abdominal</th>
<th>Vaginal</th>
<th>Laparoscopic</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>62%</td>
<td>24%</td>
<td>14%</td>
</tr>
<tr>
<td>African American</td>
<td>83%</td>
<td>10%</td>
<td>0%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>69%</td>
<td>22%</td>
<td>9%</td>
</tr>
</tbody>
</table>

African Americans had highest incidence of fibroids
Socioeconomic factors

Survival

Or Extinction?
**Laparoscopic Hysterectomy**

First performed in 1989

Twenty years later (2009):
- Abdominal Hysterectomy
  - 69%
- Vaginal Hysterectomy
  - 20%
- Laparoscopic Hysterectomy
  - 11%


---

**Why the low utilization of minimally invasive GYN surgery?**

- Emphasis on OB/GYN as a “primary care” specialty
- Insufficient number of trained faculty

**Demographics of OB/GYN residents**

**Payment for GYN surgical procedures**
- Laparoscopic Hysterectomy in Houston?
  - $800
- Obstetrical Care?
  - $1700

---

**Strategic Gap**

Massive push by patients and payers to move towards minimally invasive, office-based procedures in all specialties

Patients are leaving their traditional gynecologists to seek providers who offer these services.

OB/GYN residents need hysteroscopic training in order to survive in today’s marketplace.

CREOG recognizes the need to train hysteroscopists

---

**Fibroids**

Since fibroids are the most common indication for hysterectomy, we will concentrate on minimally invasive approaches for their treatment.

Most patients with fibroids go on to have some kind of surgery, so treating them will reduce incidence of hysterectomy.

Some of the following treatment modalities are applicable to other conditions that would result in hysterectomy.

---

**Hysterectomy in the US for AUB**

- Chronic pelvic pain 10%
- (Pre) Cancer 5%
- Prolapse 10%
- Endometriosis/Adenomyosis 15%
- Fibroids 40% (240,000/year)
- DUB 20% (120,000/year)
Invasive Treatments

- Hysterectomy
- Abdominal myomectomy
- Laparoscopic myomectomy
- Hysteroscopic myomectomy

Of the ≈600,000 hysterectomies each year, up to ≈150,000 are due to uterine fibroids

Myomectomy is performed < 40,000 times a year

The Laparoscopic Approach

Reduced post operative pain
Quick return to normal physical activities
Quick return to work
Improved cosmesis and reduced wound complications associated with large scars
Reduced nosocomial infection rates
Magnification of anatomy and pathology

It Makes Cents

Hospital cost savings
- Shorter hospital stay
- Decreased nosocomial infection rates

Employer cost savings
- Disability/ Sick Leave
- TAH = 6 week recovery period

Patient cost savings
- Replacement child care/ household services during recovery

Laparoscopy Disadvantages

- Steep learning curve
- Limited dexterity
- Counterintuitive motion
- Two dimensional field
- Limited depth perception
- Ergonomic difficulty

Reasonable Candidate for Laparoscopic Myomectomy


Source:

Accessed Jan 1, 2009
Unacceptable Candidate for Laparoscopic Myomectomy

Laparoscopic Myomectomy

Advantages of Robotic Technology
- Offers the opportunity to bridge the gap between the advantages of laparotomy & laparoscopy
- Improved dexterity
- Tremor filtration
- 3 dimensional vision offering an immersive environment
- Intraabdominal articulation using laparoscopic instruments

Disadvantages of Robotic Surgery
- Lack of Tactile Feedback
- Bulky Robotic Arms can collide
- Cumbersome set up
- Inability to move surgical table once the robot arms are attached
- Expense ~ $1 million dollars
- Instruments have to be disposed after 10 uses ($2000 for each instrument)

Surgical Dexterity and the Robot
- 8-12% surgeons report pain or numbness after performing LSC
- The robot allows for 7 degrees of motion versus the limited 4 degrees of motion in laparoscopy
- Tremor is removed

Dexterity and the Robot
- Large yellow arrows four movements allowed in traditional laparoscopy
- Small yellow arrow grip
- Red arrows endocorporeal movements by Endowrist technology
Hysteroscopic Myomectomy

Targeted destruction of fibroids using various energy systems
- Radiofrequency electricity or laser (thermomyolysis)
- Supercooled cryoprobes (cryomyolysis)
- Focused ultrasound monitored by real-time MRI
- MRgFUS (Magnetic Resonance Guided Focused Ultrasound)
- HIFU (High Frequency Ultrasound)
- Various approaches
  - Laparoscopic
  - Hysteroscopic
  - Completely noninvasive (MRgFUS)

The Search Continues for Less Invasive Techniques for Managing Myomas

Thermomyolysis
First described in 1993 using laser energy or bipolar radiofrequency current
- Coagulative necrosis and devascularization
- Laparoscopic approach – drilling of multiple concentric sites
- Extent of tissue effect difficult to monitor
- Concerns about uterine rupture, adhesions, equipment cost led to limited acceptance

Thermomyolysis Handpiece
Mature RF technology
Scalable ablations
Unique U/S integration
Disposable/Reposable
First described in 1996 using liquid nitrogen. Sclerohyaline degeneration at temperatures below -20°C caused by local tissue ischemia → thrombosis → tissue necrosis. Tissue specificity — fibroids are more sensitive to freezing than normal myometrium.

Advantages
- 62% reduction in myoma volume at 12 months
- Direct visualization of target
- Minimal collateral tissue damage

Disadvantages
- Multiple incisions and multiple freezings for larger lesions
- Need for simultaneous ultrasound
- Long-term efficacy and safety in future pregnancy is not known
- Limited to women with 1 or 2 dominant myomas that are readily accessible


Focused Ultrasound
Magnetic resonance guided focused ultrasound (MRGFU) is a non-invasive outpatient procedure that uses high intensity focused ultrasound waves to ablate (destroy) the fibroid tissue. Uses magnetic resonance imaging (MRI) to see inside the body to deliver the treatment directly to the fibroid. The ultrasound energy used in MRGFU can pass through skin, muscle, fat and other soft tissues. Procedure is FDA approved for treating uterine fibroids, but is under investigation for the treatment of breast, prostate, brain and bone cancer.
Thermoablative technique used to treat tumors in prostate, breast and liver. Can use either ultrasound or MR guidance. Significant heating only occurs where waves converge. With MR, the temperature at every treatment point can be monitored.

MR guided Focused Ultrasound (MG-FUS)

3D Anatomic Views for Planning Treatment Volume

Outcome Assessment

MG-FUS

Advantages
- Less invasive
- Purely outpatient
- Instant recovery
- Repeatable

Disadvantages
- Expensive
- Not covered
- <80% are candidates
- Uncertain durability
109 Women; mean age 44.8; mean uterine size 595 ml
Mean fibroid volume 284 ml
Less than 10% of volume sonicated
Adverse effects:
- Fever in 6%
- Transfusion in 3%
- Rehospitalization in 7%
- 5% had skin burns, and 1 had ulceration
- Sciatic nerve palsy in one patient

Symptom severity score decreased from 61.7 to 37.7 in 6 months
SF-36 scores increased significantly for all subscales
Significant decrease in disability days by 6 months post-treatment

Patients with symptomatic fibroids
- Menorrhagia and bulk symptoms
- Patients with hysterectomy/HRT concerns
- Patients wishing to avoid ANY surgery and/or long recovery
- Premenopausal patients
  - Poor surgical candidates
  - Medical: anemia, anti-coagulated, obesity, cardiac disease, …
  - Surgical: extensive adhesive disease
  - Refusing blood products
  - Patients who do not desire future fertility

Pelvic infection
Type 0 and 1 submucus myomas
Pedunculated myomas (stalk <30% fibroid diameter)
Severe contrast allergy
Arteriovenous shunting
Coagulopathy?
Renal insufficiency
Pelvic radiation

Undiagnosed pelvic mass
Suspected uterine sarcoma
Genital tract malignancy
Pregnancy
Sickle
Adenomyosis
Desire for future fertility?

Follow Up | # of pts completing follow up | Number (%) with symptoms | Reinterventions
---|---|---|---
2 years | 175/177 | 50/1| 19 hysterectomies, 1 myomectomy
3 years | 182/200 | 133 (72%) | 25 hysterectomies, 8 myomectomies, 3 repeat UFE
3 years | 186/206 | 61 (64%) | 7 hysterectomies, 1 myomectomy
5 years | 80/96 | 89.5% | 10.5% additional gynecologic interventions at 5 years
**Selection of appropriate modality**

The selection of UAE vs surgery is complicated by several factors:
- Patient motivation to preserve uterus and/or avoid surgery despite compelling clinical evidence
- Experience level of gynecologist in managing complicated fibroids is variable
- Each specialty seeks to promote their own procedure as the “best” treatment

**Best solution:**
- Determine those factors (myoma location, coexistent adenomyosis, etc.) that will reduce success of UAE and develop combined approach with gynecologist
- Develop joint surgical/radiologic guidelines for patient education based on unbiased clinical research

---

**UAE and myomectomy for fertility preservation**

Randomized prospective controlled trial of women wishing to retain fertility
- Intramural fibroid > 4 cm
- 30 embolizations, 33 myomectomies (18 l-scope, 18 open)
- Excluded type 0 and type 1 myomas, or fibroids > 15 cm
- No significant difference in morbidity or relief of symptoms
- Longer hospital stay and length of disability with myomectomy
- Significant increase in re-interventions with UAE (36.7% vs. 6.1%)
- 10 pregnancies in 17 women at time of publication
- Authors conclude that “the significantly lower of reinterventions speaks in support of surgical treatment. If a patient with fibroid uterus and planned conception is seeking a definitive one-shot therapy, the myomectomy seems to be a better choice.”

---

**Pregnancy Following UAE**

<table>
<thead>
<tr>
<th>Spontaneous abortion rate</th>
<th>Postpartum hemorrhage rate</th>
<th>Premature delivery rate</th>
<th>Cesarean section rate</th>
<th>Small for gestational age rate</th>
<th>Malpresentation rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy after UAE</td>
<td>22%</td>
<td>13%</td>
<td>28%</td>
<td>58%</td>
<td>7%</td>
</tr>
<tr>
<td>Pregnancy in the general population</td>
<td>10-15%</td>
<td>4.6%</td>
<td>5-10%</td>
<td>22%</td>
<td>10%</td>
</tr>
</tbody>
</table>

---

**Pregnancy Following Endometrial Ablation**

<table>
<thead>
<tr>
<th>Spontaneous abortion rate</th>
<th>Postpartum hemorrhage rate</th>
<th>Premature delivery rate</th>
<th>Cesarean section rate</th>
<th>SGA rate</th>
<th>Malpresentation rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy after UFE</td>
<td>21.7%</td>
<td>17.6%</td>
<td>25.1%</td>
<td>70.6%</td>
<td>12%</td>
</tr>
<tr>
<td>Pregnancy after AFE</td>
<td>32.4%</td>
<td>18.2%</td>
<td>19.2%</td>
<td>72.7%</td>
<td>5%</td>
</tr>
<tr>
<td>Pregnancy in the general population</td>
<td>15.7%</td>
<td>12.5%</td>
<td>16.7%</td>
<td>59%</td>
<td>22.2%</td>
</tr>
</tbody>
</table>

---

**Latest ACOG Recommendations**

“...because there is biologic plausibility of uterine artery embolization causing compromised endometrial perfusion resulting in abnormal placentation in women not otherwise at risk, this approach should be used with caution for women who are pursuing pregnancy. The effect of uterine artery embolization on pregnancy remains understudied.”

ACOG Practice Bulletin #96 August 2008

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**UAE Potential Outcomes/Unknowns**

- Premature menopause
  - Thought to be related to embolization of ovarian vessels via uterine collaterals
  - Decreased with the current use of larger microspheres (>500 μm)
  - Age-related

- Rate of recurrence of leiomyomata
  - Rates range from 8.56% to 28% after UAE
  - Revascularization of treated myomas
  - Growth of new myomas
  - Two independent predictors or recurrence
    - Large fibroid volumes
    - Numerous fibroids

---

ACOG Recommendations

“Based on long- and short-term outcomes, uterine artery embolization is a safe and effective option for appropriately selected women who wish to retain their uteri.”

ACOG Practice Bulletin, August 2008

Other Techniques for Uterine Artery Occlusion

Surgical ligation of uterine arteries – laparoscopic (clips, cautery, ties)
- Similar results to radiologic UAE

Temporary occlusion with doppler-enabled transvaginal clamp
- 6 hours of treatment with patient supine and immobile
- Epidural anesthesia
- Early reports of uterine injury from misplaced clamp


Drugs in Use or Under Investigation for Management of Uterine Fibroids

Androgenic agents
Gonadotropin-releasing hormone (GnRH) analogs
Estrogen antagonists or selective estrogen receptor modulators (SERMs)
Antifibrogenic agents
Somatostatin analogs
Progestosterone antagonists
Selective progesterone receptor modulators (SPRMs)

Pharmacologic agents to treat fibroids

Growth of fibroids resumes when medicine is stopped
Drug effectiveness is not uniform
Side-effects are prominent and vary with individuals
Drug cost per dose is high, and astronomical considering that treatment continues until menopause
Dependent on patient compliance with medication schedule
At this time, there are no FDA-approved drugs to treat fibroids, except for leuprolide which may be used to shrink fibroids in anticipation of surgery. All other drugs are either experimental or off-label

Pharmacologic Agents to Treat Fibroids

<table>
<thead>
<tr>
<th>Pharmacologic Agent</th>
<th>Mechanism of Action</th>
<th>Dose</th>
<th>Side Effects</th>
<th>Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Androgenic agents</td>
<td>Uterine venules decreased impedance of uterine blood flow</td>
<td>Danazol 100 mg/6 months or 400 mg/4 mo</td>
<td>Acne, hirsutism</td>
<td>24% Reduction in uterine volume</td>
</tr>
<tr>
<td>GnRH agonists</td>
<td>Downregulation of estrogen and progesterone receptors</td>
<td>Leuprolide 3.75 mg monthly</td>
<td>Menopausal symptoms, osteoporosis</td>
<td>Rapid onset, shorter time to effect</td>
</tr>
<tr>
<td>GnRH antagonists</td>
<td>Blockade of GnRH receptor</td>
<td>Vaires</td>
<td>Menopausal symptoms, osteoporosis</td>
<td>Rapid onset, shorter time to effect</td>
</tr>
<tr>
<td>Progestosterone antagonists</td>
<td>Antiprogesterone action</td>
<td>Letrozole 5 – 10 mg for 6 months</td>
<td>Hot flashes, endometrial hyperplasia</td>
<td>Prolonged reduction in fibroid volume</td>
</tr>
<tr>
<td>SERMs</td>
<td>Inhibits endometrial proliferation, decreases uterine blood flow</td>
<td>Asoprisnil Proellex 10 or 25 mg, 12.5 or 25 mg</td>
<td>26% reduction in fibroid volume at 12 weeks</td>
<td>26% reduction in fibroid volume at 12 weeks</td>
</tr>
</tbody>
</table>

Conclusions

The biology of fibroids offers a variety of opportunities for intervention with medical therapy
Numerous compounds have been evaluated
SPRMs show promising results in early clinical studies, and 1 (asoprisnil) is currently in an advanced stage of development
As medical therapies improve, it is likely that invasive therapies will become increasingly obsolete
Minimally invasive techniques exist and are getting easier.
Nonsurgical approaches are beginning to make a move.
Gene therapy, targeted immune therapy, and angiogenic therapy may not be far behind.

Now and the Future
Safe and Effective Use of Power Sources in Minimally Invasive Surgery

Jacques Moritz, MD
St. Luke's and Roosevelt Hospitals
Columbia University, College of Physicians and Surgeons

Objectives

- I have no financial relationships to disclose.

Disclosure

- To describe the evolution of energy based devices
- To discuss the basic physics, mechanisms of action, tissue effects, applications, and potential risks of
  - Monopolar Electrosurgery
  - Bipolar Electrosurgery
  - Ultrasonic Energy
- To discuss comparative differences in tissue effects and clinical outcomes between these modalities

Why Doesn’t The Patient Get Electrocuted During Surgery?

<table>
<thead>
<tr>
<th>Question</th>
<th>Whole group</th>
<th>30% attendance</th>
<th>50% attendance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cutting and coagulation effects can be produced for the same type of electrosurgical energy on the same setting</td>
<td>True</td>
<td>58/12</td>
<td>58/12</td>
</tr>
<tr>
<td>Currents delivered to the tissues are equal to the power being delivered by the generator</td>
<td>False</td>
<td>13/11</td>
<td>13/11</td>
</tr>
<tr>
<td>The tissue conductance is different from the normal conductance of the tissue</td>
<td>True</td>
<td>40/10</td>
<td>40/10</td>
</tr>
<tr>
<td>Currents from bone impedance</td>
<td>False</td>
<td>86/11</td>
<td>86/11</td>
</tr>
<tr>
<td>Complete dissolution of bone</td>
<td>True</td>
<td>92/11</td>
<td>92/11</td>
</tr>
<tr>
<td>Complete coagulation of the tumor</td>
<td>True</td>
<td>92/11</td>
<td>92/11</td>
</tr>
<tr>
<td>Wound infection with bacterial infection</td>
<td>False</td>
<td>84/11</td>
<td>84/11</td>
</tr>
<tr>
<td>Wound infection with fungal infection</td>
<td>False</td>
<td>84/11</td>
<td>84/11</td>
</tr>
<tr>
<td>Wound infection with mixed bacterial and fungal infection</td>
<td>False</td>
<td>84/11</td>
<td>84/11</td>
</tr>
</tbody>
</table>
Electrosurgery: Why Don’t You Get Electrocuted?

- Electrosurgery uses alternating current with a frequency of 200,000 to 2 million Hz.
- Neuromuscular stimulation occurs only at alternating frequencies <100,000 Hz.

Two Types of Energy Used in Surgery

- Electromagnetic Energy
  - Electrosurgery
  - Monopolar
  - Bipolar
  - Laser
- Mechanical Energy
  - Suturing
  - Stapling
  - Ultrasonic (Harmonic)

Physics 101

- Electricity always ...
  - Seeks ground (its source)
  - Seeks path of least resistance
- Electricity Must complete a Circuit or it will not flow

Universal Properties of Electricity

- Electricity = Flow of electrons
- Conductor = Carries the flow of electrons
- Circuit = Pathway for the uninterrupted flow of electrons (must be completely closed to flow)

Physics of Electricity

- Current (I) = Amount of electrons flowing (amperes)
- Voltage (V) = Driving force (volts)
- Resistance (R) = Impedance or obstacle to flow of electrons (ohms)
- Ohms Law: \( V = I \times R \)
**Physics of Electricity**

- Power (watts) = Voltage x Current
  \[ W = V \times I \]
- Current density = Amps / cm²
- Energy (heat) = (Current density)² x Resistance x Time

**Two Types of Electrical Current**

**DC - Direct Current**
- Unidirectional flow of electricity
  - Battery

**AC - Alternating Current**
- Direction reverses cyclically
  - Household electricity
  - Monopolar electrosurgery
  - Bipolar electrosurgery

**Frequency Spectrum**

- **Low Frequency** causes pain, nerve stimulation, cardiac arrest
- **High Frequency** = RF Used in Electrosurgery
- Frequency (Hertz) = times AC current reverses in one second

**Properties of Electricity**

- **Current** = Flow of electrons during a period of time, measured in amperes
- **Circuit** = Pathway for the uninterrupted flow of electrons (must be completely closed to flow)
- **Impedance** = Obstacle to the flow of current measured in ohms
- **Voltage** = Force pushing current through the resistance, measured in volt

**Cautery / Electrocautery / Electrosurgery**

- **Cautery**
  - The surgical use of heat
  - There is no current flowing through the patient (e.g., Battery operated cautery pencil, Hyfercator)

- **Electrocautery**
  - The process of destroying tissue with an object that is heated with electricity

- **Electrosurgery**
  - The use of alternating current passed through the patient to cut and coagulate tissue
The Evolution of Cutting and Coagulating Devices in Surgery

Evolution of Electrosurgery

1940: James Greenwood develops the first two-point or bipolar instrument

1960: Leonard Malis refines the instrument providing the fundamental form of bipolar energy we use today

Early 19th Century: Henri Becquerel pioneers 1st monopolar electrocautery device using DC current

1881: Jacques-Arèse d’Arsonval pioneers use of AC current

1928: W.T. Bovie refines the electrical generator to be used in the first open monopolar electrosurgical operation by Harvey Cushing

3000 BC: Use of cautery.

“...This operation was a perfect circus—many ringed. I had persuaded Dr. Bovie to bring his electrosurgical unit over to see what I could do with it... then with Dr. Bovie I proceeded to take off most satisfactorily the tumor with none off the bleeding which was occasioned in the proceeding operation” Harvey Cushing 1926

Pionners

William T. Bovie

Harvey Cushing

Evolution of Electrosurgery

1970s: Electrosurgery generator refinements

1980s: Return electrode monitoring

1990s: Bipolar Technology Improvements

Tissue sensing, current modulation and computer-controlled feedback systems

2000s: Advanced Bipolar Technology

PTC – Positive Temperature Control
### Electrical Circuits (Electrosurgery)

**Monopolar Circuit**
- Current flows from a small (active) electrode to and through the patient to a large, ground (indifferent) electrode.
- The patient is vital to completing the circuit.

**Bipolar Circuit**
- Voltage is applied to the patient using two closely approximated electrodes.
- A high frequency electrical current flows from one electrode to the other side, through the intervening tissue.

### Cutting and Coagulation Waveform

**Cutting:**
- Rapid tissue heating explodes cells
  - Constant duration
  - Monopolar only

**Fulguration:**
- Sparks coagulate and char without cutting
  - Short duration, high voltage
  - Monopolar only

**Desiccation:**
- Heat is generated in tissue as current passes, leading to coagulation
  - Low sparking, low power
  - Monopolar and bipolar

### Tissue Effects of Heat

- **<45°C** - Reversible Tissue Damage
- **>45°C** - Tissue Denatured
- **>90°C** - Liquid in Tissue Evaporates
- **>200°C** - Carbonization
Electrosurgery Generator (ESU) Safety Innovations

Grounded System

Current referenced to earth ground could seek alternate pathway.

Alternate Site Injury

- Alternate site injury resulted from the use on a ground reference generator.
- The use of isolated generators has minimized this risk.

Isolated System

Isolated ESUs decrease the risk of patient burns and are safer to use.

Contact Quality Monitoring

Return electrode contact quality monitors help prevent patient burns.

Return Electrode Site Injury

- Historically the most common injury has been a skin injury at the patient return electrode site.
- This risk has been minimized through advances in patient return electrode design and the use of return electrode contact quality monitoring.
Select ESU and Accessories to Minimize Patient Risk

- Dual-contact dispersive electrodes with nondrying hydrophilic gel
- Return electrode contact quality monitoring

Patient Return Electrode Site Selection

- Well vascularized muscle mass
- Convex area
- Close to surgical site

Patient Return Electrode Site Selection

- Prostheses
- Hair
- Scar tissue
- Bony prominences

“Avoid sites high in resistance” Ball, 2004

Patient Return Electrode Site Preparation

- Hair removal, cleaning, and drying site
- Protect return electrode from fluid invasion
- Do not use flammable agents for PRE site preparation

Tissue Response Technology

Computer-controlled system senses impedance at active electrode.

“Adjust output voltage 200 times per second (cut and blend) to maintain consistent surgical effect” Eggleston et al, 1997

Clinical Benefits of Tissue Response

- Reduced lateral thermal spread
- Fewer power setting changes
- Minimized sparking

“Consistent/precise tissue effect” Pollinger et al, 2003
General Safety Precautions

- Test alarm systems
- Set activation tone to audible level
- Plug accessories into correct receptacles
- Confirm power settings

Active Electrode

- Active electrode MUST be in a non-conductive holster when not in use
- Electrode that does not fit holster should be placed in a designated site with tip away from flammable material
- Active electrode tips should be securely seated into the hand piece

Radiofrequency Current Leakage

- Active electrode cords should not be wrapped around metal instruments
- Active electrode and other electrical cords should not be bundled together

Jewelry

- Jewelry should be removed if it is within the activation range of the active electrode

Tattoos

- Avoid placing the patient return electrode over a tattoo.
- Inks (red in particular) contain metals which could serve as a heat or electrical conductor

Active Electrodes

- Use Teflon or Silicon coated electrodes
- Prevent eschar build-up which increases resistance
- Eschar can catch fire
- Wipe with sponge
- Don’t use scratch pad
Avoid Hemostat Burns

- Use lowest power setting
- Activate low voltage (cut)
- Avoid touching patient
- Hold hemostat with full grip
- Do not open circuit activate
- Avoid metal to metal arcing

Note: Surgical gloves do not insulate against RF current

What is Surgical Smoke?

The gaseous byproducts of the disruption and vaporization of tissue protein and fat.

Chemicals and Health Effects

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Health Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaldehyde</td>
<td>Eye, skin, respiratory irritant; causes arrhythmia, coughing, pulmonary edema; may be teratogenic</td>
</tr>
<tr>
<td>Acrolein</td>
<td>Eye, skin, respiratory irritant; liver kidney damage; increased clotting time</td>
</tr>
<tr>
<td>Acetonitrile</td>
<td>Nose irritant, throat asphyxiant; liver and kidney damage in animal models</td>
</tr>
<tr>
<td>Benzene</td>
<td>Headache, fatigue, weakness, bone marrow damage; trigger for leukemia</td>
</tr>
<tr>
<td>Styrene</td>
<td>Respiratory irritant; vapors cause nose lining damage in animal models</td>
</tr>
<tr>
<td>Toluene</td>
<td>Eye, respiratory irritant; CNS function; teratogenesis with high inhalation levels</td>
</tr>
<tr>
<td>Xylene</td>
<td>Respiratory irritant; chronic exposure associated with changes in blood cells</td>
</tr>
</tbody>
</table>

Surgical Smoke

- Surgical smoke has the same mutagenicity as cigarette smoke
- CO increases during laparoscopy may lead to carboxyhemoglobin
- Chimney effect in cancer cases
- Harmonic may increase biologically viable particles

Laparoscopy

"Research studies have confirmed that this smoke plume can contain toxic gases and vapors such as benzene, hydrogen cyanide, formaldehyde, and live cellular materials and viruses"

CDC
In 1978 and 1979, two women in the United States were reported to have died from electrical complications following sterilization with unipolar coagulating devices. Both deaths followed apparent bowel injuries occurring at the time of sterilization. Numerous reports have documented the electrical accidents associated with unipolar electrocoagulation. Because unipolar electrocoagulation has greater risk for these complications than alternative sterilization techniques, without proved greater benefits, we question the need for continuing its use in female sterilization.


Complications and Recommended Practices for Electrosurgery in Laparoscopy

- 18% General Personally Experienced Electrosurgical Complication
- 33% GYN Complications
- Bowel Injury Most Common
- Small Bowel(75%)>Large(25%)
- 75% Unrecognized
- Symptoms 4-10 days after surgery

Electrothermal Injury
- Direct Application
- Insulation Failure
- Direct Coupling
- Capacitive Coupling

Zones of Potential Injury
- Zone 1 - Small area of active tip
- Zone 2 - Just behind the active electrode
- Zone 3 - Outside the surgeon's view
- Zone 4 - Outside the patient's body

Insulation Failure
- Can be caused after repeated sterilization or electrical heating.
- May also be caused by manufacturer defect.
Insulation Failure

Insulation defects can range from normal wear and tear, to stress placed on the electrode from high voltages.

Safety: Common Monopolar Electrosurgical Hazards

Direct Coupling

Capacitive Coupling

- Capacitance is stored electrical charge
- A capacitor consists of two conductors of different electrical potential separated by an insulator

Capacitive Coupling

- The higher the peak voltage, the greater the chance for capacitive discharge
- A capacitor creates an electrostatic field between the two conductors
Safety During Laparoscopy

- Inspecting insulation carefully
- Using the lowest possible power setting
- Using a low-voltage (cut) waveform
- Using brief intermittent activation vs. prolonged activation
- No activating in an open circuit
- Not activating an electrode in close proximity or direct contact with a metal/conductive object
- Using bipolar electrosurgery when appropriate
- Selecting an all metal cannula system as the safest choice in the operative channel for active electrode
- Not using a hybrid system (metal and plastic components)

Monopolar Manipulation

Advantages
- Readily available
- Rapid cutting and coagulation
- Low cost of accessories

Disadvantages
- Current passes through the patients body
- Patients dispersive electrode (return electrode) required
- Potential for unintended tissue damage through collateral spread of heat
- Surgical plume

Bipolar Electrosurgery

Mechanism of Action
- Cutting waveform
  - Delivers lower peak voltages
- High current concentrations
- Current generates heat in tissue
- Tissue needs to be in contact with blades
- The only tissue effect is desiccation
  - As tissue desiccates, resistance increases and current seeks alternate pathway
  - Current balloons around electrodes
  - Heat percolates through tissues
  - Damage extends beyond the site of contact

Traditional Bipolar Electrosurgery

- Bi-directional flow
- Reduces the risks of monopolar electrosurgery
  - Flow of delivery of energy visibly
- No feedback mechanism
- Surgeon controls
  - In-line ammeter ineffective
  - Promote excessive thermal damage
- Devices coapt tissue poorly
- Coagulation often incomplete

Conventional Bipolar Manipulation

Advantages
- Electrical current only passes locally through the device
- Good coagulator

Disadvantages
- Slow cut tissue
- Produces surgical plume
- Both active and return electrodes are on the device and must contact tissue
3 Steps of Vessel Sealing

When does conventional bipolar coagulation become vessel sealing?

Sealing requires three steps:

- Pressure
- Collagen mobilization - heating
- Collagen fixing - time

Modern Bipolar Technology

- Incorporated Mechanical Cutting
- Pulsed Technology
  - Rapid on/off cycling of energy allows for tissue cooling
  - Provides the generator with time to read, process, and make changes to the delivery of energy based on impedance changes
  - The generator will monitor the flow of current
- Integrates Adaptive Controls
  - Computer-controlled feedback system and control algorithms
  - Automatically adjusts the current and output voltage
  - Impedance
- Vessel Sealing
  - The advanced bipolar sealing devices utilize heat and compression
  - Seal 7 mm vessels

Vessel Sealing: The Crushing Phase

Necessary for two reasons

- Vessel wall lining needs to be broken
- Lining of the lumen is "designed" to prevent sticking...for obvious reasons
- Cell walls need to be broken
  - Allows collagen (a tangle of threads) to move freely

Vessel Sealing: Collagen Mobilization

- Collagen is mobilized at 80°C.
- Collagen threads from opposing vessel walls are free to intermingle during this phase.
- Intermingling of collagen threads only occurs while the tissue is moist.
- To encourage as much intermingling as possible, the seal must be held at elevated temperatures without desiccating.

Vessel Sealing: Collagen Fixing

- The intermingled collagen threads are the "glue" that holds the seal together.
- When sufficient intermingling has been achieved, the collagen is fixed by cooling.
- If the collagen is over desiccated prior to 80°C, intermingling will be limited and the seal will fail.
Ligasure
- Senses tissue impedance
- Decisions about tissue and output made every 300 milliseconds, or 3,333 times per second
- Lower power settings

Electrosurgical bipolar vessel sealing versus conventional clamping and suturing for total abdominal hysterectomy: a randomized trial.

To compare the effects of bipolar vessel sealing versus conventional clamping and suturing in women undergoing total abdominal hysterectomy.

CONCLUSION: The use of vessel sealing during abdominal hysterectomy for benign conditions appears to be associated with reduced postoperative pain and faster recovery.

PK Technology
- Advanced bipolar technology
- Only platform with true bipolar cut
- Pulsed RF Energy Waveform
  - Energy delivered in a series of pulses with low voltage and high current resulting in minimal tissue sticking, charring and thermal spread
  - Minimal amount of energy delivered to achieve desired tissue effect

PK - VP Outputs

PlasmaKinetic - VP Outputs
**PKS J-Hook**
- Simultaneous cut and coagulate in one instrument
- Unique hook tip design for skeletonization and mobilization of tissue
- Rapid hemostatic cutting to improve OR time and procedural efficiency

**PKS™ PlasmaSORD™**
- SORD - Solid Organ Removal Device
- Safe Bipolar Energy
  - No sharp spinning blades
- Efficient bipolar energy
  - Creates fewer tissue fragments
- Lightweight, ergonomic handle
  - Reduces hand fatigue in prolonged cases
- Easy to use
  - Plug and play and single-use disposable

**EnSeal**
- PTC – Positive Temperature Coefficient
  - Carbon particles are embedded in a temperature sensitive polymer material
  - The carbon particles act like discrete thermostatic switches to regulate the amount of current that passes into the tissue area with which it is in contact
  - Controls delivery of energy at approximately 100º Celsius

**EnSeal Electrode: Configuration**
- Smart Electrode Technology
  - Restricted Thermal Envelope
    - Electrode configuration focuses the energy within the jaws
    - Minimizing thermal effects to adjacent tissues
  - Polarity difference between the jaws forces the current to seek the tissue with less resistance; increases thermal spread
  - Offset electrode configuration encloses electrodes minimizing thermal spread of energy
**EnSeal Electrode Configuration**

- EnSeal 5mm
- Cross Section of EnSeal w/ Thermal Gradient

- LigaSure 5 mm
- Cross Section of LigaSure w/ Thermal Gradient

---

**I-Blade**

- **High Uniform Compression**
  - Allows for consistent compression across the length of the jaw
  - High Compression with forces up to 7500 psi

---

**EnSeal Thermography**

- Large Vessels

---

**Clinical Performance**

- Seals 7 mm vessels
- Minimal thermal spread (~1 mm)
- High uniform compression
- Burst pressures up to 7x systolic
- Maintains tissue temperature at ~100° C
- Rapid sealing times
- Minimal sticking, charring and smoke

---

**Ultrasonic Energy**

- Mechanism of Action
- Tissue Effects
- Potential Adverse Effects
Mechanical Wave Energy

Energy is transported through a solid or a liquid by means of the motion or a disturbance in the medium rather than by the medium itself.

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Type</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 20 Hz</td>
<td>Audible Range</td>
<td>Earthquake (10 Hz)</td>
</tr>
<tr>
<td>20 - 20,000 Hz</td>
<td>Ultrasonic</td>
<td>Violin (440 Hz)</td>
</tr>
<tr>
<td>&gt; 20,000 Hz</td>
<td>(Ultrasonic)</td>
<td>Dog Whistle (40,000 Hz)</td>
</tr>
<tr>
<td>261 Hz</td>
<td>(Earthquake)</td>
<td>Violin (261 Hz)</td>
</tr>
<tr>
<td>35,000 Hz</td>
<td>(Dog Whistle)</td>
<td>Dog Whistle (35,000 Hz)</td>
</tr>
</tbody>
</table>

Mechanical Waves

**Transverse Waves**
- consist of oscillations occurring perpendicular to the direction of energy transfer

**Longitudinal Waves**
- have vibrations along or parallel to their direction of travel

Ultrasonic Technology: The Hand Piece

Electrical energy from the generator is converted to mechanical motion in the hand piece.

Ultrasonic Technology: The Generator

- **Power Setting**
  - Sets the current delivered by the generator
  - Power Level 5 = 100% current set point = 100% displacement (65 microns)
  - Power Level 1 = 50% current set point = 50% displacement (33 microns)

Actions of Ultrasound on Tissue

- **Cutting**
  - Combination of Tension and Pressure

- **Coagulation**
  - Denaturing of Protein
  - Cavitation
  - Vibration —> Vapor Bubbles
  - Tissue Dissection

- **Protein Coagulation**
- Tissue Desiccation
- Eschar (satisfaction)
- Protein disorganizes to form a coagulum
- Vaporization of water desiccates tissues
- Eschar forms when tissues burn
- 50º C 100º C 150º C 400º C
Ultrasonic Coagulation

- Protein bonds are broken; protein in the cell is denatured.
- Denatured protein forms a sticky coagulum.
- Simultaneous cutting and coagulation takes place at a lower temperature than electrosurgery with minimal lateral thermal spread.

Factors Affecting Cutting and Coagulation

- Time on Tissue
- Blade Pressure
- Tissue Tension
- Power Level
- Blade Sharpness

Cavitational Effect

- Motion of the blade creates an area of transient low pressure, causing fluids to vaporize at low temperatures.
- Fluid vapor expands, causing the layers to separate, which enhances visualization of a vascular plane of dissection.
- Separates tissue planes.

Benefits of Ultrasonic Coagulation

- Vessels are sealed or welded together
- Vessel walls are not eroded
- Minimal spread of energy
- Coagulum does not stick to blade
- Minimal smoke generation
- Uniformly coagulates 5mm vessels with shears and 2mm vessels with blades.

Understanding Thermal Damage

- 5mm Bipolar
- 5mm Ultrasonic

Blade Temperature vs. Thermal Spread

- Harmonic Ace™
- Ligasure V
- Interceptor
- LCS CS

![Graph showing blade temperature vs. thermal spread.](image)
Thermal Damage - Depth
Monopolar Electrosurgery vs. Ultrasound

Thermal Damage - Lateral
Monopolar Electrosurgery vs. Ultrasound

Lateral Thermal Damage
Monopolar & Bipolar Electrosurgery vs. Ultrasonic Energy

Comparison of Energy Based Devices

Head to Head Studies

- Diamantis et al. (2006)
- Monopolar vs. Bipolar vs Ligasure vs Harmonic
- Divided short gastrics in 16 Rabbits
- Studied coag @ site and adjacent gastric wall
- LS/HS complete hemostasis
- LS least adjacent thermal injury
- LS/HS are safer and more effective than MP/BP

5mm instruments
- Ligasure and EnSeal had the highest Burst Pressure
- Ligasure was the fastest in seal times
- No Failures
Despite the continued innovation of products borne to reduce thermal damage and then marketed as being safer, it is the hands and mind of the surgeon that serve to preserve tissue. 

“Ultimately, thermal injury is linked to good surgical judgement and technique.”

Andrew Brill 2008
Thank You

- Dr. Neuwirth
- Dr. Nezhat
- Adam Winfield – Ethicon
- Adam Summers – Covidien
- Nicholas Polanco – Gyrus
Bladder and Ureteral Injury, Prevention and Management

Pamela T Soliman, MD, MPH
Associate Professor
Gynecologic Oncology

Objectives

- Incidence of bladder and ureteral injury
- Risk factors for injury
- How to prevent and injury
- Bladder repair
- Ureteral injury repair

Disclosure

- I have no financial relationships to disclose.

Urinary Injury Pelvic Surgery

- Overall incidence 1% (0.4% to 4.6)
- Bladder is more common than ureteral
- Differs by surgical approach
- Only one-third recognized at time of surgery allows for prompt repair
- Delayed recognition may result in fistula formation or severe renal complications

Risk Factors

- Most Common
  - Prior pelvic surgery
    - Cesarean 2.9-4.7%
    - Laparotomy 2.1%
  - Endometriosis
  - Pelvic irradiation
  - Obesity
  - Large pelvic mass
  - Urinary tract abnormalities

- Procedural factors
  - Surgery for malignancy
  - Advance pelvic reconstructive surgery

Table 2 Characteristics of delayed diagnoses of lower urinary tract injuries after hysterectomy

<table>
<thead>
<tr>
<th>Variables</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence (n = 1443)</td>
<td>11 (0.8)</td>
</tr>
<tr>
<td>Laparoscopy (n = 743)</td>
<td>8 (1.1)</td>
</tr>
<tr>
<td>TLH (n = 678)†</td>
<td>5 (0.7)</td>
</tr>
<tr>
<td>LRH (n = 65)†</td>
<td>3 (4.6)</td>
</tr>
<tr>
<td>Laparotomy (n = 700)</td>
<td>3 (0.4)</td>
</tr>
<tr>
<td>TAH (n = 455)§</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>RH (n = 245)‡</td>
<td>2 (0.8)</td>
</tr>
</tbody>
</table>

Lim et al. 2010
The Best Offense is a Good Defense

KNOW THE ANATOMY!!!
"At this time, the AAGL Practice Committee recommends that surgeons and institutions consider routine implementation of cystoscopy at the time of laparoscopic total hysterectomy."

**Bladder/Ureteral Injury**
- Crushed with a clamp
- Kinked or ligated with a suture or staple
- Lacerated or transected during sharp or blunt dissection
- Thermal injury with energy device
- Devascularization or denervation

**Mechanism of Ureteral Injury**
- Crushed with a clamp
- Kinked or ligated with a suture or staple
- Lacerated or transected during sharp or blunt dissection
- Thermal injury with energy device
- Devascularization or denervation
**Principles of Ureteral Repair**

1. Meticulous dissection preserving adventitia
2. Tension free
3. Watertight closure with absorbable suture
4. Protect with peritoneum or omentum
5. Drain with closed bulb suction
6. Stent ureter
7. Consider proximal diversion

**Ureteroneocystostomy**

- Ligate distal ureteral stump
- Mobilize bladder and ureter
- Open bladder
- Spatulate ureter
- Implant into bladder
- Reinforce/protect
- Stent ureter
- Suction drain

**Psoas Hitch**

- Close bladder vertically
- Secure to psoas tendon
- Be mindful of genitofemoral

**Boari Flap**

- Oblique flap with wide base
- Preserve blood supply
- Tubularize flap

**Ureteroureterotomy**

- Mobilize
- Dissect nonviable tissue
- Reanastomose over stent
- Maintain vascularity
- Protect with omentum

**Ureteroileocystostomy**

- Isolate healthy ileum
- End-to-side ureteroileostomy
- Anastomose end of ileum to dome of bladder
- Suction drain essential

*Images credit: Mendez L, Surg Clin North Am, 2001*
Summary

- Urinary tract injuries are uncommon
- Risk for injury varies based on procedure and approach
- Intraoperative recognition allows for prompt repair
- Delayed recognition could result in long term effects

Thank You!
Evidence-Based Medicine
Versus
Real-Life Evidence
in Obstetrics and Gynecology

Anthony M. Vintzileos, MD
Chair, Department of Obstetrics & Gynecology
Winthrop University Hospital, Mineola, NY
Professor, Obstetrics, Gynecology & Reproductive Medicine
Stony Brook University School of Medicine
Honorary Doctorate,
University of Patras School of Medicine, Greece

Disclosure

- Speakers' bureau (HOLOGIC)

Objectives
At the end of the lecture the participants will be able to:

- Apply evidence-based medical practice
- Evaluate the shortcomings of randomized controlled trials in Obstetrics and Gynecology
- Recognize that “real-life” evidence is the highest level of evidence.

Evidence-Based: The Buzz Words of The Last Two Decades

- Definition:
  - Something that furnishes proof*
  - Obvious, apparent, clear**

- Legal definition
  - Something legally submitted to a tribunal to ascertain the truth of a matter*
  - Testimony, statement, deposition**

Evidence-Based Symposium
THE NATURE & MANAGEMENT OF LABOR PAIN
(Suppl to Am J Obstet Gynecol 2002, vol 186)

- Unintended effects of epidural analgesia during labor: A Systematic Review. Authors EL and COD (Ob department)
  **CONCLUSION:** Epidural is associated with a lower rate of SVD, higher rates of instrumental delivery, long labors, intrapartum fever, pediatric evaluations for sepsis. Women should be informed of unintended effects of epidural analgesia.

- The effects of epidural analgesia on labor, maternal, and neonatal outcomes: A Systematic Review. Authors BLL and SHH (Anesthesia Department)
  **CONCLUSION:** Epidural is associated with the greatest pain relief, patient satisfaction, normal neonatal acid-base status, normal 5-min Apgar scores and has no effect on C/S rate, instrumental delivery, long-term low back pain, lactation or urinary incontinence at 3 or 12 months.
Evidence-Based Symposium
THE NATURE & MANAGEMENT OF LABOR PAIN
(Suppl to Am J Obstet Gynecol 2002, vol 186)

- Methods and interpretation in systematic reviews:
  Commentary on two parallel reviews of epidural analgesia during labor.
  Authors Thacker SB and Stroup DF (from CDC)

CONCLUSION:
“A study can be affected by how the study was conducted, as well as how the data were analyzed and the results interpreted”
“The interpretation of the results by the authors often reflects their interest and bias”

Other Concerns

- There are serious discrepancies between the conclusions drawn from meta-analyses and subsequent large RCTs on the same topics

- Are systematic reviews (or meta-analyses) “peer-reviewable”?

Correction of Nonvertex Presentation With Moxibustion:
A Systematic Review and Metaanalysis
(Vas J et al, Ob/Dyn Journal X, 2009)

- Moxibustion: Stimulation of the acupoint Bl 67 (outer corner of the 5th toe) with heat generated by a burning stick containing the herb Artemisia vulgaris (moxa)
- 6 studies (n=1,087 pts)

MATERIAL AND METHODS:
“Eligibility (of the reviewed articles for inclusion) was determined independently by 4 reviewers, 2 for articles in English and another 2 for languages in Chinese. Articles in languages other than English or Chinese were translated into Spanish and evaluated by the reviewers who had assessed the articles in English.”

CONCLUSION:
- Significant effect of moxibustion (cephalic version rates, 72% vs. 53%)

Survey to Reviewers

QUESTION: In reviewing papers on systematic reviews or meta-analyses, as a referee, please check how often you verify by your own independent analysis the following:
(ANSWERS: Always-Frequently-Infrequently-Never)

- The initial set of articles 72%
- All additional articles 80%
- Articles which needed to be removed 80%
- Authors’ exclusion criteria 79%
- Authors’ selection criteria 73%
- Appropriateness of included studies (systematic reviews) 51%
- Appropriateness of excluded studies (meta-analysis) 52%
- Heterogeneity of the included studies 68%
- Publication bias of the included studies 67%
- If the data synthesis was appropriate 65%
- If the statistical analyses were appropriate 86%

Always (2%-17%)
(range 51%-86%)

MY CONCLUSION:
- Editors of medical journals should be conducting their own independent research on how to improve the produced quality of the evidence
**What is Evidence-Based Medicine?**

**(DEFINITION)**

- The use of clinical expertise (VARIES)
- Current best evidence (VARIES?)
- Individual patients (VARIES)

Sackett et al. 1997

**Evaluation of Evidence**

(U.S. Preventive Services Task Force Classification)

- I At least one properly designed RCT
- II Cohort or case-control studies
- III Opinions of respected authorities, descriptive studies or reports of expert committees

NOTE: Meta-analysis is not included in classification of evidence

---

**In Real Life, Opinion Prevails Over the RCT Results!!**

*(FEW RECENT EXAMPLES)*

**Prevention of Recurrent Preterm Delivery by 17α-(OH)P-C**


Weekly injections of 250 mg 17α-(OH)P-C starting at 16-20 weeks

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>17-OHP-C</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTB &lt; 37 wks</td>
<td>55%</td>
<td>36%</td>
<td>0.66 (0.54, 0.81)</td>
</tr>
</tbody>
</table>

Authors’ conclusion: 17OHP-C works

Another interpretation: Placebo (control group) had unusually high PTB rate (55%); could be the castor oil in the placebo injections; 17OHP-C does not work

**Multicenter Randomized Trial of Cerclage For Preterm Birth Prevention In High-Risk Women With Shortened (≤ 25 mm) Mid-Trimester Cervical Length**


All patients

- PTB < 33 wks 16% 9% (45% REDUCTION, P=0.02)

Authors’ conclusion: PG gel prevents preterm birth < 33 wks when CL=10-20 mm

Another interpretation: PG gel prevents preterm birth < 33 wks when CL=10-20 mm

**Multicenter Randomized Trial of Cerclage For Preterm Birth Prevention In High-Risk Women With Shortened (≤ 25 mm) Mid-Trimester Cervical Length**


Authors’ conclusion: Cerclage prevents preterm birth when CL < 15 mm

Another interpretation: Cerclage does not work because the primary outcome was not statistically different

**Vaginal progesterone reduces the rate of preterm birth in women with a sonographic short cervix: a multicenter, randomized, double-blind, placebo-controlled trial**


- Multicenter, randomized, placebo-controlled trial (44 centers, 10 countries)
- Asymptomatic women with CL=10-20 mm at 19 - 23 6/7 wks

**RESULTS:**

- PTB < 33 wks
  - PLACEBO 16%
  - PG GEL 9% (45% REDUCTION, P=0.02)

Authors’ conclusion: PG gel prevents preterm birth < 33 wks when CL=10-20 mm

FDA’s interpretation (after re-analyzing the results): PG does not prevent preterm birth, especially in USA
Reported Bias
- Contamination bias
- Withdrawal bias
- Compliance bias
- Therapeutic personality bias
- Unacceptability bias
- Expectation bias
- Substitution game
- Contamination bias
- Withdrawal bias
- Compliance bias
- Therapeutic personality bias
- Unacceptability bias
- Expectation bias
- Substitution game
- Popularity bias
- Centripetal bias
- Referral filter bias
- Diagnostic access bias
- Diagnostic suspicion bias
- Unmasking (detection signal) bias
- Mimicry bias
- Previous opinion bias
- Wrong sample size bias
- Admission rate (Berkson) bias
- Prevalence-incidence (Neyman) bias
- Diagnostic vogue bias
- Diagnostic purity bias
- Procedure selection bias
- Missing clinical data bias
- Non-contemporaneous control bias
- Starting time bias
- Unacceptable disease bias
- Migration bias
- Membership bias
- Volunteer bias
- Post-hoc significance bias
- Data dredging bias
- Scale degradation bias
- Tidying-up bias
- Repeated peeks bias
- Mistaken identity bias
- Cognitive dissonance bias
- Magnitude bias
- Family information bias
- Exposure suspicion bias
- Recall bias
- Attention bias
- Hawthorne revisited
- Instrument bias
- The biases of rhetoric
- The all's well literature bias
- One-sided reference bias
- Positive results bias
- Hot stuff bias

Conflict of Interest Disclosure in Obstetrics & Gynecology
(Slagle L et al Obstet Gynecol 2011;118:1108-10)
- All original research articles published 7/2008-6/2010
- One third (31%) of articles with disclosures were RCTs

Conflict of interest disclosures by level of evidence
- Level I 34%
- Level II 16%
- Level III 17%

The History of RCTs
- Introduced by R.A. Fisher (1920’s)
- In health care by Sir Austin Bradford Hill (1940’s)
- Poor quality of RCTs for 50 years
- Standards for reporting RCTs in the biomedical literature, Ann Intern Med and JAMA (1994)
- Improving the quality of reporting RCTs
  - The CONSORT statement by JAMA (1996-checklist of 21-items)
  - Revised list, JAMA (2001-checklist of 25-37 point items)

The Practice of Medicine
BALANCE OF:
- Personal expertise
- Best available clinical evidence
- Patient individual needs & wishes
- Logic-common sense-intuition

Parachute Use to Prevent Death and Major Trauma Related to Gravitational Challenge: A Systematic Review of Randomized Controlled Trials
(Smith GCS, Pell JP. BMJ 2003;327:1459-1461)
CONCLUSION:
"Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomized controlled trials"
"We think that everyone might benefit if the most radical protagonists of Evidence Based Medicine organized and participated in a double blind, randomized, placebo controlled, cross over trial of the parachute."

This is where we should use logic-common sense, not RCTs
RCTs in Fetal Surveillance: Should they be the “gold” standard?

- RCTs are often premature
- RCT’s may not represent real-life scenarios
- Possibility of “Hawthorne” effect
- Small number of included patients (prone to type II error)

Perfect setup for erroneous conclusions as applied to every day practice

How About “Real Life Evidence”?

Evidence Generated From What Happens In Real Life, In Defined Populations

Obstetrical Breakthroughs

- Electronic FHR monitoring
- Ultrasound

None of the RCT’s have concluded that these are useful

- Premature
- Small numbers
- Incompetent study designs

Summary of The Effects of EFM on PNM Based on the Retrospective Studies Published 1972-1976

<table>
<thead>
<tr>
<th></th>
<th>No EFM</th>
<th>EFM</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBR (per 1000)</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>NMR (per 1000)</td>
<td>11</td>
<td>6</td>
</tr>
<tr>
<td>PNM (per 1000)</td>
<td>19</td>
<td>12</td>
</tr>
</tbody>
</table>

Reduction of PNM from 19/1000 to 12/1000 (37% reduction)

Sample size estimation for a RCT:

- EFM use prevents 66% of PNM
- EFM use prevents 50% of PNM

<table>
<thead>
<tr>
<th>ASSUMPTIONS</th>
<th>REQUIRED SAMPLE SIZE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Per group (n)</td>
</tr>
<tr>
<td>EFM use prevents 66% of PNM</td>
<td>12,612</td>
</tr>
<tr>
<td>EFM use prevents 50% of PNM</td>
<td>23,669</td>
</tr>
</tbody>
</table>

* Type I error (alpha) = 0.05
  Power (1-beta) = 0.8 (or 80%)

Published FHR Monitoring RCTs (Comparing EFM vs. Auscultation)

<table>
<thead>
<tr>
<th></th>
<th>EFM</th>
<th>IA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Havercamp (1976)</td>
<td>242</td>
<td>241</td>
</tr>
<tr>
<td>Renou (1976)</td>
<td>175</td>
<td>175</td>
</tr>
<tr>
<td>Kelso (1978)</td>
<td>253</td>
<td>251</td>
</tr>
<tr>
<td>Havercamp (1979)</td>
<td>459</td>
<td>231</td>
</tr>
<tr>
<td>Wood (1981)</td>
<td>445</td>
<td>482</td>
</tr>
<tr>
<td>McDonald (1985)</td>
<td>6474</td>
<td>6490</td>
</tr>
<tr>
<td>Neldam (1986)</td>
<td>482</td>
<td>487</td>
</tr>
<tr>
<td>Luthy (1987)</td>
<td>122</td>
<td>124</td>
</tr>
<tr>
<td>Vintzileos (1993)</td>
<td>746</td>
<td>682</td>
</tr>
</tbody>
</table>

Cochrane Collaboration

(Alfirevic Z, Devane D, Gyse GM. Cochrane Database of Systematic Reviews 2006)

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>RR 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative VD</td>
<td>18,151</td>
<td>1.16 (1.01, 1.32)</td>
</tr>
<tr>
<td>Cesarean</td>
<td>18,151</td>
<td>1.66 (1.30, 2.13)</td>
</tr>
<tr>
<td>Neon Seizures</td>
<td>32,386</td>
<td>0.50 (0.31, 0.80)</td>
</tr>
<tr>
<td>Cerebral palsy</td>
<td>13,252</td>
<td>1.74 (0.97, 3.11)</td>
</tr>
<tr>
<td>Perinatal death</td>
<td>33,513</td>
<td>0.85 (0.59, 1.23)</td>
</tr>
</tbody>
</table>
Participating hospitals: National Maternity Hospital, Rotunda, Coombe Women’s Hospital

**REAL LIFE EVIDENCE:** Trends in intrapartum fetal death, 1979-2003


**EFM use**
- Term singleton cephalic: 3%
- Early neonatal death: 5%
- Post-neonatal death: 95%

**Real Life Observations:**
- Fetal death rates (per 1,000 births) in The USA (NCHS)
- Fetal death rates at 20-27 weeks
- Fetal death rates at >28 weeks

**Trends in Stillbirths & PNM in the US (Years 1990-2004)**

**EFM use**
- Risk of mortality
  - Early neonatal: 0.75 (0.69, 0.81)
  - Late neonatal: 0.50 (0.44, 0.57)
  - Post-neonatal: 0.80 (0.76, 0.84)

**EFM and its relationship to neonatal and infant mortality in the US**

**REPORTS OF MAJOR IMPACT**

**Real Life Observations:**
- Trends in High-Risk Conditions in the US (Years 1990-2004)
- Evidence-Based Medicine Versus Real-Life Evidence in Gynecologic Surgery
RCT: Laparoscopy Compared With Laparotomy for Uterine Cancer (Stages I and IIA): GOG Group Study LAP2

Study Period: Years 1996-2005

- Intraoperative complications: 8% vs. 10%
- Post-op (grade > 2) complications*: 21% vs. 14%
- Post-op antibiotics*: 23% vs. 16%
- Hospital stay > 2 days*: 94% vs. 52%
- Quality of life indices*: --- vs. Better

Short-term outcomes (* significant)

- Operative time in min (median, IQR range)*: 130 (102-167) vs. 204 (160-252)

The study provides no real life information regarding individual (physician or institutional) operative times

Real-Life Evidence

Why don’t surgeons monitor their own individual statistics and counsel patients accordingly?

DISCUSSION: “Analysis of institutional variability was attempted by examining whether conversion rates were lower in institutions contributing large number of participants. However, other factors such as physician preference, conventions of individual institutions, and surgeon expertise level are also likely important factors that are more difficult to quantify.”

Other Concerns Regarding GOG Group RCT Study LAP2

- Patient enrollment started in 1996
- Results were published 2009 (13 years later) and 2012 (16 years later)
- Are the RCT findings relevant today?
- Are the finding relevant to minimally invasive robotic surgery?

Technology and EBM

Can EBM keep up with the pace of technology?

Does EBM, as defined today, inhibit progress?
References


LAPAROSCOPIC MANAGEMENT OF VASCULAR INJURY: CLIP APPLICATION, SUTURING REPAIR AND HEMOSTATIC AGENTS

Ceana Nezhat, MD
Director
Atlanta Center for Special Minimally Invasive Surgery
Atlanta, Georgia
www.Nezhat.com  Ceana@Nezhat.com

Complications
- Unavoidable
- Knowledge of anatomy
- Surgical skill
- Support

Complications Outcome
Prevention  Recognition  Management

First Paper on Laparoscopic Treatment of Stage IV Endometriosis

- Presented at AAGL annual meeting in 1984

"Wherever in the body a cavity exists or a cavity can be created, operative laparoscopy is indicated and probably preferable. The limiting factors are: skill and experience of the surgeon and the availability of proper instrumentation."


Disclosure
- Consultant: Intuitive Surgical, Lumenis, Karl Storz Endoscopy-America
- Speaker’s Bureau: Conceptus Incorporated, Ethicon Women’s Health & Urology, Hologic
- Other: Medical Advisor - Plasma Surgical, Scientific Advisory Board – SurgiQuest
Treatment of vascular injury

1. Prompt recognition is key in successful treatment
2. Conversion to open repair
3. Laparoscopic repair has been described

Special consideration in vascular injury repair
- Surgeon’s skills
- Reconstruction
- Diminished visibility
- Special instrumentation

Suturing for ligation

Ready-to-use, pre-tied endoloops for primary vessel ligation and hemostasis are commercially available

OPERATING ROOM TEAMWORK AMONG PHYSICIANS AND NURSES: TEAMWORK IN THE EYE OF THE BEHOLDER

Makary MA, Sexton JB, Freischlag JA, Holzmueller CG, Millman EA, Rowen L, Pronovost PJ.
Appropriate Questions in Reviewing a Case Report

1. What were the early warning signs that this could be developing?
2. If one had known it was coming, could the team have been better prepared?
3. Once confronted with the problem, what was done correctly and what could be done better the next time?
4. Could this case shed light on a mechanism of disease?

Trocar Injuries

- Trocar injury is one of the most serious and potentially preventable complications
- Disposable trocars have features intended to prevent these injuries

Trocar injuries in laparoscopic surgery


Results: Types of trocar injuries reported to the FDA from 1993 to 1996

<table>
<thead>
<tr>
<th>Trocar Injury</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths</td>
<td>32</td>
</tr>
<tr>
<td>Non-fatal vascular injuries</td>
<td>382</td>
</tr>
<tr>
<td>Non-fatal visceral injuries</td>
<td>176</td>
</tr>
<tr>
<td>Abdominal wall hematomas</td>
<td>30</td>
</tr>
<tr>
<td>Unclassified</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>628</td>
</tr>
</tbody>
</table>

Cause of death in fatal trocar injuries

<table>
<thead>
<tr>
<th>Type of injury</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unrecognized bowel injury</td>
<td>6</td>
</tr>
<tr>
<td>Aorta</td>
<td>6</td>
</tr>
<tr>
<td>Inferior Vena Cava</td>
<td>3</td>
</tr>
<tr>
<td>Mesenteric Vessel</td>
<td>2</td>
</tr>
<tr>
<td>Iliac Artery and Vein</td>
<td>2</td>
</tr>
<tr>
<td>Aorta and Inferior Vena Cava</td>
<td>1</td>
</tr>
<tr>
<td>Iliac Artery</td>
<td>1</td>
</tr>
<tr>
<td>Gastroduodenal Artery</td>
<td>1</td>
</tr>
<tr>
<td>Hypogastric Artery</td>
<td>1</td>
</tr>
<tr>
<td>Omental Vessel</td>
<td>1</td>
</tr>
<tr>
<td>Portal Vein</td>
<td>1</td>
</tr>
<tr>
<td>Unspecified Vessel</td>
<td>7</td>
</tr>
<tr>
<td>Total number</td>
<td>52</td>
</tr>
</tbody>
</table>

Types of nonfatal visceral injuries

<table>
<thead>
<tr>
<th>Viscera Injured</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowel (unspecified)</td>
<td>74</td>
</tr>
<tr>
<td>Small Bowel</td>
<td>25</td>
</tr>
<tr>
<td>Large Bowel</td>
<td>23</td>
</tr>
<tr>
<td>Stomach</td>
<td>5</td>
</tr>
<tr>
<td>Duodenum</td>
<td>1</td>
</tr>
<tr>
<td>Liver</td>
<td>20</td>
</tr>
<tr>
<td>Omentum</td>
<td>9</td>
</tr>
<tr>
<td>Bladder</td>
<td>5</td>
</tr>
<tr>
<td>Uterus</td>
<td>6</td>
</tr>
<tr>
<td>Pancreas</td>
<td>1</td>
</tr>
<tr>
<td>Ureter</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>170</td>
</tr>
</tbody>
</table>
Complications of Operative Laparoscopy

- Incidence of major injury during laparoscopy is unknown and probably under-reported

Injury to Major Retroperitoneal Vessels

- The most common cause of death associated with laparoscopy, aside from anesthetic complications

Major Vascular Injuries

- Rare, under-reported
- Results in serious morbidity
- Major cause for litigation

Hemorrhagic Complications of Operative Laparoscopy

- Inferior epigastric vessels are not considered major vessels
- Delayed diagnosis of injury to these vessels leads to significant morbidity and mortality

Results: Type of procedures in fatal trocar injuries

<table>
<thead>
<tr>
<th>Type of Laparoscopic Procedures</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholecystectomy</td>
<td>16</td>
</tr>
<tr>
<td>Diagnostic Laparoscopy</td>
<td>3</td>
</tr>
<tr>
<td>Tubal Ligation</td>
<td>2</td>
</tr>
<tr>
<td>Appendectomy</td>
<td>2</td>
</tr>
<tr>
<td>Lymphadenectomy</td>
<td>1</td>
</tr>
<tr>
<td>Unspecified</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
</tr>
</tbody>
</table>

Conclusions

- Safety shields and direct-view trocars do not prevent serious injuries
Conclusions

- Vascular injuries are more likely to be fatal if they involve the aorta or inferior vena cava

Conclusions

- An unrecognized bowel injury is highly lethal

Results

- The diagnosis of enterotomy was delayed in 10% of cases
- The mortality rate in this group was 21%

Conclusions

- Bowel injuries commonly go unrecognized
- In which case they are highly lethal

Major vascular injury and laparoscopy.

- Iatrogenic vascular trauma
- CO2 embolism during insufflation

Umbilical Bleed
Devices used for dissection and hemostasis in laparoscopic surgery

- Surgical clip
- Suture ligation
- Surgical stapler
- Electrosurgery
- Advanced bipolar sealing systems
- Ultrasonic desiccation
- Radiofrequency sealants
- Haemostatic agents

Hemostatic agents

Because control of bleeding by sutures or cautery is not always effective or practical, a variety of products have been developed to achieve bleeding control by alternative means:

- **Hemostatic agents**
  - Used to halt bleeding
  - Applied directly to a bleeding site
  - Work in the presence of actively flowing blood
- **Sealants**
  - Used to prevent the leakage of liquids, gases and solids from surgical sites
  - Applied to dry or clamped tissue surfaces to create a barrier
- **Glues/adhesives**
  - Used to attach tissues

Microporous Polysaccharide Hemospheres (Arista- AH)

- Arista absorbs the serum (liquid portion of the blood) and creates a scaffold to support the fibrin mesh
- Biologically inert
- No bovine, porcine or human blood, protein or tissue sources
- Synthesized from plant material
- No risk of viral disease transmission
- Enzymatically degraded within 24 hours
- A fast acting, versatile clotting agent that produces an “instant gelling” followed by the formation of a fibrin mesh in 1-2 minutes
- Rapid control of bleeding
- Easily irrigated
- Cost and time savings

Polyethylene Glycol Matrix (Coseal)

- Biocompatible polyethylene glycol polymer that rapidly cross-links with proteins in tissue to immediately adhere to the area of application
- Indicated for use in vascular reconstructions to achieve haemostasis by mechanically sealing areas of leakage.
- Fully synthetic, not containing any animal or human proteins or Gluteraldehyde
- Successfully adheres to synthetic materials

Combined Human-Origin Thrombin and Bovine-Origin Gelatin Matrix (FloSeal)

- FloSeal indicated in surgical procedure except in ophthalmic surgeries.
- Fossil matrix contains bovine-derived gelatin matrix components and a human thrombin component.
- Don’t use in patients who are allergic to materials in bovine, on skin incisions, do not inject or compress FloSeal matrix into the blood vessels.
- FloSeal is indicated in invasive*1 or surgically invasive*2 procedures as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical

FloSeal
Thank you

Ceana Nezhat, MD
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Robotic and Laparoscopic Technique: Avoiding a Cuff Dehiscence in Obese Patients

Pamela T Soliman, MD, MPH
Associate Professor
Gynecologic Oncology

Disclosure
• I have no financial relationships to disclose.

Objectives
• Clinical presentation
• Etiology
• Published literature
• Strategies of prevention
• Details on surgical technique
• Role of suture material
• Surgical or conservative management

Clinical Presentation
• Vaginal bleeding
• Discharge
• Pelvic pain
• Vaginal fullness
• Protruding mass

Etiology
• Spontaneous
  - shorten vagina
  - thinning of vaginal apex
  - enterocele and Valsalva
• Post-surgical
  - use of electrocautery
  - suboptimal tissue approximation
  - suture fraying
  - suture material

Strategies of prevention
• Use of absorbable sutures
• Proper approximation of vaginal wall
• Avoidance of electrocautery
• Use of suboptimal tissue approximation
• Minimize suture fraying

Role of suture material
• Absorbable vs. non-absorbable sutures
• Strength and durability
• Cost and availability

Surgical or conservative management
• Surgical repair
• Conservative management
  - Rest and activity restriction
  - Physical therapy
  - Pain management

Published literature
• Studies on the prevalence of cuff dehiscence
• Comparison of techniques
• Outcomes of surgical or conservative management
• Factors influencing dehiscence

Rate of vaginal cuff separation following laparoscopic or robotic hysterectomy

<table>
<thead>
<tr>
<th>Technique</th>
<th>Cuff Separation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laparoscopic (n=300)</td>
<td>5.7% (17/286)</td>
</tr>
<tr>
<td>Robotic (n=300)</td>
<td>7.6% (23/298)</td>
</tr>
<tr>
<td>Electromechanical</td>
<td>5.7% (17/286)</td>
</tr>
<tr>
<td>Radical hysterectomy</td>
<td>7.6% (23/298)</td>
</tr>
</tbody>
</table>
### Laparoscopic Vaginal Closure

#### Ti-Knot

- Single angle
- 8 barbs/cm
- 1 helix/5.08 mm

#### Endo Stitch

- Dual angle
- 20 barbs/cm
- 1 helix/1.52 mm

### Suture Material

- **Quill** vs. **VLoc**

#### LapraTy Absorbable Suture

- Absorbable polydioxanone
- Tensile strength: 14 days
- Absorbed: 90 days

### Risk factors for vaginal cuff separation.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Vaginal cuff dehiscence/visceration (n = 7)</th>
<th>No vaginal cuff dehiscence/visceration (n = 408)</th>
<th>P-value <em>a</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Current smoker, no. of patients (%)</td>
<td>2 (29)</td>
<td>41 (11)</td>
<td>0.16</td>
</tr>
<tr>
<td>Diabetes, no. of patients (%)</td>
<td>1 (14)</td>
<td>33 (8)</td>
<td>0.45</td>
</tr>
<tr>
<td>Risk factors for peripheral vascular disease, no. of patients (%)</td>
<td>2 (29)</td>
<td>153 (37)</td>
<td>1.00</td>
</tr>
<tr>
<td>Radical hysterectomy, no. of patients (%)</td>
<td>4 (57)</td>
<td>51 (12)</td>
<td>0.007</td>
</tr>
</tbody>
</table>

*a* p-value from Fisher’s exact test.
**Strategies for Prevention**

- Patient selection
- Surgical technique
  - Colpotomy
  - Tissue approximation
- Suture tools & material
  - Vicryl
  - Quill
  - Vloc
  - Delayed absorbable monofilament suture
- Postoperative counseling

**Management**

- NPO
- Steep Trendelenburg
- Moist gauze packing
- Status
  - Stable: Abdominal x-ray
  - Unstable: OR immediately
- Repair
  - Abdominal: laparotomy vs laparoscopy
  - Vaginal

**Conclusion**

- Incidence of evisceration is low
- Surgical technique essential in prevention
- Suture material
- Early recognition is vital
- Repair often feasible by vaginal approach
- Patient counseling

Thank You!
Anesthesia for Operative and Robotic Surgery: How to Convince an Anesthesiologist to Place Obese or Non-obese Patient in Steep Trendelenburg

Disclosure

I have no financial relationships to disclose.

Laparoscopy

• Invented by Hans Christen Jacobaeus
• Minimally invasive surgery - began with advent of procedures to reduce surgical trauma to patient and improve visualization of operative area
• Preferred surgical modality
  • Patients & Surgeons

Surgical Numbers

• 95% Cholecystectomies
• 90% Nissen fundoplication
• 80-90% Gastric bypass procedures
• 70% Ectopic pregnancy procedures
• 50% Pelvic Gyn/GU procedures

Laparoscopy-Advantages

• Cosmesis
• Shorter immediate recovery
• Decreased blood loss
• Shorter hospital stay
• Less post-operative analgesic requirements
• Decreased intra-abdominal adhesions
• More rapid return to normal activities
Laparoscopy-Disadvantages

- Patient altered physiology
- Steep learning curve for the surgeon
- Two dimensional field of view
- More set up time
- Greater equipment issues
- Upfront costs

From Laparoscopy to Robotic

- Shortcoming in laparoscopy
- Surgeons acceptance
  - Degree of freedom
  - Technical advantages
  - Tremor filtration

Technical

- Wrist instrumentation
- High-definition stereoscopic 3D optics
- Ergonomics
- Motion scaling
- Intuitive movements
- Total visual immersion
- Autonomy of camera control

Robotic system-Old

- Leonardo de Vinci
- 1495 developed the armored knight

Robotic system-New

- 2000: da Vinci-general laparoscopic surgery
- 2002: MV surgery
- 2005: Gyn surgery
da Vinci Surgery

- Cardiac
- Colorectal
- General
- Gynecologic
- Head & Neck
- Thoracic
- Urologic

Modern day applications

- Ortho.
- ENT
- Ophthalmology
- GI
- Cardiac
- Urologic/Gyn
- Neuro.
- Drill guidance

Advantages

- Bridge between laparotomy and laparoscopy
- Improves surgical dexterity
- Filters surgeons tremor
- 3D field of view

Disadvantages

- Expensive
- Cumbersome set up
- Inability to move table
- Lack of tactile surgical feedback
- Pathophysiologic alterations to patient

Pathophysiologic alterations to the patient

- Laparoscopy
  - CO₂ intraperitoneal insufflation
- Robotic
- Surgical instrumentation
- Both
  - Patient positioning
- Hemodynamic
- Respiratory
- Endocrine
- Other...
Pneumoperitoneum

Cardiovascular

| IAP<10mmHg | VR —— CO |
| IAP 10-20mmHg | VR —— CO |
| IAP >20mmHg | VR —— CO |

BP = CO x SVR

— BP

Respiratory

| Lung volume-FRC | ↓ |
| Airway resistance | ↓ |
| Pulmonary compliance | ↓ |
| Airway pressure | ↓ |
| V/Q mismatch | ↓ |
| Barotrauma risk | ↓ |

Neurohumoral

<table>
<thead>
<tr>
<th>RAA system activation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renin</td>
</tr>
<tr>
<td>Angiotensin</td>
</tr>
<tr>
<td>Aldosterone</td>
</tr>
</tbody>
</table>

Sympathetic system activation

| Catecholamines | ↓ |

Gastrointestinal

| Aspiration risk | ↓ |
Absorption of CO₂

- Hypercapnia → acidosis
- Arrhythmic threshold lowered
- Sympathetic NS stimulation

<table>
<thead>
<tr>
<th>Absorption of CO₂</th>
<th>Direct effect</th>
<th>Indirect effects</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hypercarbia</td>
<td>SNS stimulation</td>
</tr>
<tr>
<td></td>
<td>Acidosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Contractility</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>SVR</td>
</tr>
<tr>
<td></td>
<td>↓ HR</td>
<td>↑ HR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PVC</td>
<td>↑ Contractility</td>
<td></td>
</tr>
<tr>
<td>Asystole</td>
<td>↑ SVR</td>
<td></td>
</tr>
</tbody>
</table>

Surgical factors

- Surgical injury
- Gas embolism
- Pneumothorax
- Subcutaneous emphysema
- Post operative vision loss

Surgical complications
Trendelenburg

- Friedrich Trendelenburg (1844-1924)
- Born Berlin
- Trained at University of Glasgow
- Surgeon-in-chief Leipzig Germany
- 1885 - "position used"

Trendelenburg Reverse

<table>
<thead>
<tr>
<th>Cardiovascular</th>
<th>Trendelenburg</th>
<th>Reverse Trendelenburg</th>
</tr>
</thead>
<tbody>
<tr>
<td>VR</td>
<td>↑</td>
<td>↓</td>
</tr>
<tr>
<td>CO</td>
<td>↑</td>
<td>↓</td>
</tr>
<tr>
<td>BP</td>
<td>←</td>
<td>↓</td>
</tr>
</tbody>
</table>

Trendelenburg Reverse

<table>
<thead>
<tr>
<th>Respiratory</th>
<th>Trendelenburg</th>
<th>Reverse Trendelenburg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung volumes</td>
<td>↓</td>
<td>←</td>
</tr>
<tr>
<td>VQ Mismatch</td>
<td>↑</td>
<td>←</td>
</tr>
<tr>
<td>Atelectasis</td>
<td>↑</td>
<td>←</td>
</tr>
</tbody>
</table>
Effects of positioning

Review of literature

- Study design
  - Investigate the combined effects of position & CO2 pneumoperitoneum

- Methods
  - 31 consecutive patients undergoing robotic surgery

### Table 1

<table>
<thead>
<tr>
<th>Measured variables</th>
<th>Pre-Trendelenburg</th>
<th>Trendelenburg</th>
<th>Post-Trendelenburg</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR (beats/min)</td>
<td>62 (12)</td>
<td>63 (10)</td>
<td>68 (11)*</td>
</tr>
<tr>
<td>MAP (mm Hg)</td>
<td>79 (14)</td>
<td>76 (11)*</td>
<td>78 (13)</td>
</tr>
<tr>
<td>CVP (mm Hg)</td>
<td>8 (4)</td>
<td>8 (6)</td>
<td>8 (6)</td>
</tr>
<tr>
<td>MABP (mm Hg)</td>
<td>71 (11)</td>
<td>70 (12)</td>
<td>69 (13)</td>
</tr>
<tr>
<td>HR (beat/min)</td>
<td>99 (1)</td>
<td>98 (1)</td>
<td>98 (1)</td>
</tr>
<tr>
<td>MAP (mm Hg)</td>
<td>79 (4)</td>
<td>74 (4)*</td>
<td>74 (5)*</td>
</tr>
<tr>
<td>Ptp (KPa)</td>
<td>4.12 (0.40)</td>
<td>4.79 (0.40)*</td>
<td>4.52 (0.40)*</td>
</tr>
<tr>
<td>Ptp CO2 (mm Hg)</td>
<td>14 (4)</td>
<td>84 (5)*</td>
<td>10 (4)</td>
</tr>
<tr>
<td>Total volume (ml)</td>
<td>542 (35)</td>
<td>529 (66)</td>
<td>551 (70)</td>
</tr>
<tr>
<td>Lung compliance (%)</td>
<td>50 (1)</td>
<td>43 (1)*</td>
<td>45 (13)*</td>
</tr>
</tbody>
</table>

CONCLUSIONS: IOP reached peak levels at the end of steep Trendelenburg position, on average 13 mm Hg higher than the preanesthesia induction value. Surgical duration and ETCO2 were the only significant predictors of IOP increase in the Trendelenburg position.

- Increase
  - Dopamine
  - Vasopressin
  - Epinephrine
  - Norepinephrine
Patient Factors

- ASA physical status classification
- Preoperative comorbidity
- CAD-ischemia, CHF, cardiomyopathy, DM
- Asthma, COPD, emphysema
- Volume status

What we have to do...

- Know patients starting physiology
- Game plan...talk to the surgeon
- Treat immediate problems
- Vigilance
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](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](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](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.