Didactic/Simulation Lab:
Fibroid Tissue Extraction: A Hands-on Workshop

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Target Audience
This educational activity is developed to meet the needs of surgical gynecologists in practice and in training, as well as other healthcare professionals in the field of gynecology.

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EXTR-710: Didactic/Simulation Lab:  
Fibroid Tissue Extraction: A Hands-on Workshop

Sarah L. Cohen, Chair  
Faculty: Mobolaji Ajao, Douglas N. Brown, Amanda Nickles Fader, K. Anthony Shibley

Lab Faculty: Shan M. Biscette, James A. Greenberg, Hye-Chun Hur, Kimberly A. Kho, Louise P. King,  
Charles E. Miller, Matthew T. Siedhoff, Michael L. Sprague, Frank F. Tu, Alison Vogell

This course provides both didactic explanations and hands-on simulation opportunities to practice the  
most current approaches to fibroid tissue extraction at the time of minimally invasive gynecologic  
surgery. Following an overview of safety concerns regarding extraction of fibroid specimens, principles  
of contained morcellation will be reviewed. Participants will gain exposure to manual morcellation via  
minilaparotomy and colpotomy while employing a variety of containment bags and devices. Contained  
power morcellation, including an overview of available devices and FDA-approved systems, will also be  
highlighted. Specific surgical techniques for tissue extraction will be taught using box trainer models and  
beef tongue to simulate the uterine tissue. This course is appropriate for novice and advanced surgeons  
who want to refine their tissue extraction skills.

Learning Objectives: At the conclusion of this course, the clinician will be able to: 1) Screen and counsel  
patients regarding minimally invasive tissue extraction options; 2) perform safe and efficient contained  
manual morcellation via minilaparotomy or colpotomy; and 3) apply contained power morcellation  
techniques where appropriate.

Course Outline

12:30 Welcome, Introductions and Course Overview S.L. Cohen
12:35 Safe Tissue Extraction: How to Screen and Counsel Your Fibroid Patients A. Nickles Fader
1:00 Contained Manual Morcellation: Minilaparotomy and Colpotomy B. Ajao
1:25 Contained Power Morcellation K.A. Shibley
1:50 Unanswered Questions and Future Directions S.L. Cohen
2:15 LAB: Demonstration of Contained Morcellation Techniques (10 stations for each)  
• Minilaparotomy
• Vaginal
• Laparoscopic
4:15 Questions & Answers All Faculty
4:30 Adjourn
PLANNER DISCLOSURE
The following members of AAGL have been involved in the educational planning of this workshop (listed in alphabetical order by last name).
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Sarah L. Cohen
Consultant: Olympus
Amanda Nickles Fader
Other: Honorarium: Apple Medical Corporation
K. Anthony Shibley
Consultant:  Olympus
Royalty:  Advanced Surgical Concepts
Content Reviewer has no relationships.

Asterisk (*) denotes no financial relationships to disclose.
Safe Tissue Extraction: Perspectives of a GYN Oncologist on How to Screen and Counsel Your Patients with Fibroids

Amanda Nickles Fader, MD
Associate Professor and Director,
The Kelly Gynecologic Oncology Service
Johns Hopkins Hospital

Disclosures

Other: Honorarium: Apple Medical Corp.

I’m a gynecologic oncologist
– 75% cancer
– 25% complex benign

Treat a high volume of uterine sarcoma and study rare tumors

Have utilized morcellation throughout my career

“It is only about things that do not interest one that one can give really unbiased opinions, which is no doubt the reason why an unbiased opinion is always valueless.”
-Oscar Wilde

Talk Objectives

• Appraise the FDA and the Joint Commission safety statements regarding open power morcellation

• Review strategies to reduce the risk of encountering occult uterine malignancies during morcellation

• Consider the best practices in patient counseling regarding fibroids

Institutional and Departmental Responses Have Been Mixed

• Maintain the status quo

• Banning open power morcellation

• Mandating

• Allowing power morcellation within a containment system

• Allowing scalpel-based morcellation

• Allowing scalpel-based morcellation within a containment system
Information Asymmetry and the FDA

- Only one point of view with respect to the medical device or medication in question
  - Not a full evaluation of the alternatives
- Black box warning for antidepressants in adolescent/pediatric patients
- Black box warning for HRT
- Some of the most controversial FDA decisions in the last decade have impacted gynecologic patients, from adolescence to menopause.

The Realities

- Minimally invasive surgery benefits women—one of the greatest advancements in the last half century
- Morcellation allows more women to undergo MIS
- However, more than a handful of women worldwide are diagnosed with an occult uterine cancer that is accidentally morcellated or incompletely removed
- Need cool heads and scientific reasoning to answer the question: Is the status quo our best, or can we do better?

The Realities

The Realities

Answered Questions/Assumptions

- When conscientious, expert surgeons are involved:
  - Morcellation has allowed hundreds of thousands of women to undergo MIS procedures safely
  - Rate of occult uterine malignancy in reproductive-aged women undergoing hysterectomy/myomectomy for presumed benign indications is extremely low.

- The prognosis of women diagnosed with a high grade sarcoma of any stage is poor

Conscientious, expert surgeon is an appropriate bar to set

- Know that high volume surgeons have better outcomes
- Guideline-adherent, quality care in surgery to reduce preventable harm
  - Proper timing and admin of preop antibiotics
  - Systemic compression devices

What is the Incidence of Occult Uterine Sarcoma at Benign GYN Surgery?

- Rate of uterine sarcoma = 0.0 to 9.1%
- Few studies in which overall hysterectomy denominator is known and even fewer with in house patients only
- But many elderly patients included
Incidence of Occult Uterine Cancers Detected After Morcellation: Age Matters

- Incidence uterine malignancy 0.3%
- Significant correlation between occult cancer incidence and advancing age

October 19, 2016

Hopkins Morcellation Data

- 2005-2014—All in-house hysterectomies and myomectomies performed for benign indications
- Only one occult sarcoma detected in a cohort of 4173 pts over a 10-year period (0.09% risk of malignancy in overall cohort; 0.16% in MIS cohort)
  - 1 myxoid leiomyosarcoma in 2009
- Morcellation cohort
  - No occult cancers identified in women <50 years (n=401)

Ricci et al, AAGL, 2014

October 19, 2016

Uterine Sarcoma

<table>
<thead>
<tr>
<th>Sarcoma Type</th>
<th>Prevalence</th>
<th>Median Age at Diagnosis</th>
<th>Tumor Behavior</th>
<th>5-Year Survival Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>LMS</td>
<td>1-2% of all uterine cancers</td>
<td>58 years</td>
<td>Very aggressive, high grade (exception myxoid)</td>
<td>40%</td>
</tr>
<tr>
<td>ESS</td>
<td>&lt;1% of all uterine cancers</td>
<td>47 years</td>
<td>Indolent, lower grade</td>
<td>90%</td>
</tr>
</tbody>
</table>

October 19, 2016

Ricci et al, Gynecol Oncol, 2013

Summary Re: Incidence of Occult Uterine Cancer During Fibroid Surgery

- The FDA statement is not correct that 1:350 reproductive aged women undergoing presumed benign fibroid surgery will have a uterine sarcoma diagnosed
- Age, clinical presentation and appropriate patient selection matter!!!
- Caution with morcellation in postmenopausal/elderly, postmenopausal women or those with a higher risk of uterine cancer

October 19, 2016

Does Morcellation, Myomectomy or Supracervical Hysterectomy Worsen Outcomes for LMS?

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Study Period</th>
<th>Open Lap Hysteroscopic</th>
<th>Endpoint</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perri et al</td>
<td>2009</td>
<td>1969-2005</td>
<td>21/16</td>
<td>&quot;Tumor injury&quot;</td>
<td>Increased recurrence/Decreased survival 2.59 recur 3.07 death</td>
</tr>
<tr>
<td>Park et al</td>
<td>2011</td>
<td>1989-2010</td>
<td>31/25</td>
<td>Morcellation</td>
<td></td>
</tr>
<tr>
<td>George et al</td>
<td>2014</td>
<td>2007-2012</td>
<td>39/19</td>
<td>Intraperitoneal morcellation</td>
<td>3.18 recur increased</td>
</tr>
</tbody>
</table>

October 19, 2016


Hopkins/Duke/UNC Leiomyosarcoma Series: Survival Poor for “Intact”, Early Stage Dz

- 108 cases of early stage (I-II), “intact” LMS
- Overall recurrence rate: 71% (median F/U time 42 months)
- 65% dead of disease within 5 years
- Stage and chemotherapy associated with survival on MV analysis

October 19, 2016

Ricci, Fader, Gynecol Oncol, 2013

October 19, 2016
Does Type of Tissue Extraction Matter?

- A data-free zone!
- Open power morcellation may not increase risks of dissemination any more so than open myomectomy, hysteroscopic myomectomy or scalpel-based abdominal or vaginal morcellation.
- **BOTTOM LINE:** Risks of disseminated occult cancer exceptionally small in appropriate morcellation candidates. But must not falsely reassure ourselves that open scalpel-based morcellation is safer.


Being Intellectually Honest…

- Jury out on whether morcellation truly worsens survival for LMS or ESS
  - Retrospective data with major flaws
- Empirically, we must acknowledge the (strong) possibility that “cut through” procedures of the uterus may worsen outcome due to disruption of margins and residual disease status
- GYN surgical community must take the lead to reduce the risks associated with occult cancer morcellation


Dissemination of Benign Disease After Morcellation

- It happens!
- Three referred cases to Hopkins in 2012-2013 mimicking cancer (elevated tumor markers and carcinomatosis) requiring debulking surgery and multi-organ resection
- Endometriosis & adenomyomas
- Tissue extraction techniques critical


- Surgery is the only potentially curative treatment for LMS and ESS of any anatomic site
  - Surgical resection with appropriate negative margins is the primary treatment for most patients w/ soft tissue sarcomas
  - "The surgical procedure necessary to resect the tumor with appropriate negative margins should be used"
  - "Dissection should be through grossly normal tissue planes uncontaminated by tumor"
- In the setting of myomectomy or fragmented specimen with sarcoma, consideration of imaging and reoperation


Hopkins Morcellation Protocol

- Preoperative peer-review
- Imaging (MRI for fibroids)
- Endometrial evaluation
- Exclusion criteria for morcellation
  - Caution in Postmenopausal Women
  - History of tamoxifen use
  - Pelvic radiation
  - BRCA mutation carrier status
  - Hereditary cancer syndromes
- Enhanced surgical consent
- High volume surgeons only
- Contained morcellation only


Detecting Sarcomas Preoperatively

- True or false: A uterine sarcoma cannot be detected by endometrial biopsy.
- Among 72 women with sarcomas, preop sampling suggested an invasive tumor in 86% and predicted the correct histologic diagnosis in 64%.
- Rate of detection of an invasive cancer by preoperative sampling was not statistically different among sarcomas and epithelial tumors (86% vs. 84%, p=0.76).
- Preoperative sampling was significantly less reliable in predicting the correct histology for uterine sarcomas (64% vs. 81%, p<0.0001).

October 19, 2016 Bansal et al, Gynecol Oncol, 2008
FDA Statement on Open Power Morcellation Nov 2014

• Black box warning on open power morcellation
• “The FDA is warning against using laparoscopic power morcellators in the majority of women undergoing hysterectomy or myomectomy for uterine fibroids.”
• Contraindicated in peri and postmenopausal women or in those with suspected cancer

Joint Commission Recommendations 2014

• Ensure appropriate training and credentialing for MIS, including power morcellation
• Consider evidence-based guidelines
• Rigorous informed consent process
• Analyze internal data from patients safety and quality outcomes perspective
• If need to morcellate, obtain consensus

Avoid Being Too Reactionary...But Keep Patient's Informed and Safe

• WHI Study and Impact on HRT administration
  – Stroke and cardiovascular disease are rare and affect elderly, comorbid women
  – HRT benefits thousands of women who are appropriate candidates for this therapy
• Tamoxifen and Breast Cancer—
  – Improves survival and decreases risk of recurrence for breast cancer
  – 2-4 fold increased risk of uterine cancer... more common than risk of dissemination of sarcoma at a morcellation procedure

An Impossible Standard

• The expectation that the only way morcellation practices will survive is to ensure no women will be at risk for a disseminated occult cancer is untenable
  – A Lose:Lose situation for surgeons and their patients
• For the FDA or other regulatory agencies to eliminate or strongly curtail power morcellation in its current form would hurt far more women than it will help

Can We Do Better? YES!!!!

• Most cases of occult cancer can be avoided with meticulous, thoughtful preoperative planning and patient risk stratification
• Cannot think in absolutes (ie, ban ALL morcellation or use MIS techniques in ALL women)
• Individualized, patient-centered care plans with rigorous informed consent

Conclusions

• Broad applications of MIS—including use of uterine morcellation—have significantly improved outcomes for the vast majority of women with benign and cancerous GYN conditions
• Occult uterine cancers are RARE in reproductive-aged women and occur FAR more common in postmenopausal/elderly women
Conclusions

- Reducing or eliminating the use of open morcellation technique or supracervical hyst in symptomatic high-risk or postmenopausal women may significantly reduce the incidence of morcellated cancers.
- Meticulous preoperative planning with endometrial sampling and imaging and critical appraisal at peer reviewed conferences may help significantly reduce the risk of unexpected findings at surgery.

Thank you!
Contained Manual Morcellation

November 15, 2016

Mobolaji Ajao, MD
Instructor in Obstetrics, Gynecology and Reproductive Biology
Harvard Medical School
Division of Minimally Invasive Gynecologic Surgery
Brigham and Women’s Hospital
Boston, MA

Objectives

Select route of specimen extraction:

- Manual morcellation – Mini-lap
- Manual morcellation – Vaginal

History/Background

- 2013 – A case of morcellated LMS gained widespread publicity and call for ban of electromechanical morcellation (EMM).4
- April/November 2014 – FDA statement discouraging use of EMM. FDA review → 1/350 risk of unsuspected uterine sarcoma.5,6,7
- April - Nov 2014 – Shibley; Einarsson et al.; Cohen et al. Contained morcellation.8,9,10

Disclosure

I have no financial relationships to disclose.

History/Background

- Some institutions banned power morcellation.
- Johnson and Johnson pulled morcellator from market.
History/Background

- Intense spotlight
- FDA statements
- Benefits of MIS

  - Alternate specimen extraction methods

Minilap vs Vaginal (colpotomy)

- Total hysterectomy vs Supracervical/Myomectomy
- Size and shape of pathology

  - Vaginal capacity
  - Physician preference

Minilap

- Umbilical vs Suprapubic
  - Cosmesis
  - Pain
  - Herniation

Minilap

- Additional Equipment
  - Specimen bag
  - Disposable self retaining retractor
  - Size 6 or 7 glove / Small or mini Gel port
  - Total of 3 atraumatic graspers
  - Triple hooks/Tenaculum/Penetrating towel clamps
  - Extra scalpels

  - Optional
    - Electrosurgical unit with hand-held electrode for open surgery

Minilap - Suprapubic

1. Extend suprapubic port site / create 2-5 cm suprapubic incision.
2. Place Self retaining retractor
3. Insert specimen bag (oriented)
4. Re-establish pneumoperitoneum with glove
5. Return to laparoscopy and place specimen into bag
6. Exteriorize the opening of the bag
7. Optional – place self retaining retractor inside the bag
8. Maintain pneumoperitoneum to keep viscera distant
Minilap - Umbilical

1. Extend umbilical port site to 2-5 cm.
2. Place Self retaining retractor
3. Insert specimen bag (oriented)
4. Re-establish pneumoperitoneum with gel port (or glove)

Minilap - Umbilical

1. Return to laparoscopy and place specimen into bag
2. Exteriorize the opening of the bag
3. Optional – place self retaining retractor inside the bag
4. Maintain pneumoperitoneum to keep viscera distant

Colpotomy

1. Insert specimen bag vaginally or through largest laparoscopy port
   - Vaginally - deployable or free-standing bag
   - Laparoscopic port – Free standing bag
2. Place specimen into bag
3. Exteriorize the opening of the bag though colpotomy
4. Optional – place self retaining retractor inside the bag
5. Maintain pneumoperitoneum to keep viscera distant

Colpotomy

- Additional Equipment
  - Specimen bag
  - Optional - Disposable self retaining retractor
  - Total of 3 atraumatic graspers
  - Triple hooks/Tenaculum/Penetrating towel clamps
  - Extra scalpels

Technique

- Rocking rotational movement
  - “Paper roll” technique. Wong et al.¹¹
  - “ExCITE” Technique – Extracorporeal C-Incision Tissue Extraction. Truong and Advincula.¹²
Evidence – Developing

- Contained manual morcellation (minilap)
  - Serur and Lakhi reported on technique/feasibility of contained manual morcellation – 2011.1
- Contained manual morcellation (colpotomy)
  - Solina E et al. Prospective study of 12 patients showed 33% bag leakage.
- Power vs Minilap vs Colpotomy
  - Moawad GN et al. Retrospective comparison morcellation methods – 2016.13
  - Operative time 24 mins longer for power vs minilap

References

Criticism of techniques

- Wasting time
- No supporting data
- Bag leakage rate
Thank you!
Contained Power morcellation

Tony Shibley MD

Disclosures

- Consultant: Olympus
- Royalty: Advanced Surgical Corporation

Objectives

- Convey the history of contained power morcellation.
- Review the evolution of insufflated bag for contained power morcellation
- Summarize the evidence supporting contained power morcellation
- Compare options for contained power morcellation
- Illustrate the FDA approved Pneumoliner technique

History of Power Morcellation

- Power morcellation introduced in 1990’s and published in 1993 by Urologist Dr Ralph Clayman*
- Initially morcellation was designed for use within containment bags*

* Kurt Kerbl, Ralph V Clayman, Elspeth McDougall, Louis R Kavoussi; Laparoscopic Nephrectomy: BMJ volume 307,4 December 1993
U.S. Patent No.s 5037379, 5215521 and 5618296

Early Bagged Power Morcellation

Power Morcellation Risks

- Mechanical Injury-visceral or vascular
- Infection
- Dissemination and seeding of benign tissue
- Dissemination and seeding of malignant tissue
Insufflated Bag 2012*
– Laparoscopy shifts from inside an inflated abdomen to inside and inflated bag
– Provides direct vision
– Provides complete containment
– Provides safe distance between target tissue and surrounding viscera
– Retracts bowel creating more operative space
– *US patents 8,920,431; 8,956,286; 9,265,492

Insufflated Containment - Artificial Pneumoperitoneum
• AAGL 2012: Initial feasibility presented*
• 2014: Expanded multicenter feasibility published **
  – Feasible, with no visual signs of leakage


Insufflated Bag
Ability to Distinguish Target Tissue from Viscera

Contained Morcellation versus Uncontained
• Uncontained Compared With Contained Power Morcellation in Total Laparoscopic Hysterectomy
  – Comparison of uncontained vs contained in an insufflated bag at the time of TLH resulted in 20min increase in operative time


Contained Power Morcellation Options
• LESS Shibley technique with existing on shelf bags
• Multiport by bag puncture after insufflation
• Multiport bag with sleeves or valves*
• Pneumoliner**

*"Morsafe" CE approval not US cleared
** Only FDA approved device for power morcellation
contained morcellation: single port vs multiport

- multiport approach requires bag puncture for scope insertion and allows multiport morcellation just as in uncontained
- cellular leakage risk is approximately 9%*

*pohen et al. contained tissue extraction using power morcellation: prospective evaluation of leakage parameters. ajog. published online.

the solution? pneumoliner containment

- only fda cleared containment system for removal of tissue
- different fda review process (de novo clearance)
  - required more rigorous testing to support clearance
  - conforms to each patient’s abdominal size and creates a clearly visualized working space
  - creates a barrier between the targeted tissue and non-targeted abdominal contents to minimize the risk of inadvertent damage to adjacent structures

pneumoliner containment system

- conforms to each patient’s abdominal size and creates a clearly visualized working space
- creates a barrier between the targeted tissue and non-targeted abdominal contents to minimize the risk of inadvertent damage to adjacent structures

ce cleared. fda de novo clearance pending. not available for sale in the united states.
Limitations of Pneumoliner

- Utilizes the LESS technique
- May not accommodate all specimen sizes
- Training is required by the FDA
- Errors in technique could lead to bag disruption

Important Success Factor: Training!

- MD Training Validation Study*
  - During formal training protocol validation, no tearing or leakage of containment system was shown
- FDA mandated training before clinical use
  - To ensure Pneumoliner integrity is not compromised
- MDs who complete formal training and demonstrate proficiency will be tracked
  - Recorded and data kept on file per FDA requirement in case of adverse events

* N=31 MDs representing varying surgical experience: residents to expert MIG surgeon, 2015

FDA Required Training Process

- Morcellation is a single port operation with 4 steps
- Steps 1 and 2- device overview and live demonstration
- Step 3 hands on training with any needed assistance from the trainer.
- Step 4 is a test to demonstrate independent use of the device

Pneumoliner Procedure Steps

- 20-25mm umbilical incision
- Insert port, adjust and trim, insufflate
- Insert camera
- Insert and deploy pneumoliner
- Manipulate tissue into pneumoliner
- Close pneumoliner and pull tether to exteriorize. Stop at marking

Pneumoliner Steps Cont’d

- Open pneumoliner
- Replace port cap, orient cap and insufflate
- Place 5mm camera
- Place morcellator
- Insert tenaculum and morcellate specimen
- Remove pneumoliner when fragments are smaller than 4 grid markings

Important Tips

- Pre-position the tissue in right upper quadrant for easier placement in the deployed pneumoliner
- The introducer has a tip ribbon that should point up to insure the pneumoliner orientation
- Never approach tissue with an open tenaculum
- Position tissue in the center of the pneumoliner
- Partially withdraw the morcellator for grasping then advance for morcellation.
Pneumoliner Procedural Animation

References

• Kurt Kerbl, Ralph V Claymen, Elspeth McDougall, Louis R Kavoussi; Laparoscopic Nephrectomy: BMJ volume 307,4 December 1993
• Shibley KA. Feasibility of intra-abdominal tissue isolation and extraction within an artificially created pneumoperitoneum, at laparoscopy for gynecologic procedures. JMG 2012;19:S75.

Evaluation Question

• What type of approval process did the FDA require of the pneumoliner?
  • A. 510-K
  • B. 403-B
  • C. De Novo
  • D. PMA
  • E. WD-40
UNANSWERED QUESTIONS

1. What is the incidence of leiomyosarcoma?

Textbook teaching: exceedingly rare, 1:10,000
Now quoting 1:350-1:8,000

FDA review of literature (included 9 of 18 studies)
1:352 risk for any sarcoma
1:498 for leiomyosarcoma

Critiques:
- old data - different definitions of sarcoma
- referral centers
- predominantly retrospective
- ? incomplete evidence base

What is the incidence of leiomyosarcoma?

Pritts et al; Gynecol Surg 2015

- Updated studies
I don't know what the politics are of name ordering! I figured I should be near the end, but the very end seems to be for VIPs... I leave it to you.
No clear answer: incidence of leiomyosarcoma

? somewhere between 1:500 to 1:8,000
(symptomatic patients having surgery)

- Impairs ability to assess screening tests, outcome models

UNANSWERED QUESTIONS

2. Does the route of morcellation matter?

Studies on worsened prognosis with tumor disruption
N\O limited to power morcellation

Include: abdominal and hysteroscopic myomectomy, LAVH, TVH, intraperitoneal scalpel morcellation

Does the route of morcellation matter?

\textit{Cusido et al. JMIG 2015.}

\textgreater 4000 fibroid surgeries; 37 cases of sarcoma
8 cases with morcellation

Median disease free-survival

- No morcellation: 149.9 months
- Vaginal fragmentation: 11.9 months
- Laparoscopic morcellation: 6.3 months

Does the route of morcellation matter?

Uncontained power morcellation \textbf{looks} worse

- Insufficient evidence to compare modalities
- No evidence that \textit{any} uncontained morcellation is safe

UNANSWERED QUESTIONS

3. How much protection do containment systems provide?

Leakage happens

What is the clinical significance?
How much protection do containment systems provide?

Cohen et al. Pilot study, morcellated 500g beef tongue
- Compared multi-port, single port plastic isolation bag, nylon bag
- Blue dye and cytology
- Spill in 1 of 12 trials

- Laparoscopic renal morcellation
  - Pig model, 24 cases
  - LapSac and power morcellation
    - Filled with water, 16% with leak
    - Intact bags - impermeable to bovine serum albumin, indigo carmine, mouse bladder tumor cells

Prospective study
- Contained power morcellation
  - 7 sites in Boston
  - Multi-port approach, varying bags
    - 76 cases
    - No bag tears
    - 7 cases of dye or tissue leakage
    - 9% leakage

Solima et al. JMIG 2015
- 12 TLH, vaginal morcellation
  - Mean uterine weight 370g (range 240, 510)
  - Morcellation time 4-19 min
  - No gross rupture of bag seen
  - 4 bags with leaks upon fill with blue dye
    - 33% leakage

Why does leakage happen?
*Important to understand to improve techniques
- Bag lacerated with knife or morcellator?
- Bag torn during insertion process?
- Bag perforated intentionally?
- Bag material permeable?
- Surgical technique NOS?

How can we test the protective value of containment bags?
- In absence of morcellating known cancer in clinical scenarios…
  - Pelvic Washings studies
  - Other markers?
If leakage occurs, what is the clinical significance?
If perfection not attainable, what is acceptable rate of leakage?

NEXT STEPS
1. Work towards better preoperative identification of occult malignancy

NEXT STEPS
2. Involve patients in decision making
   Patient Centered Outcomes Research
   What degree of risk is tolerated?
   Relative value of various health outcomes

NEXT STEPS
3. Work with industry partners to develop better containment/tissue removal technology

NEXT STEPS
4. Large prospective studies on outcomes with various modes of tissue removal
REFERENCES


CULTURAL AND LINGUISTIC COMPETENCY

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

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

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