Surgical Tutorial 1:
Tissue Extraction

PROGRAM CHAIR
Sarah L. Cohen, MD, MPH

Bernd Bojahr, MD  Steve Yu, MD
Professional Education Information

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.

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

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# Table of Contents

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

Disclosure...................................................................................................................................................... 2

Prevalence of Leiomyosarcoma among 10,731 Laparoscopic Supra-Cervical Hysterectomies  
B. Bojahr ....................................................................................................................................................... 3

Uncontained Morcellation: Rationale and Technique  
S. Yu .............................................................................................................................................................. 6

Contained Morcellation  
S.L. Cohen...................................................................................................................................................... 9

Cultural and Linguistics Competency ........................................................................................................ 14
Surgical Tutorial 1: Tissue Extraction

Sarah L. Cohen, Chair

Faculty: Bernd Bojahr, Steve Yu

The recent controversy concerning the prevalence of leiomyosarcoma (LMS) among women having surgery for presumed uterine fibroids has focused attention on the risks of tissue extraction in women with undiagnosed LMS. Methods for both contained and uncontained morcellation have been developed to reduce intra-peritoneal tumor spread, which might potentially change the patient's prognosis. The prevalence of LMS, derived from a large study, will be presented, and both contained and uncontained morcellation techniques will be illustrated with video.

Learning Objectives: At the conclusion of this course, the participant will be able to: 1) Discuss the prevalence of leiomyosarcoma among women having surgery for presumed uterine fibroids; 2) describe techniques for both contained and uncontained morcellation.

Course Outline

11:00 Welcome, Introductions and Course Overview S.L. Cohen
11:05 Prevalence of Leiomyosarcoma among 10,731 Laparoscopic Supra-Cervical Hysterectomies B. Bojahr
11:20 Uncontained Morcellation: Rationale and Technique S. Yu
11:35 Contained Morcellation S.L. Cohen
11:50 Questions & Answers All Faculty
12:00 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).
Art Arellano, Professional Education Manager, AAGL*
R. Edward Betcher*
Amber Bradshaw
Speakers Bureau: Myriad Genetics Lab
Other: Proctor: Intuitive Surgical
Sarah L. Cohen
Consultant: Olympus
Erica Dun*
Joseph (Jay) L. Hudgens
Contracted Research: Gynesonics
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Suketu Mansuria
Speakers Bureau: Covidien
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Karen C. Wang*
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Kevin J.E. Stepp
Consultant: CONMED Corporation, Teleflex
Stock Ownership: Titan Medical
Karen C. Wang*

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).
Bernd Bojahr*
Sarah L. Cohen
Consultant: Olympus
Steve Yu*
Content Reviewer has no relationships.

Asterisk (*) denotes no financial relationships to disclose.
Prevalence of Leiomyosarcoma among 10 731 Laparoscopic Supra-Cervical Hysterectomies

Objective:
This study aims to evaluate the number of occult uterine malignancies in all LASH surgeries at the MIC clinic (Berlin) and to verify how the operative technique affects the prognosis of the disease. Especially the prevalence of leiomyosarcomas and the results will be analyzed and discussed.

Disclosures:
I have no financial relationships to disclose.

Prof. Bernd Bojahr
Klinik für MIC Minimally Invasive Center
Berlin, Germany

Prevalence of Leiomyosarcoma among 10 731 Laparoscopic Supra-Cervical Hysterectomies

AAGL: Advancing Minimally Invasive Gynecology Worldwide: Statement to the FDA on Power Morcellation
Jubilee Brown
Journal of Minimally Invasive Gynecology, Vol. 21, Issue 6, p870-971
Published online: September 3 2014

• 600 000 hysterectomies each year (MIS 30% - 2002 - 63% - 2012)
• 50 000 - 150 000 annually with morcellation
AAGL: Morcellation is contraindicated in presence of documented or highly suspected malignancy!
(proper preoperative screening guidelines – including endometrial biopsy and cervical cytology)
35-65% of leiomyosarcomas can be detected in this manner
Data insufficient to discontinue power morcellation in appropriately screened patients at low risk.
Leiomyosarcoma - aggressive malignancy / Outcomes are suboptimal with and without morcellation
"Decision Analysis Model" was constructed based on available literature:
Converting all hysterectomies currently performed with morcellation to abd. hysterectomy would result in an increase of 17 more women dying from surgery each year and a substantial morbidity from open surgery.

AAGL: Our obligation is not only to patients with leiomyosarcoma but to all of our patients!
We must not sacrifice the well-being of our patients in response to a rare event!
We should improve but not abandon power morcellation
Power morcellation with appropriate informed consent should remain available to appropriately screened women at low risk!
Malignancy rate of 10,731 uteri morcellated during laparoscopic supravaginal hysterectomy (LASH)
Bernd Bojaehr, Rudy Leon De Wilde, Garri Tchartchian
Arch Gynec Obstet (2015) 292: 665-672

<table>
<thead>
<tr>
<th>indication</th>
<th>patients</th>
<th>%</th>
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<tbody>
<tr>
<td>uterine myoma</td>
<td>8720</td>
<td>81.3</td>
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<tr>
<td>bleeding disorder</td>
<td>1015</td>
<td>9.4</td>
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<tr>
<td>suspicion</td>
<td>361</td>
<td>3.4</td>
</tr>
<tr>
<td>adenomyosis/pain</td>
<td>636</td>
<td>5.8</td>
</tr>
</tbody>
</table>

Malignant uteri, sarcoma, endometrial cancer, or any pelvic malignancies

- The youngest patient with a sarcoma was 43 years old.
- Until today, we did not find a sarcoma during myomectomies.
- 2014: 1,499 operations (LASH, LAVH, Myomectomies, Hysteroscopic Myomresections) – no sarcoma and no atypical myomata

Aim for the future:
- Improvement of Morcellation Technique
- Evaluation of all cases after morcellation of sarcomas
- (Follow up)
- Register for all sarcomas (national/international)?
- Bag Techniques should be investigated for safety and outcomes.

ESGE, AEG, DG DGACOG, AAGL, AUGS, SGO, SKG:
Support further use of morcellation for patients with appropriate informed consent and low risk.
**Recommendation:**
- Abundant lavage at the end of laparoscopy
- Removal of all abdominal remnants of myomas and tissues
- Careful control of the area of operation (incl. middle and upper abdomen)

**Conclusions**

All patients should be informed about the very low incidence of sarcomas during preoperative counseling.

*(FDA 1/350) own datas 1/1788 - 0,06%*

With a timely follow up surgery according to the oncologic guidelines our datas suggest a very good prognosis in terms of survival after LASH with morcellation of malignant tumors in the uterus.

Thank you for your attention!
Uncontained Morcellation: Rationale and Technique

Steve Yu, MD
Assistant Clinical Professor
Department of Obstetrics and Gynecology
David Geffen School of Medicine
University of California, Los Angeles

I have no financial relationships to disclose.

Objectives

• Explain the rationale for uncontained morcellation.

• Demonstrate the techniques of controlled tissue extraction.

Rationale

• Cells are aerosolized during hysterotomy.

• Blood from the myoma/sarcoma spills into the peritoneal cavity during dissection & repair.

• Morcellation in a bag increases O.R. time.

• Morcellation in a bag has its inherent complications.

Dissemination of Cells
**Technique**

- Controlled morcellation
- Extract all visible myoma fragments.
- Copious irrigation

**Sample size:** 20

**Positive washing:** 6

3 samples positive
Pre-morcellation & Post-morcellation

3 samples positive
Post-morcellation

**Sample size:** 5

Washing prior myomectomy
0 positive

Washing after myomectomy
3 positive

**Controlled Morcellation**
Copious Irrigation

References


Sandberg, EM, et al., Disseminated leiomyoma cells can be identified following conventional myomectomy. BJOG (2016); DOI: 10.1111/1471-0528.14265
Surgical Tutorial: Tissue Extraction
Contained Morcellation

Sarah L. Cohen, MD MPH
Director of Research
Division of Minimally Invasive Gynecologic Surgery
Brigham and Women’s Hospital

Disclosures

- Consultant: Olympus

Objectives

- Review options, tips and tricks for contained morcellation
  - Power
  - Vaginal
  - Minilaparotomy

From innovation to possible solution

- KA ‘Tony’ Shibley MD
  - Video at AAGL in 2012 detailing tissue isolation and extraction within artificial pneumoperitoneum
  - Initially developed for use with single-site laparoscopic supracervical hysterectomy

Single port Shibley Video

Contained Power Morcellation


Many follow-up studies demonstrating variations on technique, equipment
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.
Contained Power Morcellation: How long does it take?
- Vargas et al. JMIG. 2015
  - Compared OR time 3 months before and after implementing in bag power morcellation
  - 36 IBM, 49 open morcellation; IBM added 26 minutes to OR time
- Winner et al. Obstet Gynecol. 2015
  - 101 uncontained morcellations, 51 contained between 2012-2015
  - 20 minute increase in OR time

Contained Power Morcellation: Is it safe?
- Cohen et al. AJOG 2015.
  - Prospective study across 7 sites in Boston
  - Multi-port approach, varying bags used
  - Primary outcome: leakage of tissue or blue dye
  - Enrollment goal 400, early stop at 89 patients due to leakage events
  - 7 cases of dye or tissue leakage on post morcellation survey

Surgical equipment catches up
- Paul et al. JMIG 2015.
  - MorSafe Bag, designed with sleeve
  - Rimbach et al. Arch Gynecol Obstet. 2015
    - Optic trocar access with sleeve to protect camera
    - Pig model of 8 cases of LSH
    - 12 mins added OR time
    - Negative peritoneal cytology washings

FDA approved containment bag
- Pneumoliner – images and video
What if I don’t have a power morcellator, or don’t want to use one?

**Vaginal specimen removal:**

- Useful for total hysterectomy cases
- Most efficient with parous patients, adequate pelvic outlet or smaller pathology

**Contained Vaginal Morcellation**

- Insert containment bag of choice
- Based on specimen size, use abdominal wall incision (12-15mm) or colpotomy site
- Place specimen into bag with cervix directed to opening of bag

**Contained Vaginal Morcellation**

- Exteriorize bag at introitus
- May utilize self retaining retractor to facilitate unhindered exposure
- Rocking motion during manual morcellation with scalpel

Video

What if I don’t have a power morcellator, or don’t want to use one?

**Minilaparotomy:**

- Useful for myomectomy, supracervical hysterectomy
- Large specimens (>16-18 wks)

**Contained Minilaparotomy Morcellation**

- Umbilicus or suprapubic, 2.5-5cm
- Tips to extend port at umbilicus
- Insert containment bag of choice
Contained Minilaparotomy Morcellation

- Single port device helpful to allow for return to LSC view
- Place specimen in bag, exteriorize bag at abdominal wall
- 11 blade scalpel, morcellate in strips allowing specimen to roll

Minilaparotomy Technique

Useful Products

- GelPOINT mini (Applied Medical) – single port device useful for minilap morcellation
- Alexis Contained Extraction System (Applied Medical) – bag with stiff trim, 17cm diameter, 6500mL capacity
- Alexis Wound Retractors (Applied Medical) – varying sizes, useful to keep bag orifice open
- LapSac (Cook Medical) – 8x10cm, 1500mL capacity, comes with optional introducer
- EndoCatch (Covidien) – 15mm device with introducer and bag has 12.7cm diameter, 1000mL capacity
- EcoSac Specimen Retrieval Bags (Espiner) – varying sizes, capacity upwards of 2000mL
  - 180 bag is 17x24cm
- Lahey/Containment bag (3M) – thin material, accommodates very large specimens, 50x50cm

In Summary

- Many tissue removal options exist
- Contained extraction via vagina, minilaparotomy or with power morcellation
- Much of the equipment we are currently using for contained morcellation was not created for this purpose
- Further study, technique refinement and work with industry required for continued improvement

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13
CULTURAL AND LINGUISTIC COMPETENCY

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

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

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

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

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

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