SYLLABUS

PLENARY 4:
Hysteroscopy
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.

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

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2. By email or phone to: The Executive Director, Linda Michels, at lmichels@aagl.org or (714) 503-6200.

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For more information or to view the policy please go to:
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Plenary 4: Hysteroscopy

Moderator: Kari M. Plewniak, Kelly H. Roy

Description
This session presents a full spectrum of hysteroscopic topics that will be addressed, including the transurethral removal of perforated intrauterine device, dysmorphic uterus, vNOTES, and post-ablation cavity evaluation.

Objectives
Learning Objectives: At the conclusion of this activity, the participant will be able to: 1) Study the new approaches to common problems that can be addressed by operative hysteroscopy, often in an office setting; and 2) evaluate the results of these interventions.

4:10  EMIG Simulation Systems Construct Validation Trial: Hysteroscopic Component
      Discussant: A.R.P. Panazzolo
      M.G. Munro

4:20  Transurethral Removal of Perforated Intrauterine Device
      Discussant: B. Sanders
      T.M. Lombardi

4:30  Dysmorphic Uterus. Should We Update the Current Classification?
      Discussant: S. Henderson
      J.A. Carugno

4:40  Transvaginal Natural Orifice Transluminal Endoscopic Surgery
      Hysterectomy (vNOTES): A Walkthrough
      Discussant: J.B. Gebhart
      Z. Guan

4:50  A Novel Robotic Endoscopic Device Used for Operative Hysteroscopy
      Discussant: D. Fridman
      L.F.B. Harvey

5:00  Post-ablation Cavity Evaluation: A Prospective, Multicenter, Observational Study to Assess Hysteroscopic Evaluation of the Uterine Cavity in Subjects Who Have Undergone Water Vapor Endometrial Ablation for the Treatment of Heavy Menstrual Bleeding
      Discussant: A.I. Brill
      C.M. Basinski
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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 Director, AAGL*
Linda D. Bradley, Medical Director, AAGL*
Erin T. Carey
Consultant: MedIQ
Mark W. Dassel
Contracted Research: Myovant Sciences
Erica Dun*
Adi Katz*
Linda Michels, Executive Director, AAGL*
Erinn M. Myers
Speakers Bureau: Laborie Medical Technologies, Teleflex Medical
Other: Unrestricted educational grant to support NC FPMRS Fellow Cadaver Lab: Boston Scientific Corp. Inc.
Amy Park*
Grace Phan, Professional Education Specialist, AAGL*
Harold Y. Wu*
Linda C. Yang
Other: Ownership Interest: KLAAS LLC

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Amanda C. Yunke
Consultant: Olympus
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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).
Cindy M. Basinski
Consultant: Aegea Medical, Channel Medical Systems, Inc, Hologic, Inc
Speakers Bureau: Hologic, Inc
Andrew I. Brill
Consultant: AbbVie, Boston Scientific Corp. Inc., Channel Medical, Ethicon Endo-Surgery, Karl Storz, Meditrina
Jose A. Carugno*
Dmitry Fridman*
John B. Gebhart
Royalty: Elsevier, UpToDate
Other: Advisory Board: UroCure
Zhenkun Guan*
Lara F. Harvey*
Stephanie Henderson*
Tresa M. Lombardi*
Malcolm G. Munro
Consultant: AbbVie, Caldera Medical, Hologic
Stock Ownership: Aegea Medical, Channel Medical, Gynesonics
Ana Rita P. Panazzolo*
Kari M. Plewniak*
Kelly H. Roy*
Barry Sanders*

Content Reviewer has nothing to disclose.

Asterisk (*) denotes no financial relationships to disclose.
EMIG Simulation Systems Construct Validation Trial: Hysteroscopic Component
Malcolm G. Munro, MD for the EMIG Steering Committee

Disclosures
Malcolm G. Munro, MD
- Consultant: AbbVie, Caldera Medical, Hologic
- Stock Ownership: Aegea Medical, Channel Medical, Gynesonics

Objective
- Discuss the EMIG manual skills construct validation trial and how the systems show promise as tests of hysteroscopic psychomotor skills at four levels of training and experience.

EMIG Manual Skills Construct Validation Trial: Hysteroscopic Component
A collaboration of: the AAGL CREOG and ACOG
Part of the EMIG Project

Background
EMIG Manual Skills Construct Validation Trial: Hysteroscopic Component
Why EMIG?
- Obstetrics and Gynecology is a surgical specialty
- Novices training on patients not ideal
- Simulation-based surgical education:
  - Protects patients
  - Improves training in a reduced stress environment
  - Higher starting point in the OR
- Formal assessment of procedural skills
  - allows programs and trainees to evaluate progress
Background
EMIG Manual Skills Construct Validation Trial
CREOG Endoscopic Requirements

Edge Objectives

What is expected of the Obstetrics and Gynecology resident?

Background
EMIG Manual Skills Construct Validation Trial
CREOG Endoscopic Requirements to Understand and Perform

Hysteroscopy

- Laparoscopy

Core Procedures

- Hysteroscopy (diagnostic/operative)
- Laparoscopy
- Minimally invasive surgery
- Endoscopic fiber-optic

Expected Performance Levels

- Expert
- Advanced
- Basic
- Novice

Manual Skills

- Laparoscopic suturing
- Laparoscopic clipping
- Laparoscopic dissection

Expected Performance Levels

- Expert
- Advanced
- Basic
- Novice

Laparoscopy

- Hysteroscopy
- Laparoscopic suturing
- Laparoscopic dissection

Expected Performance Levels

- Expert
- Advanced
- Basic
- Novice

Background
EMIG Manual Skills Construct Validation Trial
The State of US and Canadian Endoscopic Training

Per fellowship PDs % First Year Fellows Able to Perform:

- Vaginal Hysterectomy = 20%
- Basic Hysteroscopic Procedures = 34%
- Laparoscopic Hysterectomy = 46%

“These results suggest that general Ob/Gyn residency is ineffective in preparing fellows for advanced training and should prompt a revision of the goals and objectives of resident education to correct these deficiencies.”

Background
EMIG Manual Skills Construct Validation Trial
Why EMIG?

- Current GYN surgical education:
  - Uneven residency training in gynecologic surgery
  - Soft standardized training goals
  - Lack of standardized testing of manual surgical skills specific to Gynecology
- What was needed:
  - Standardized surgical didactic content
  - Standardized testing of surgical skills for obstetrics and gynecology
- When possible surgery should be “minimally invasive”, focusing on achievable endoscopic surgical skills was a reasonable and achievable goal
  - Laparoscopy and laparoscopic surgery for gynecologists
  - Hysteroscopy and hysteroscopic surgery
Background
EMIG Manual Skills Development

- Test definition
- Job task analysis
- Test blueprint survey
- Model search
- Evaluate models
- Develop models
- Study design
- Pilot Validation Trial
- Multicenter Construct Validation Trial
- Data analysis

Background
EMIG Manual Skills Construct Validation Trial EMIG Simulation Systems

- Laparoscopic
  - Uses the FLS Low-Fidelity "Box Trainer"
  - New proprietary "LaparoBowl" insert for testing
  - Capital instruments and most supplies similar to FLS
- Hysteroscopic
  - New proprietary EMIG configurable trainer
  - With or without computerized scoring system
  - Requires hysteroscopic equipment
    - Sheath
    - Hysteroscope
    - Grasping instrument
    - Proprietary targeting instrument

Task H1 Targeting

Required Equipment
- AAGL Hysteroscopic Trainer
- Targeting module
- Targeting probe
- 30° Hysteroscope
- Hysteroscopic sheath with 5 Fr channel
- Light source and fiberoptic cable
- Endoscopic camera
- Video monitor

Task H2 Polyp Removal

Required Equipment
- AAGL Hysteroscopic Trainer
- Polyp removal module
- Polyp cannister with 10 loaded silicone polyps
- 5 Fr grasping forceps
- 30° Hysteroscope
- Hysteroscopic sheath with 5 Fr operating channel
- Light source and fiberoptic cable
- Endoscopic camera
- Video monitor
Hypotheses (Primary Outcomes)

• A manual skills system designed for testing laparoscopic skills for gynecologists will distinguish between novice residents (PGY-1) and those early in their third postgraduate year (PGY-3).

• A manual skills system designed for testing hysteroscopic skills for gynecologists will distinguish between novice residents (PGY-1) and those early in their third postgraduate year (PGY-3).

• A manual skills system designed for testing laparoscopic skills for gynecologic surgeons without fellowship training (Proficient Surgeons) and those who have completed a 2-year FMIGs fellowship (Expert Surgeons).

• A manual skills system designed for testing hysteroscopic skills for gynecologic surgeons without fellowship training (Proficient Surgeons) and those who have completed a 2-year FMIGs fellowship (Expert Surgeons).

Methods
EMIG Manual Skills Construct Validation Trial

Study Design

• Prospective comparative cohort study

• Four cohorts
  - Novice (PGY-1) in first three months of training
  - Mid-level residents (PGY-3) in first three months of training
  - Proficient* (ABOG certified)
  - Expert (2-Year FMIGS)

• Sample size (study psychometricians)
  - Minimum of 30 in each group

• Multi-institutional; Multinational
  - Even geographic distribution throughout US
  - Canadian site (University of Toronto)

* In Canada, FRCSC
Methods
EMIG Manual Skills Construct Validation Trial

Time Window

Limited time window to avoid the confounding of experience

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<th>Mar</th>
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Methods
EMIG Manual Skills Construct Validation Trial

Study Flow

Identification of Candidates (Site FIT)

Excluded
- Wrong category
- Insufficient prior experience
- Excess prior experience

Included
- Voucher and number
- Booked testing date and time

EMIG Study Team Site Visit

1-Hour Orientation
- Video
- Proctor Supervised Simulator Practice

Proctor Supervised Testing
- Laparoscopic (L-1 through L-5)
- Hysteroscopic (H-1 & H-2)

Data Acquisition and Entry
- Field data set
- Control data set
- Third review as necessary

EMIG Study Team visited participating sites for 2-3 days
- Standardisation of proctors
- Standardisation of test administration
- Minimization of bias

Methods
EMIG Manual Skills Construct Validation Trial

Study Sites

Locations

Coordinating Center

Methods
EMIG Manual Skills Construct Validation Trial

Manual Skills Validation Trial Timeline

ACOG IRB Approval

Begin Data Acquisition

End FMIG Data Acquisition

End Data Acquisition

2016-7

2018

2019
EMIG Manual Skills Construct Validation Trial

Hysteroscopy (H1-H2): Completion Times By Task

Results

<table>
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<th>Mean Completion Time (seconds)</th>
<th>SEM</th>
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Results

EMIG Manual Skills Construct Validation Trial

H-1 Accuracy Rates

Discussion

EMIG Manual Skills Construct Validation Trial

• The EMIG Hysteroscopic system and the two modules performed well
• Completion times for each of the hysteroscopic tasks/exercises:
  - Reliably differentiated novices (PGY-1) from mid-level trainees (PGY-3) within 100 days of commencement of their third postgraduate year.
  - Reliably differentiated (FMIGS 2-year) from proficient (ABOG Certified) subjects.
• The “Expert” group with 2-Year FMIGS training performed at superior level to all other candidates
• Accuracy as measured by H-1 and H-2 was not discriminatory
• Further development of the electronic component of the targeting exercise might add fidelity to components of accuracy
• Discriminating skill with more advanced hysteroscopic skills may require evaluation of other EMIG Hysteroscopic Modules.

Study Strengths

• Large sample size
• Multi-institutional, multiregional, binational
• Discrete inclusion criteria
• Rigorous data acquisition methodology and quality assessment

Study Weaknesses

• Potential for selection bias
  - Residents at academic centers with interest in simulation
  - FMIGS attendees at National Meeting
  - Proficient also at academic centers
  - Relatively low level hysteroscopic skills readily learned

Conclusions

EMIG Manual Skills Construct Validation Trial

Hysteroscopic Component
Conclusions
EMIG Manual Skills Construct Validation Trial

- These systems show promise as tests of hysteroscopic psychomotor skills at four levels of training and experience.
- The modules tested measure basic psychomotor skills, and may not be adequate to evaluate skills required for advanced hysteroscopic surgery.
- Further large scale cohort and comparative study will be necessary to determine the generalizability of these conclusions.
Transurethral Removal of Perforated Intrauterine Device

Presenter: Tresa M. Lombardi, MD
Scripps Clinic, San Diego, CA

Video Objective: To describe the management of a perforated IUD into the bladder, with removal of a fractured arm via a transurethral approach.

Setting: 36yo G1P1 with expired ParaGard IUD in place who experienced spontaneous detachment of the IUD strings with attempted removal in the office. Pelvic ultrasound showed evidence of one IUD arm perforating the bladder, which was also confirmed on office cystoscopy. She was scheduled to undergo attempted hysteroscopic IUD removal, but also consented for laparoscopy as she desired a permanent sterilization procedure.

Interventions: Cystoscopy was first performed, confirming one arm of the IUD perforating the bladder dome. Laparoscopy was performed, noting the incidental finding of the second IUD arm perforating the uterine fundus. Adhesions between the fundus, bladder dome, and omentum were noted. Hysteroscopy was performed in attempt to remove the IUD while under laparoscopic guidance. With traction on the IUD body, the IUD was partially removed, but one of the arms was noted to have fractured off. Laparoscopically, it was evident the arm perforating the fundus remained in situ. While attempting to remove the fractured arm via laparoscopy, the arm spontaneously retracted into the myometrium. Bilateral salpingectomy was performed for permanent sterilization. The bladder adhesion was divided and the cystotomy from the perforated arm was repaired. Repeat hysteroscopy was performed but the fractured arm was not visualized. Repeat cystoscopy revealed the fractured arm free within the bladder. The arm was removed transurethrally with a cystoscopic grasper.

Conclusion: When planning surgery to remove a perforated IUD, a surgeon must consider and be prepared to perform multiple approaches for removal in the event of IUD fracture.
Dysmorphic Uterus. Should We Update the Current Classification?

Presenter: Jose Antonio Carugno, MD
Obstetrics, Gynecology and Reproductive Sciences, University of Miami
Pembroke Pines, FL

**Video Objective:** To describe three different subtypes of dysmorphic uteri identified using 3D ultrasound and hysteroscopy.

**Setting:** Endoscopy unit of an assisted fertility center.

**Interventions:** 3D transvaginal ultrasound and diagnostic hysteroscopy.

**Conclusion:** We identified three different subtypes of dysmorphic uterus. The T-shaped uterus, with thick lateral walls with normal uterine fundus and interstitial distance; the Y-shaped uterus, with thick lateral walls, fundal septum or subseptum and reduced interstitial distance; the I-shaped uterus, with very thick lateral walls (even above the isthmus) and severe reduction of the interstitial distance.
Transvaginal Natural Orifice Transluminal Endoscopic Surgery Hysterectomy (vNOTES): A Walkthrough

Presenter: Zhenkun Guan, BS
Gynecology, Third Affiliated Hospital of Guangzhou Medical University
Guangzhou, China

Video Objective: To present a thorough yet concise explanation of the methodology for the completion of a successful transvaginal hysterectomy via natural orifice transluminal endoscopic surgery.

Design: A narrated instructional video guide detailing each procedure (Canadian Task Force Classification III).

Setting: University Hospital, Baylor College of Medicine, Houston, Texas

Patients: Our patient is a 46-year-old G2P1011 who had two notable previous surgeries: a tubal ligation and an adnexa removal surgery. She possessed a narrow vagina and non-descent uterus while having a strong preference for maintaining a high level of cosmesis.

Interventions: A complete transvaginal hysterectomy utilizing solely natural orifice transluminal endoscopic surgery was performed on the patient. Transvaginal entry was established and with the gelpoint mini port in place we began circumferential dissection of the cervix anteriorly at the bladder fold. Utilizing the laparoscopic single tooth tenaculum, we hooked the anterior lip of the cervix for countertraction and hydro dissected the anterior cervix with 20 units of Vasopressin (Pitressin) in 20 ml of saline. Next, the monopolar hook was employed to cut the anterior colpotomy and begin the circumferential incision around the cervix. Following this, we used the LigaSure bipolar forceps to sever bilateral ureteral sacral ligament. The same strategy is used at the anterior cervix to separate the bladder from the uterus. Following bladder mobilization, the cardinal ligaments and uterine arteries were cauterized and transected by LigaSure. The right fallopian tube was removed utilizing the LigaSure first, before proceeding with the left fallopian tube; the pelvis was inspected with hemostasis noted throughout. Finally, the vaginal cuff was closed in traditional vaginal fashion after the deflation of the abdomen.

Conclusion: Despite certain drawbacks, utilizing pure natural orifice transluminal endoscopic surgery in hysterectomy is a safe and feasible procedure that maintains a high-level of cosmesis for patients while still offering the most minimally invasive route.
A Novel Robotic Endoscopic Device Used for Operative Hysteroscopy

Presenter: Lara F.B. Harvey, MD, MPH
Minimally Invasive Gynecology, Vanderbilt University Medical Center
Nashville, TN

**Video Objective:** To trial the use of a novel robotic endoscopic surgery platform for operative hysteroscopy.

**Setting:** A uterine tissue model with simulated polyps in various locations (Gynesim).

**Interventions:** The robotic endoscope is a surgical platform that simultaneously delivers two instruments that are 2-3mm in size using concentric tube technology. These instruments extend from the tip of a standard rigid endoscope outer sheath and are controlled robotically by an operator distant from the surgical field. In this pilot, a probe and monopolar needle were used to resect simulated endometrial polyps. Surgical principles of adequate exposure and traction and counter-traction are demonstrated.

**Conclusion:** The robotic endoscope platform may offer advantages over conventional hysteroscopy that could be useful for some applications. These advantages include: improved exposure, finer dissection capability, and use of two handed technique to allow traction and counter-traction. Further study regarding the safe, efficient, and cost-effective use of the robotic endoscope in gynecology is needed.
Post-ablation Cavity Evaluation: A Prospective, Multicenter, Observational Study to Assess Hysteroscopic Evaluation of the Uterine Cavity in Subjects Who Have Undergone Water Vapor Endometrial Ablation for the Treatment of Heavy Menstrual Bleeding

Cindy Maiden Basinski M.D.
Indiana University School of Medicine
Evansville IN

Disclosures
• Consultant: Aegea Medical, Channel Medical Systems, Inc, Hologic, Inc
• Speakers Bureau: Hologic, Inc

Objective
• Discuss the hysteroscopic evaluation of the uterine cavity in subjects who have undergone water vapor endometrial ablation for the treatment of heavy menstrual bleeding.

Why is Cavity Access Post-ablation Important?
• Diagnostic or therapeutic intervention may be required in cases of:
  • Recurrent Abnormal Uterine Bleeding
  • Menopausal Bleeding
  • Cyclic Pelvic Pain
  • IUD contraception following endometrial ablation

• Challenges accessing cavities post-ablation is well documented in medical literature:
  • Ahonkialo et al1: Following thermal endometrial ablation, endometrial biopsy was not possible in 23%.
  • McCausland et al2: Cyclic pain can be related to scarring, intrauterine adhesions and obstruction to menstrual flow in the presence of regenerated endometrium years following endometrial ablation.
  • Wortman3: 14% of referrals for re-operative hysteroscopy were for unsuccessful attempts at endometrial biopsy

Water Vapor Endometrial Ablation
• 2-minute water vapor treatment as part of office-based 4-minute procedure
• Treats patients traditionally not indicated for endometrial ablation:
  • Cavity lengths from 6 to 12 cm
  • Any uterine width
  • Cavities with certain types of fibroids
  • A history of low-transverse c-section
  • Essure®
• Console
  • Automated water vapor delivery system
  • IntegrityPro™ technology uniquely confirms cavity sealing and proper device placement prior to water vapor delivery
  • Water Vapor Probe
  • Slender, soft, flexible tip
  • Cervical collar aids in device placement just beyond the internal cervical os
  • SmartSeal™ technology provides redundant cervical sealing with its triple balloon sealing system plus cervical thermocouple

PACE Study Overview
• Objective: To perform a diagnostic hysteroscopic exam in subjects >3 years following water vapor endometrial ablation
• N=70 of 125 subjects who had completed 3-year follow-up at 7 international sites in the single-arm pivotal clinical trial that earned FDA-approval4
• Hysteroscopy with standard equipment and technique
• IRB approval/ Subjects consented
• Independent Reviewer of all hysteroscopy videos assessed:
  • The ability to access the endometrial cavity
  • The ability to visualize one or both tubal ostia in cavities accessible
  • The presence and severity of adhesions in the cavities accessed using criteria by March et al
  • The feasibility of performing a Pipelle endometrial biopsy and/or placing an IUD
• Selection bias analysis between those subjects completing 36 month follow-up and those who consented to PACE hysteroscopic exam
PACE Results: Cavity Access and Cornu/Ostium Visualization

<table>
<thead>
<tr>
<th>Access</th>
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<tbody>
<tr>
<td>Cavity Access</td>
<td>90% (63/70)</td>
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<td>Cavity Access with Visualization of Ostia</td>
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<td>Cavity Access with No Visualization of Ostia</td>
<td>21% (13/63)</td>
</tr>
<tr>
<td>No Cavity Access</td>
<td>10% (7/70)</td>
</tr>
</tbody>
</table>

Accessible uterine cavities with visualization of landmarks in the majority of subjects a mean 4 years after water vapor ablation procedure.

PACE Results: Adhesions

<table>
<thead>
<tr>
<th>Adhesions</th>
<th>Subjects N =70</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adhesions Absent</td>
<td>75% (47/63)</td>
</tr>
<tr>
<td>Adhesions Present</td>
<td>25% (16/63)</td>
</tr>
</tbody>
</table>

Characterization of Adhesions

- Minimal: 11% (7/63)
- Moderate: 11% (7/63)
- Severe: 3% (2/63)

Adhesion Evaluation following March Criteria

- Minimal: less than one-fourth of uterine cavity, and thin or filmy adhesions, and minimal adhesions to the serosa.
- Moderate: one-fourth to three-fourths of uterine cavity, no adhesions to the serosa.
- Severe: more than three-fourths of uterine cavity, adhesions to the serosa, or adhesions to the uterine corpus or cervical canal.

Objective Trial Design

- Independent reviewer blinded to details of the endometrial ablation procedure and subject follow-up to eliminate investigator bias in assessment of hysteroscopy videos.
- Selection bias analysis between PACE participants and the remaining subjects who completed 36-month follow-up in the pivotal trial did not indicate clinically meaningful differences between the two populations.

Case Study

- 40 years old
- 4.4 years since endometrial ablation
- Baseline PBLAC 348.2 to 0 at 12 months
- Bleeding status
  - 24 months Amenorrhea
  - 36 months Amenorrhea
- PACE Baseline Light
- Very satisfied through 36 months
- Accessible cavity, adhesions light
- Biopsy and IUD thought feasible

Conclusions

- Long-term cavity access is an important consideration to gynecologists treating patients for heavy menstrual bleeding with endometrial ablation.
- Water vapor endometrial ablation allows for an accessible cavity in the majority of subjects 4 years after water vapor endometrial ablation, with minimal incidence of adhesions observed.
- Long-term cavity access can potentially facilitate ongoing minimally-invasive diagnosis and treatment.
- Further research with prospective comparative trials would be useful to determine if there are differences in long-term healing and cavity access among various endometrial ablation modalities.
References


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• Charles Miller, Naperville, IL
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.

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](http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2078538).