AGL 2022

51st GLOBAL CONGRESS ON MIGS

December 1–4, 2022 | Gaylord Rockies Resort and Convention Center | Aurora, Colorado

SYLLABUS

Surgical Tutorial 4: Alternatives to Hysterectomy in the Treatment of Fibroids

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Minda A. Green, MD*
Bruce B. Lee, MD – Consultant: Hologic

Surgical Tutorial 4: Alternatives to Hysterectomy in the Treatment of Fibroids

Chair: *Sarah L. Rassier Cohen, MD, MPH*

Faculty: *Minda A. Green, MD, and Bruce B. Lee, MD*

Course Description

This surgical tutorial includes dynamic speakers and procedural videos detailing less invasive options for individualized treatment of uterine fibroids. The bulk of this talk will focus on laparoscopic and transcervical radiofrequency ablation procedures for fibroids, including tips for patient selection, patient counseling and efficient operative techniques. We will also discuss rationale for avoiding hysterectomy in various patient scenarios and will review medication and radiologic options for treatment of fibroids. This course will conclude with a slideshow of complex cases inviting audience feedback on the optimal treatment option.

Learning Objectives

At the conclusion of this course, the participant will be able to: 1) Effectively counsel patients on individualized treatment planning for fibroids; 2) Confidently perform radiofrequency ablation procedures in appropriate patients; and 3) Collaborate with colleagues in diagnostic and interventional radiology for care of fibroid patients.

Course Outline

11:30 am	Welcome, Introduction and Course Overview	S.L. Rassier Cohen
11:35 am	Radiofrequency Ablation of Fibroids	M.A. Green
11:50 am	Laparoscopic Radiofrequency Ablation of Fibroids	B.B. Lee
12:05 am	Why Don't We Just Do a Hysterectomy?	S.L. Rassier Cohen
12:20 pm	Questions & Answers	All Faculty
12:30 pm	Adjourn	

Transcervical Fibroid Ablation (TFA) for Symptomatic Uterine Fibroids

MINDA A. GREEN, MD, FACOG
VIRTUA HEALTH
MINIMALLY INVASIVE GYNECOLOGIC SURGERY
VOORHEES, NJ

- I have no financial relationships to disclose.

Sonata Clinical Evidence Summary

5 YEAR OUTCOMES

- **1-, 2-, 3-, and 5-year long-term published clinical outcomes** demonstrating durable and significant reduction in symptoms, with high patient satisfaction and low reintervention rates
- Multiple prospective, multicenter, controlled trials from various stakeholders, including an FDA IDE Pivotal Trial, all showing consistent, sustained, and significant symptom relief

14 STUDIES

- 14 clinical research trials, studies, and sub-studies, including 3 health economic outcomes research studies
- SAGE registry provides real-world data supporting favorable safety profile established in other studies

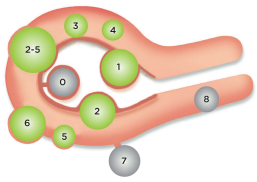
~40 PUBLICATIONS

- Nearly 40 publications, with additional in development
- "Ultrasound-Guided Transcervical Ablation of Uterine Leiomyomas" (12-month results of the Sonata pivotal clinical trial), as published in Obstetrics and Gynecology (the Green Journal), was included among the article choices in 2019 by the American Board of Obstetrics & Gynecology for Maintenance of Certification

3 ECONOMIC STUDIES

- 3 health economic outcomes research studies demonstrate significant cost savings for payers and facilities when utilizing Sonata compared to hysterectomy and myomectomy, including the CHOICES Comparator Trial of TFA with Sonata versus Myomectomy

TFA Treats a Wide Range of Fibroid Types and Sizes



The Sonata System is designed to ablate or partially ablate all non-pedunculated uterine fibroid types in GREEN

FIGO Leiomyoma Subclassification System

OTHER	Submucosal	0	Pedunculated intracavity
		1	<50% Intramural
		2	≥50% Intramural
	Intramural	3	Contacts endometrium; 100% intramural
		4	Intramural
	Subserosal	5	Subserosal, ≥50% intramural
		6	Subserosal, <50% intramural
		7	Subserosal pedunculated
		8	Other (specify e.g. cervical, parasitic)
HYBRID	Transmural	2-5	Submucosal and subserosal, each with less than half the diameter in the endometrial and peritoneal cavities respectively.

Adapted from: Munro MG, Critchley HOD, Fraser IS, FIGO MDC. *Int J Gynaecol Obstet.* 2018;393-406.

Patient selection

- TFA with Sonata can be an appropriate treatment option for any patient who is considering myomectomy and other alternatives to hysterectomy
- Size: **10 cm is a reasonable limit**
  - Need to ablate majority of fibroid: diameter of largest ablation = 4.9 cm
  - 10 cm is general upper limit for UAE, FUS, even LFA
  - Larger fibroids, if significantly treated, would result in large necrotic volume (1L or more) with potential risks
- Number: **up to 10 fibroids is a generally reasonable limit** (time, challenge of tracking ablated fibroids)

Patient selection

- Preferably premenopausal
  - Incidence of uterine sarcoma significantly increases at age 50 and again at age 60
  - New warning in IFU:

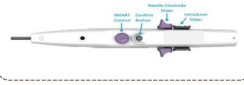
> Added warning
> *Uterine tissue may contain unsuspected malignancy, particularly in patients who are post-menopausal. Insufficient data exist on which to evaluate the safety and effectiveness of Sonata procedure for treatment of cancerous uterine tissue. Thoroughly discuss the benefits and risks of all treatments with patients.*

- Pregnancy
  - Limited data
  - Pregnancies to date:

System Overview

Sonata 2.2 System

- **Sonata 2.1 Next Generation System** CE Mark and FDA Cleared in 2020
- **Sonata 2.2 Next Generation System** Scheduled for 510(k) clearance in Q1 2021
- **New graphic user interface** with simplified and streamlined work-flow
- **Improved visualization with enhanced display graphics and procedure cues** shortens learning curve and enriching user experience



Sonata RFA Handpiece

RFA250 Single Use Cable
Obtained FDA Clearance and CE mark in 1H 2020

RFA250 Phase 2 program on-track - including reusable cable - CE and FDA Clearance scheduled for Q1 2021

Sonata System Technology

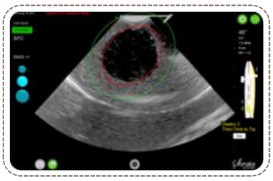
Sonata System Hardware and Software

- No manual measurements - all done graphically
- Scalable ablations up to 4.9 cm x 4.2 cm
- 1 to 7-minute ablation times
- RF generator modulates power (150W) to keep electrode tip temperatures ~105° C

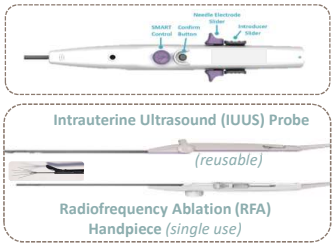
Sonata Treatment Device

- Combines intrauterine ultrasound with delivery of RF energy
- 8.75 mm tip diameter (27 Fr dilatation)

System Components



Graphical user interface for the graphical guidance software (GGS) utilizing the The SMART™ Guide display



Procedure: Pre-treatment

- Draping
- EUA
- Straight cath/Foley
- Place 2 dispersive electrodes
- Dilate cervix: 27 Fr

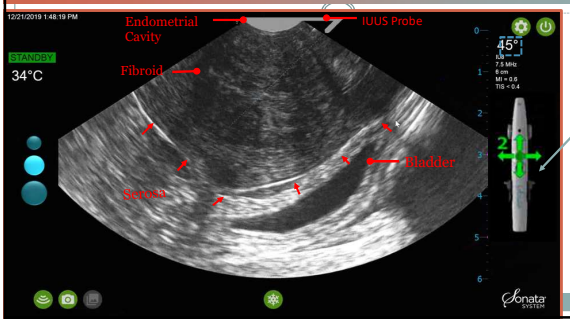
- Assemble treatment device
- Inspection needle electrodes & cables
- Union of RFA handpiece with IUUS probe
- Purge air from device

Procedure: Treatment

- Introduce device into endometrial cavity
- Fibroid mapping: confirm # and location, identify other structures
- Targeting: positioning of SMART Guide

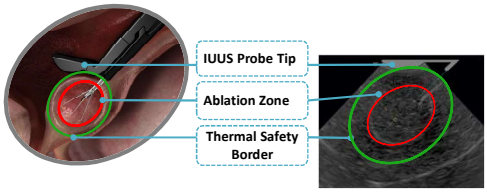
- Deploy introducer & needle electrodes: verify thermal safety border
- Activate & deliver RF energy: monitor temperature, hold device steady
- Careful exam of ablated region

Intrauterine Ultrasound Imaging and Anatomy



Control sequence Indicator on the right side of screen

SMART Guide: Graphical Overlays on Live Ultrasound Image



Ablation Zone: (red inner ellipse)
A graphical representation of the average region of tissue ablation

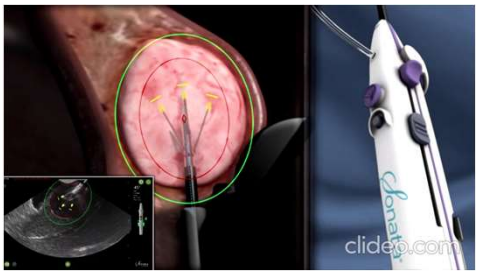
Thermal Safety Border: (green outer ellipse)
The distance at which tissue is safe from potential of thermal damage

Procedure: Post-treatment

- Device removal
- Reverse order of operations

- Remove treatment device
- Remove dispersive electrodes

Sonata Procedure Animation



Patient Profile

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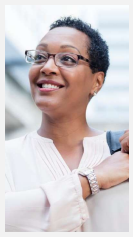
Overview

Name:
Age:
Patient Overview:
Procedure:
Outcome:



SONATA Pivotal IDE Clinical Trial

12-Month Results Demonstrate Safe and Effective Treatment of Symptomatic Uterine Fibroids

1-Year Results

- **99%** Without surgical reintervention for HMB at 12 months
- **97%** Were satisfied with their treatment at 12 months
- **95%** Experienced reduction in menstrual bleeding at 12 months
- **50%** Return to normal activity the next day

Highlights of Patient Outcomes at 12 Months

- 99% free from surgical reintervention (0.7% surgical reintervention rate for heavy menstrual bleeding)
- 95% experienced a reduction in their menstrual bleeding (65% reported ≥50% reduction)
- 97% of women were satisfied with their treatment
- 96% reported symptom improvement
- 98% of women found the procedure tolerable
- 97% of women would recommend the procedure
- Significant improvements in symptom severity and quality of life scores
- Significant improvement in work and activity impairments due to fibroids
- No device-related adverse events
- 50% of women returned to normal activity by the next day

JOURNAL OF GYNECOLOGIC SURGERY
Volume 00, Number 0, 2020
Mary Ann Liebert, Inc.
DOI: 10.1089/gyn.2020.0021

Three-Year Results of the SONATA Pivotal Trial of Transcervical Fibroid Ablation for Symptomatic Uterine Myomata

Andrea Lukes, MD,[1] and Minda A. Green, MD[2]

Abstract

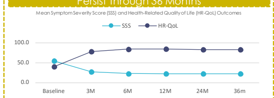
Objective: This article reports on 3-year clinical outcomes of the Sonography Guided Transcervical Ablation of Uterine Fibroids (SONATA) pivotal trial of transcervical fibroid ablation (TFA) in women with symptomatic uterine myomata.
Materials and Methods: The SONATA, prospective, controlled, multicenter interventional trial enrolled 147 premenopausal women with symptomatic uterine fibroids who underwent uterus-preserving, sonography-guided

Results Through 3 Years Demonstrate Significant and Sustained Symptom Relief

Study Overview

OBJECTIVE	To evaluate the 3-year safety and effectiveness of transcervical fibroid ablation (TFA) with the Sonata® System for the treatment of symptomatic uterine leiomyomas
TRIAL DESIGN	• Prospective, controlled, longitudinal, multicenter, single-arm interventional trial • Patients treated on an outpatient basis with follow-up of 3 years
3-YEAR ENDPOINTS	• Surgical reintervention for heavy menstrual bleeding • Treatment satisfaction and symptom improvement • Quality of life and symptom severity measures • Reduction in work and activity impairment • Safety
N=	132 of 147 enrolled patients (90%) were accounted for in 3-year follow-up
CONCLUSIONS	Women treated with TFA in the SONATA Pivotal Trial experienced significant and durable improvement in fibroid-related symptoms with low surgical reintervention rates over 3 years of follow-up

Significant Quality of Life Improvements Persist Through 36 Months



Patient Outcomes

	1 YEAR	2 YEAR	3 YEAR
% of Patients without Surgical Reintervention from HMB	99%	95%	92%
% of Patients Satisfied with their Treatment	97%	94%	94%
% of Patients Reported Symptom Improvement	96%	88%	88%

95% Experienced **reduction in menstrual bleeding** at 12 months

50% **returned to normal activity** the next day

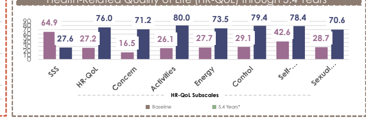
90% of enrolled patients **completed their 3-year follow-up**

VITALITY Clinical Study 5-Year Long-Term Clinical Outcomes

Study Overview

OBJECTIVE	To evaluate the long-term (>5-year) clinical outcomes of transcervical radiofrequency ablation of uterine fibroids (TFA) with the Sonata® System
STUDY DESIGN	Retrospective, single center, single-arm clinical study using patient cohort from FAST-EU Trial
ENDPOINTS	• Surgical reintervention for heavy menstrual bleeding (HMB) • Quality of life measures
N=	17 patients
CONCLUSIONS	TFA with the Sonata System produced substantial durable clinical benefits beyond 5 years with a low surgical reintervention rate

Mean Symptom Severity Score (SSS) and Health-Related Quality of Life (HR-QoL) through 5.4 Years*



Demographics

Patients treated	17
Total number of fibroids originally treated with the Sonata System	35
Mean fibroids / patient	2.4
Mean MP score at baseline	343.8 ± 144.85
Mean follow-up	5.4 years ± 4.5 months

Incidence of Surgical Reintervention for HMB

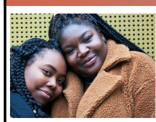
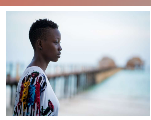
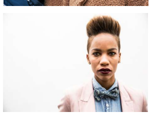
0% reintervention in first 3.5 years

2.2% reintervention rate / year

11.8% cumulative reintervention rate at 5.4 years*

* Average follow-up time of 5.4 years

Disparities in Fibroid Treatment Among Black Women and Other Underserved Populations


- Black women have a higher prevalence of uterine fibroids, with a greater fibroid burden per patient, more severe morbidity and poorer clinical outcomes compared to white women with fibroids[1]
- Black women are more likely than white women to undergo surgical treatment for symptomatic uterine fibroids[2, 3]
- Multiple studies have demonstrated that Black women have a significantly higher rate of hysterectomy, and hysterectomy complications, compared with white women, and this is especially marked in counties with higher socioeconomic status[1, 4–6]
- When undergoing hysterectomy, Black and Latina women may be more likely to have abdominal hysterectomy rather than an outpatient, minimally invasive option[6–9]
- Black women are nearly three times more likely to prefer a uterus-conserving procedure when treating symptomatic fibroids[10]

1. Laughlin-Tommaso SK, Jacoby VL, Myers ER. Disparities in Fibroid Incidence, Prognosis, and Management. *Obstet Gynecol Clin North Am.* 2017;81-94.
2. Baird DD, Dunson DB, Hill MC et al. High cumulative incidence of uterine leiomyoma in black and white women: ultrasound evidence. *Am J Obstet Gynecol.* 2003;100-107.
3. Eltoukhi HM, Modi MN, Weston M et al. The health disparities of uterine fibroid tumors for African American women: a public health issue. *Am J Obstet Gynecol.* 2014;194-199.
4. Gartner DR, Delamater PL, Hummer RA et al. Patterns of black and white hysterectomy incidence among reproductive aged women. *Health Serv Res.* 2021;1-7.
5. Gartner DR, Delamater PL, Hummer RA et al. Integrating Surveillance Data to Estimate Race/Ethnicity-specific Hysterectomy Inequalities Among Reproductive-aged Women: Who's at Risk. *Epidemiology.* 2020;385-392.
6. Katon JG, Bossick AS, Doll KM et al. Contributors to Racial Disparities in Minimally Invasive Hysterectomy in the US Department of Veterans Affairs. *Med Care.* 2019;930-936.
7. Price JT, Zimmerman LD, Koelper NC et al. Social determinants of access to minimally invasive hysterectomy: reevaluating the relationship between race and route of hysterectomy for benign disease. *Am J Obstet Gynecol.* 2017;572.e1-572.e10.
8. Robinson WR, Cheng MM, Howard AG et al. For U.S. Black women, shift of hysterectomy to outpatient settings may have lagged behind White women: a claims-based analysis, 2011-2013. *BMC Health Serv Res.* 2017;526.
9. Callegari LS, Katon JG, Gray KE et al. Associations between Race/Ethnicity, Uterine Fibroids, and Minimally Invasive Hysterectomy in the VA Healthcare System. *Womens Health Issues.* 2019;48-55.
10. Stewart EA, Nicholson WK, Bradley L, Borah BJ. The burden of uterine fibroids for African-American women: results of a national survey. *J Womens Health (Larchmt).* 2013;807-816.

ACOG Practice Bulletin #228 (2021): Management of Symptomatic Uterine Fibroids

- "Radiofrequency ablation (RFA) can be delivered by a laparoscopic, transvaginal, or transcervical approach…All of the approaches are similarly effective…"
- "…RFA is a reasonable option to consider for the treatment of symptomatic uterine leiomyomas…"
- NB: This support comes within two years of commercialization of the Sonata System in the US

ACOG The American College of Obstetricians and Gynecologists

Virtua Health Experience (Southern NJ)

- Approval through outpatient surgery center
- Largest challenge – insurance coverage
  - Gynesonics has a team who provide physician and institution support to help with preauthorization process
- **Always submit**, as many payors are being added on an ongoing basis
- Imaging is very important. Without size and location of the fibroids noted on received paperwork, the insurance companies will automatically deny . Pelvic US or MRI
- Many receive an initial denial, or a Level 1 appeal → a Level 2 appeal → IRO (many are won in 3-5 months)
- Institution-based support: self-funded plan and covers cost of procedure

Virtua Health Experience (Southern NJ)

- First cases: keep it simple
- A larger uterus with multiple fibroids should not be tackled initially
- Can consider doing hysteroscopy to visualize endometrial cavity before and/or after Sonata
  - Can perform resections and other concomitant procedures
- Try to schedule 2 or more cases in one day
- Social media
- Many patients willing to wait

Virtua Health Experience (Southern NJ)

- Began Sept 2021
- Myself and my partner involved in safety trial several years ago – now 5 surgeons performing
- Total number of Sonata cases performed

Anesthesia options - performed with:

- General anesthesia
- Conscious sedation (nearly 50% of patients in the SONATA clinical trial)
- Regional anesthesia (spinal, epidural)
- Multimodal – PO meds and local, paracervical blockade

Postop: Consider NSAIDs prior and after due to procedure

- Narcotics if necessary

Tips & Tricks

- Consider bladder filling – to assist during intraoperative ultrasound
- Misoprostol administration
- Culdocentesis – push fluid in culdesac
- For larger fibroids: will need multiple ablations. If fibroid is difficult to penetrate, make a small ablation – this will soften the surface to improve penetration/engagement
- Most difficult fibroids to ablate are in the lower uterine segment – may need to ablate at 45 degrees

Summary

- Clinical trial results demonstrate TFA is a safe and effective uterus-preserving, incisionless treatment for women with symptomatic uterine fibroids
- Patients report rapid return to normal activity
- Patients realized significant reductions in perfused and total fibroid volume, menstrual bleeding, overall symptoms, and improvements in quality of life
- High patient satisfaction
- Studies demonstrate a low rate of surgical reintervention through 5+ years

Laparoscopic Radiofrequency Ablation of Uterine Fibroids:

AAGL 51st Global Congress
Surgical Tutorial – Alternatives to Hysterectomy for Treatment of Fibroids
December 3, 2022

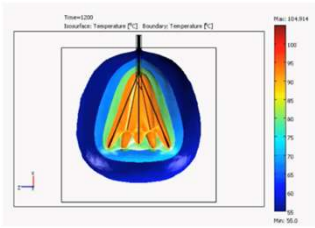
Bruce B. Lee, MD

Agenda

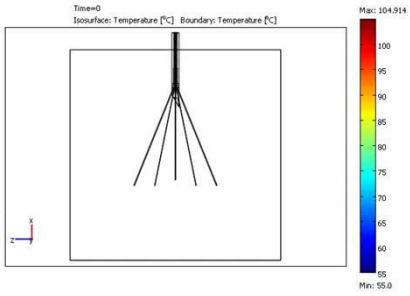
1. What is radiofrequency ablation?
2. What is Acessa?
3. Acessa Pros and Cons
4. Acessa Procedure Basics
5. Tips and General Considerations

Radiofrequency Ablation

- RFA utilizes a low voltage, high frequency (460–500kHz) alternating current transmitted to fibroid tissue through a needle electrode(s). The rapidly alternating current causes intra-cellular ions to oscillate, generating resistive or frictional heating.
- The heat generated then spreads by conduction, falling off rapidly with increasing distance from the electrode (1/d4). The current flows through the body to the electrode dispersive pads and then returns to the generator, closing the loop.
- Cell membranes are lysed and proteins are denatured
- Fibroids are not excised but reabsorbed by the surrounding tissue. The reabsorption may be partial to complete.



Mechanism of Action



Coagulative Necrosis[1]

Cell Death
- Function of temperature and time at a given temperature
- RFA → Hypoxia → Dehydrates Cell & Denatures Proteins & Enzymes
- Innocuous mass (little/no blood flow) reduced by fragmentation & phagocytosis

Human Cells
- 42-46°C for 45 minutes
- 60°C nearly instantaneous
- 100°C H2O vaporization, tissue desiccation/charring

Ablation Volume
- Temperature & duration of time at given temperature
- Needle probe characteristics (size, shape, number of electrodes)
- Target tissue characteristics (heat sinks, scarring, heterogeneity)

Coagulative Necrosis versus Ischemic Necrosis

RF Ablation of Fibroids ≠ "Myolysis"

Myolysis
- Bipolar cauterization of fibroid capsule and myometrium/serosa
  - Uterine ruptures in pregnancy
- Multiple punctures around the periphery of tumors visible by laparoscopy
- No needle guidance or intra-operative myoma imaging

RFVT Ablation:
- Volumetric thermal tissue ablation
- Ultrasound (laparoscopic) guided, all fibroids visible by U/S = Treatable
- Limited to the fibroid, sparing the myometrium

1. Lee BB, Yu SP. Radiofrequency Ablation of Uterine Fibroids: a Review. *Curr Obstet Gynecol Rep*. 2016;5(4):318-324. doi:10.1007/s13669-016-0183-x
Image adapted from SG Chudnoff, et al. Outpatient Procedure for the Treatment and Relief of Symptomatic Uterine Myomas. *Obstetrics and Gynecology*, 2013;121(5):1075–82

What is Acessa?

Evolution of the Acessa Procedure

- Liver Ablation
- Clinical Studies
- Acessa Guidance
- Acessa ProVu—3rd Generation
- 4000+ Cases

FDA Clearance

Granted November 5, 2012

Indications for Use:

- The Acessa System is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic guidance.

Guidance from ACOG PB #228 Supports **RADIOFREQUENCY ABLATION**

Clinical Management Guidelines for OBGYN on Management of Symptomatic Uterine Leiomyomas

- **The guidance concludes that, "Lap-RFA can be considered as a minimally invasive treatment option for the management of symptomatic leiomyomas in patients who desire uterine preservation and are counseled about the limited available data on reproductive outcomes."***
- The practice bulletin highlights two meta-analysis which show Lap-RFA to be effective, clinically proven, and safe.[1,2] It also points out that while all RFA approaches are similarly effective, the laparoscopic approach has been studied the "most rigorously."
- The ACOG bulletin encourages physicians to offer all treatment options to women - and includes Lap-RFA, or the Acessa® procedure, as one of those treatment options.

ACOG

ACOG PRACTICE BULLETIN

Clinical Management Guidelines for Obstetrician–Gynecologists

NUMBER 228 *(Replaces Practice Bulletin Number 96, August 2008)*

Committee on Practice Bulletins—Gynecology. This Practice Bulletin was developed by the ACOG Committee on Practice Bulletins–Gynecology in collaboration with Elizabeth A. Stewart, MD; Marisa R. Adelman, MD; and Vanessa L. Jacoby, MD, MAS.

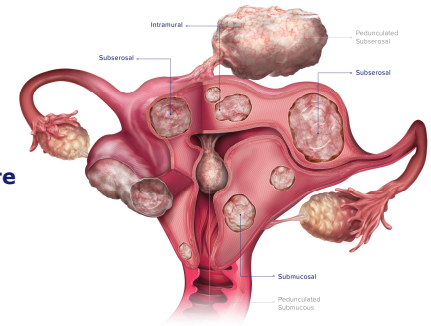
Management of Symptomatic Uterine Leiomyomas

- While hysterectomy is no doubt an effective form of treating uterine fibroids, ACOG notes that "many patients benefit from and seek out management options other than hysterectomy…". The practice bulletin also states that, "goals of treatment should be defined for each patient." Thus, a hysterectomy could be considered unsuccessful if it doesn't align with the patient's goals.
- ACOG's recognition of Lap-RFA treatment as an alternative to hysterectomy or myomectomy expands knowledge of and access to this important evidence based minimally invasive uterine fibroid solution.

*Note: Insufficient data exists on which to evaluate the safety and effectiveness of the Acessa procedure in women who plan future pregnancy. Therefore, the Acessa procedure is not recommended for women who are planning future pregnancy.

1. Bradley LD, Pasic RP, Miller LE. Clinical performance of radiofrequency ablation for treatment of uterine fibroids: systematic review and meta-analysis of prospective studies. *J Laparoendosc Adv Surg Tech A* 2016;26:1107. (Systematic Review & Meta-Analysis) 2. Lin L, Ma H, Wang J, Guan H, Yang M, Tong Z, et al. Quality of life, adverse events, and reintervention outcomes after laparoscopic radiofrequency ablation for symptomatic uterine fibroids: a meta-analysis. *J Minim Invasive Gynecol* 2016;24:409-16. (Systematic Review & Meta-Analysis)

"What types of fibroids can the Acessa procedure treat?"



Symptom Relief Timeline

Suggestions based on physician working group experience, observational data, as well as clinical studies

Time after Lap-RFA	Normal to experience[2]	What to do[2]
First Month	Menstrual cramping may be normal, less, or greater	Use magnesium, non-steroidal anti-inflammatories
	Menstrual bleeding decreases in 1–3 months	Heating pad/hot water bottle
	Pressure symptoms improve	
	Urinary frequency decreases	Use pads for protection
1–3 months[2]	Menstrual bleeding decrease (duration and heaviness)	
	Uterine size decrease becomes noticeable	
	Urinary frequency/retention resolves	
	Pressure symptoms decrease substantially	
	Increase in energy	
3–6 months[3]	Abdominal distension decreases substantially	Follow-up ultrasound at 3, 6, 12 months[3]
	Pressure symptoms resolve	
6 months +	Uterine size may continue to decrease	

Note: This information based on physician feedback and observations. This chart is not intended to be representation of single study or clinical data.

Source:
1. SG Chudnoff, et al. Outpatient Procedure for the Treatment and Relief of Symptomatic Uterine Myomas. Obstetrics and Gynecology, 2013;121(5):1075-82.
2. Physician Working group
3. Jay M. Berman, MD, Richard S. Gurdo, MD, Joel Gerardo Garza Leal, MD, Rodolfo Robles Pemueller, MD, Fredrick S. Whaley, PhD, Scott G. Chudnoff, MD, MS, Three years' outcome from the Halt trial: a prospective analysis of radiofrequency volumetric thermal ablation of myomas, *The Journal of Minimally Invasive Gynecology* 2014; 21(5):787.

Acessa Pros

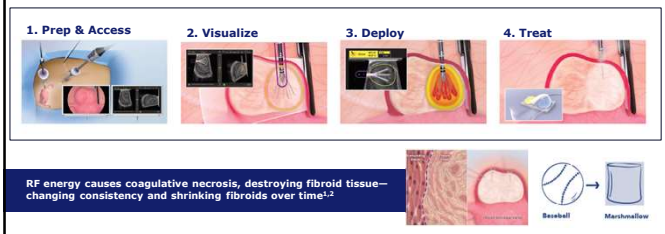
- Safe
- Efficacious
- Outpatient
- Minimally Invasive
- Minimal blood loss
- Low re-intervention rate
- High Patient Satisfaction
- Durable results
- Rapid Recovery
- Minimal postop pain
- Detects more fibroids
- Treats most fibroid types
- Treats fibroids in most locations (cervical, broad Lig)
- No laparoscopic suturing required
- Cosmetic (two trocar +one needle insertion sites)
- Uterine sparing GYN procedure

Acessa Cons

- Requires ultrasound proficiency
- Learning curve
- Volume reduction with Large myomas
- Can be lengthy in cases with many/very large myomas

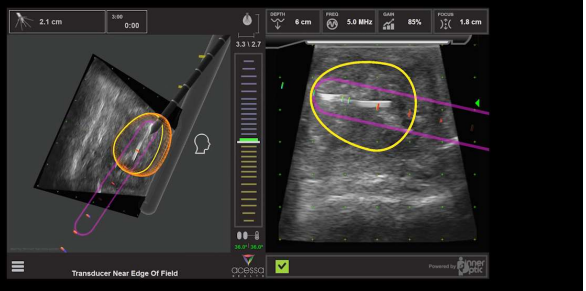
The Acessa Procedure

Procedure Steps



RF energy causes coagulative necrosis, destroying fibroid tissue—changing consistency and shrinking fibroids over time[1,2]

1. Leppert PC, Jayes FL, Segars JH. The extracellular matrix contributes to mechanotransduction in uterine fi broids. *Obstet Gynecol Int.* 2014;2014:783289. doi: 10.1155/2014/783289
2. Lee BB, Yu SP. Radiofrequency Ablation of Uterine Fibroids: a Review. Curr Obstet Gynecol Rep. 2016;5(4):318-324. doi: 10.1007/s13669-016-0183-x 3. SG Chudnoff, et al. Outpatient Procedure for the Treatment and Relief of Symptomatic Uterine Myomas. *Obstetrics and Gynecology*, 2013;121(5):1075–82



Acessa – Learning Curve

Initial Users

- Understand RFA and the various ablation shapes
- ** Learn/practice laparoscopic ultrasound (models + intraoperatively)
- Use Acessa 3-D Guidance
- Case selection
- Setting outcome expectations
- Thorough preoperative evaluation
- Instrument placement (midline)
  - Cephalad – laparoscope
  - Caudal – Laparoscopic ultrasound transducer
  - In between - Acessa Handpiece
- Treatment expectations (complete is ideal but may not be realistic initially)

Intermediate Users

- Focus on fibroid periphery (even smaller myomas)
- Check temperatures to confirm ablation margins
- Learn techniques for FIGO 3 and submucosal myomas
- Learn techniques for medium to large myomas
- Become adept at identifying and treating sub-1 cm myomas
- Combination cases (myomectomy + Acessa)
- Appreciate the myoma shape in all dimensions
- Learn techniques to "fit" ablations within irregularly shaped myomas
- Improve preoperative evaluation to better reflect intraoperative findings

Advanced Users

- Become comfortable with very large/numerous myomas
- Become comfortable treating fibroids in very large uteri (>20 weeks)
- Cervical/broad ligament myomas
- Cases with numerous "back-to-back myomas"
- Cases with significant adhesions/endometriosis
- Patients who desire pregnancy/fertility
  - FIGO 3, submucosal myomas

Acessa
Surgical Recommendations

Surgical Recommendations

- Select patients with pathology appropriate to your skill level and experience
- Be as thorough as possible
- Treat the fibroid periphery
- Always confirm appropriate needle placement by scanning in all 3 planes before beginning an ablation
- Treat systematically by region
- Adjust uterine position to optimize fibroid accessibility whenever possible
- Check temperatures to determine/confirm extent of ablations
- Keep uterus in a "home position" when treating medium and large myomas
- Safety first

Advanced Case Videos

To be added

Thank you !

Why don't we just do a hysterectomy?

Sarah L. (Cohen) Rassier MD, MPH
Director of Fibroid Clinic, Mayo Clinic Rochester MN

Disclosure

I have no financial relationships to disclose

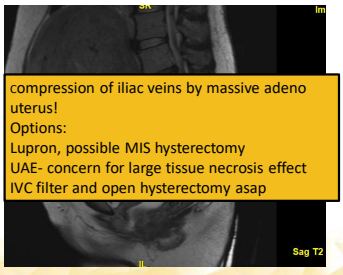
Objectives

- Review data on hysterectomy-associated comorbidity
- Understand patient selection and counseling for fibroid treatments
- Recommend optimal treatment choice for various patient scenarios

To Hyst, or not to Hyst

- 400-600,000 hysterectomies annually in US*
- Overall well tolerated especially when minimally invasive approach
- A great treatment for many benign conditions!

40 y/o presents with cardiac arrest due to massive PE, 28 wk uterus



compression of iliac veins by massive adeno uterus!
Options:
Lupron, possible MIS hysterectomy
UAE- concern for large tissue necrosis effect
IVC filter and open hysterectomy asap

Why not hysterectomy?

- Uterus as purely reproductive organ?
- Associations demonstrated between hysterectomy (ovary-sparing) and:
  - cardiovascular disease
  - metabolic disorders
  - depression
  - pelvic floor dysfunction
  - earlier menopause
  - osteoporosis

Why not hysterectomy?

Caveats:

1) association does not mean causation

2) many studies have substantial limitations
   - short f/u, homogenous populations, variable degrees of accounting for confounding factors or confirmation of medical conditions

ORIGINAL ARTICLES

Cardiovascular and metabolic morbidity after hysterectomy with ovarian conservation: a cohort study

Laughlin-Tommaso, Shannon K. MD, MPH[1,2]; Khan, Zaraq MBBS[3]; Weaver, Amy L. MS[3]; Smith, Carin Y. BS[3]; Rocca, Walter A. MD, MPH[3,4,5]; Stewart, Elizabeth A. MD[2,3,7]

Author Information

Menopause: May 2018 - Volume 25 - Issue 5 - p 483-492
doi: 10.1097/GME.0000000000001043

- 2,094 women who underwent benign ovary-sparing hysterectomy
- Age-matched (±1 y) to a referent woman, 22 years median follow-up
- Increased *de novo* risk of hyperlipidemia, hypertension, obesity, cardiac arrhythmias & coronary artery disease
- Hysterectomy ≤35 years old had a 4.6-fold increased risk of congestive heart failure and a 2.5-fold increased risk of coronary artery disease

Biologic plausibility?

- Elevated baseline risk?
- Unknown endocrine function of uterus?
- Decreasing ovarian reserve?

Unanswered questions

- At what age do hysterectomy-associated risks begin to accumulate?
- How much to baseline medical factors/lifestyle mitigate this risk?
- Who should really be getting a hysterectomy??

Treatment Options

MEDICATIONS

INTERVENTIONS

EXTIRPATIVE SURGERY

What are patient goals?

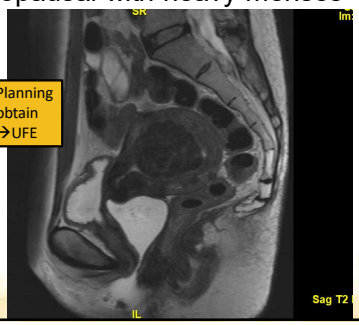
- Which symptoms are most bothersome?
- Interest in future pregnancy?
- Desire to retain uterus
  - Cultural?
  - Long-term health outcomes?
- Size, number and location of fibroids?

SUMMARY OF FIBROID INTERVENTIONS

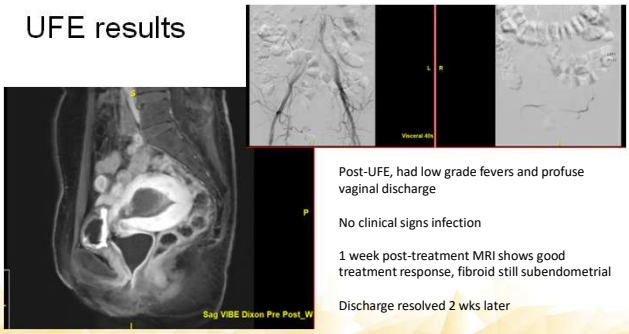
UAE	FUS	LSC RFA	VAG RFA
Longest experience	→	→	Newest
Can treat variety Best results <10cm	Better for <8cm fibroids		
1 week recovery	1-2 day recovery	1-2 week recovery	1-2 day recovery
1 night hospitalization		Requires LSC surgery and GETA	
30-50% volume decrease	30% volume decrease	50-70% volume decrease	50-70% volume decrease
All with lack of indication for use in patients desiring pregnancy, but promising outcomes			

Perimenopausal with heavy menses

4cm type 2 fibroid- Planning TC RFA, but did not obtain insurance approval →UFE



UFE results



Post-UFE, had low grade fevers and profuse vaginal discharge

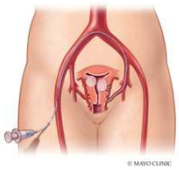
No clinical signs infection

1 week post-treatment MRI shows good treatment response, fibroid still subendometrial

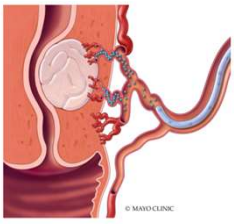
Discharge resolved 2 wks later

Uterine Artery Embolization

- Can treat wide variety of fibroids
  - Less efficacy if >10cm
  - Not ideal for large Type 0/1
- 1 night hospital stay for pain control
- Post embolization syndrome
- 1-2 week recovery
- Progressive improvement over 3-6 months



UFE OUTCOMES



- >80% improvement in bleeding
- 30%-50% volume reduction*
- Risk of non-target embolization (effect on ovarian reserve) similar to hysterectomy
- Risk of abnormal placentation in future pregnancies

Gupta JK, Cochrane Database Syst Rev. 2014

Reintervention risk: UAE vs MMY

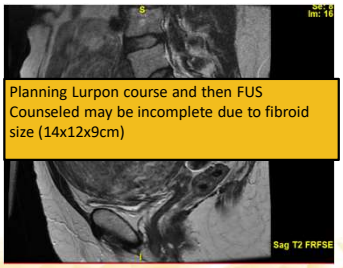
- Comparable quality of life, symptom and sexual function scores
- Similar ovarian function and pregnancy loss
- Lower pregnancy rates (2.2x)
- 14-20% reintervention within 5 years
  - For comparison, myomectomy had 12-15% reintervention in similar studies

Sandberg et al, Fertil Steril. 2018;109(4):698-707
Cope et al, J Minim Invasive Gynecol. 2021; 28(3):442-452

Slide 14

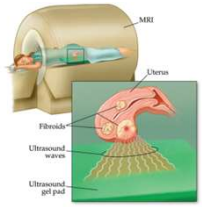
SC0 Sir to find additional case
Sarah Cohen, 2022-09-21T02:08:48.957

43 y/o heavy prolonged bleeding, wants quickest recovery, did not tolerate GnRH antag



Planning Lurpon course and then FUS
Counseled may be incomplete due to fibroid size (14x12x9cm)

Focused Ultrasound Surgery



- Treatment time depends on fibroid burden
- <1 week recovery
- Very low complication rates
  - Abdominal wall inflammation
  - Subcutaneous edema
- More difficult for insurance coverage

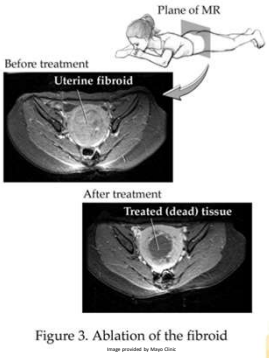


Figure 3. Ablation of the fibroid

- Ideal candidate: single T2 dark fibroid 4-7cm
  - Can treat multiple fibroids
  - Can move bowel to access posterior fibroids
  - Lower size limit 2cm
  - Upper limit is fundus at umbilicus
  - Can't treat peripherally calcified fibroids
  - Avoid hypercellular fibroids
  - Limited in patients with extensive abdominal wall scarring

FUS OUTCOMES

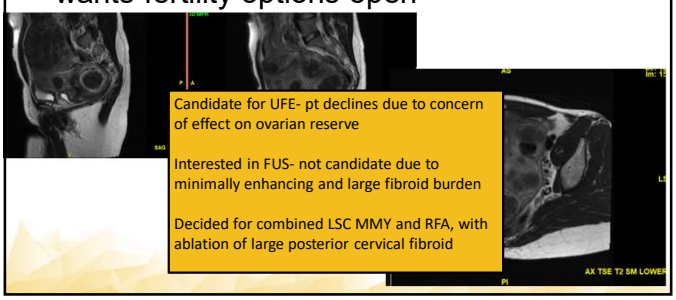
- 30% of fibroid volume decrease over 6 months
- Promising data on future pregnancy
- Similar sexual function scores as MMY
- Reintervention risk varies widely in literature
  - Some quote similar to MMY, some as high as 50% at 5 years
  - At high volume centers, approx. 25% at 5 yrs

Verpalen IM, Eur J Radiol. 2019 Mohr-Sasson A, Am J Obstet Gynecol. 2018

SHARED DECISION MAKING

- What is the best option for patient's goals?
- How to counsel patient non-paternalistically?
- "What would you do, Doc?"

41 y/o with bulk and bleeding symptoms, wants fertility options open



Candidate for UFE- pt declines due to concern of effect on ovarian reserve

Interested in FUS- not candidate due to minimally enhancing and large fibroid burden

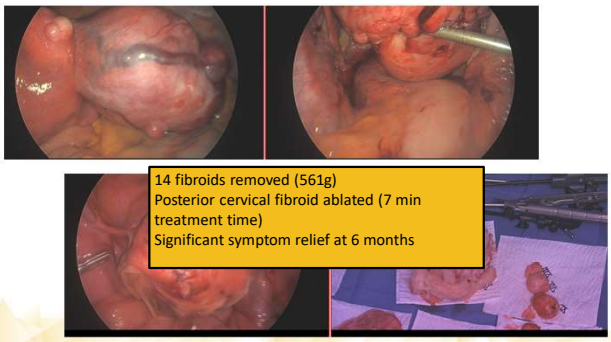
Decided for combined LSC MMY and RFA, with ablation of large posterior cervical fibroid

Slide 19

SC0 SLR to find additional case
Sarah Cohen, 2022-09-21T02:09:01.810

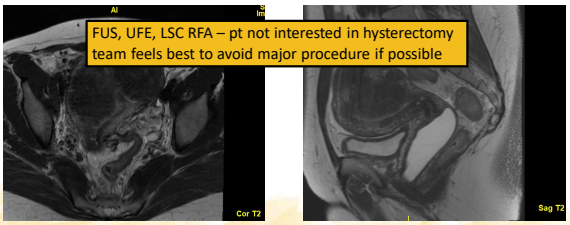
Slide 24

SC0 Update following case scenarios and add new ones
Sarah Cohen, 2022-09-21T02:12:13.910



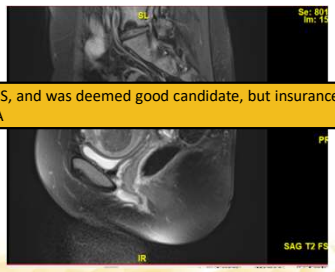
14 fibroids removed (561g)
Posterior cervical fibroid ablated (7 min treatment time)
Significant symptom relief at 6 months

Perimenopausal, bleeding and bulk; malignant HTN, prior intracranial hemorrhage and DVT



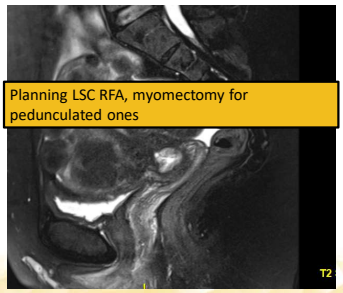
FUS, UFE, LSC RFA – pt not interested in hysterectomy team feels best to avoid major procedure if possible

41 y/o with heavy bleeding, not responsive to hormonal suppression, very active job



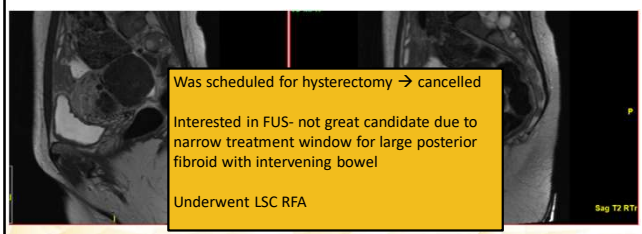
Patient wanted FUS, and was deemed good candidate, but insurance did not approve
Underwent TC-RFA

45 y/o with primarily bulk symptoms



Planning LSC RFA, myomectomy for pedunculated ones

47 y/o with pain and rectal pressure

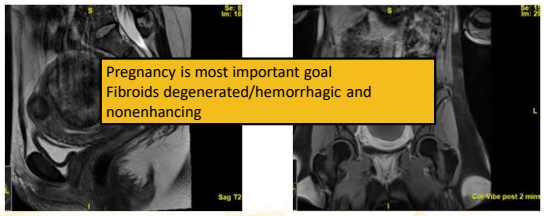


Was scheduled for hysterectomy → cancelled

Interested in FUS- not great candidate due to narrow treatment window for large posterior fibroid with intervening bowel

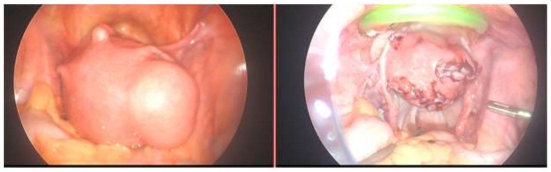
Underwent LSC RFA

34 y/o G4P0 with recent 16 wk loss

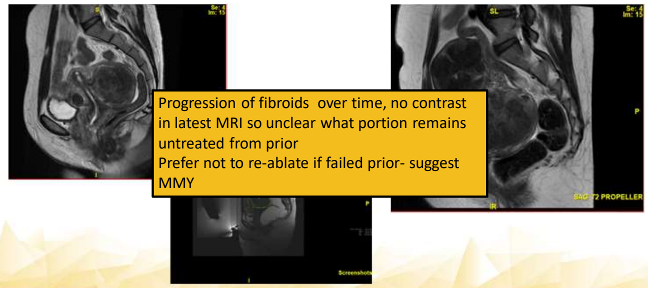


Pregnancy is most important goal
Fibroids degenerated/hemorrhagic and nonenhancing

Underwent LSC Myomectomy



46 y/o desiring fertility, prior FUS



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CULTURAL AND LINGUISTIC COMPETENCY & IMPLICIT BIAS

The California Medical Association (CMA) announced new standards for Cultural Linguistic Competency and Implicit Bias in CME. The goal of the standards is to support the role of accredited CME in advancing diversity, health equity, and inclusion in healthcare. These standards are relevant to ACCME-accredited, CMA-accredited, and jointly accredited providers located in California. AAGL is ACCME-accredited and headquartered in California.

CMA developed the standards in response to California legislation (Business and Professions (B&P) Code Section 2190.1), which directs CMA to draft a set of standards for the inclusion of cultural and linguistic competency (CLC) and implicit bias (IB) in accredited CME.

The standards are intended to support CME providers in meeting the expectations of the legislation. CME provider organizations physically located in California and accredited by CMA CME or ACCME, as well as jointly accredited providers whose target audience includes physicians, are expected to meet these expectations beginning January 1, 2022. AAGL has been proactively adopting processes that meet and often exceed the required expectations of the legislation.

CMA CME offers a variety of resources and tools to help providers meet the standards and successfully incorporate CLC & IB into their CME activities, including FAQ, definitions, a planning worksheet, and best practices. These resources are available on the CLC and IB standards page on the CMA website.

Important Definitions:

Cultural and Linguistic Competency (CLC) – The ability and readiness of health care providers and organizations to humbly and respectfully demonstrate, effectively communicate, and tailor delivery of care to patients with diverse values, beliefs, identities and behaviors, in order to meet social, cultural and linguistic needs as they relate to patient health.

Implicit Bias (IB) – The attitudes, stereotypes and feelings, either positive or negative, that affect our understanding, actions and decisions without conscious knowledge or control. Implicit bias is a universal phenomenon. When negative, implicit bias often contributes to unequal treatment and disparities in diagnosis, treatment decisions, levels of care and health care outcomes of people based on race, ethnicity, gender identity, sexual orientation, age, disability and other characteristics.

Diversity – Having many different forms, types or ideas; showing variety. Demographic diversity can mean a group composed of people of different genders, races/ethnicities, cultures, religions, physical abilities, sexual orientations or preferences, ages, etc.

Direct links to AB1195 (CLC), AB241 (IB), and the B&P Code 2190.1:

Bill Text – AB-1195 Continuing education: cultural and linguistic competency.
Bill Text – AB-241 Implicit bias: continuing education: requirements.
Business and Professions (B&P) Code Section 2190.1

CLC & IB Online Resources:

Diversity-Wheel-as-used-at-Johns-Hopkins-University-12.png (850×839) (researchgate.net)
Cultural Competence In Health and Human Services | NPIN (cdc.gov)
Cultural Competency – The Office of Minority Health (hhs.gov)
Implicit Bias, Microaggressions, and Stereotypes Resources | NEA
Unconscious Bias Resources | diversity.ucsf.edu
Act, Communicating, Implicit Bias (racialequitytools.org)
https://kirwaninstitute.osu.edu/implicit-bias-training
https://www.uptodate.com/contents/racial-and-ethnic-disparities-in-obstetric-and-gynecologic-care-and-role-of-implicitbiases
https://www.contemporaryobgyn.net/view/overcoming-racism-and-unconscious-bias-in-ob-gyn
https://pubmed.ncbi.nlm.nih.gov/34016820/