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Post-Market Safety of Laparoscopic Ultrasound-Guided Radiofrequency Ablation

Steve Yu, MD, Kaylen Silverberg, MD, Bala Bhagavath, MD, S. Abbas Shobeiri, MD, Anthony Propst, MD, David Eisenstein, MD

ABSTRACT

Background and Objectives: Postoperative safety outcomes with laparoscopic intra-abdominal ultrasound-guided radiofrequency ablation, as performed by gynecologic surgeons new to the procedure, were evaluated and compared to the premarket, pivotal study. Post-procedure feedback from surgeons was reported.

Methods: This was a post-market, prospective, single-arm analysis with 4 to 8 weeks follow-up among surgeons (n = 29) with varying levels of laparoscopic surgery experience participating in the ongoing, multinational Treatment Results of Uterine Sparing Technologies randomized clinical trial. Patients were premenopausal adult women (n = 110) desiring uterine-conserving treatment for symptomatic fibroids. During run-in, surgeons received proctored training. Following training, and after performing ≥ 2 procedures, surgeons provided self-assessment and feedback using a standardized form.

Results: Surgeons performed 105 procedures with 100 per-protocol patients. The average number of proctored cases per surgeon was 2.48. No acute (≤ 48 hours) serious adverse events occurred (0/101, 0.0%) compared with 2 acute serious adverse events in the premarket study (2/137, 1.46%). Both studies reported 1 near-term (~30 days) serious adverse event (< 1% for both). In this study, the near-term complication was fever of unknown origin requiring hospitalization related to uterine entry/manipulation. This was categorized as probably device-related; the patient was treated with antibiotics and discharged. Twenty-six surgeons completed the evaluation form; none reported experiencing problems with the procedure.

Conclusion: Minimally invasive gynecologic surgeons can learn laparoscopic intraabdominal ultrasound-guided radiofrequency ablation and perform it safely (in terms of acute and near-term serious adverse events) after ≥ 2 proctored cases. There were no significant differences in safety outcomes compared to the premarket, pivotal study.

Key Words: Fibroids, Gynecology, Intraabdominal, Myoma, Surgery.

INTRODUCTION

Symptomatic uterine fibroids pose a significant societal and healthcare burden.[1] Each year, nearly 1% of U.S. women seek treatment for these benign, solid tumors.[2] In November 2012, the U.S. Food and Drug Administration (FDA) approved percutaneous, laparoscopic intra-abdominal ultrasound-guided radiofrequency ablation (Lap-RFA; Acessa Health, Inc., Austin, TX) for the treatment of symptomatic uterine fibroids.[3] Lap-RFA is a uterine-sparing,

Department of OB/GYN, David Geffen School of Medicine, University of California – Los Angeles, Los Angeles, CA (Dr Yu).

Texas Fertility Center, Austin, TX (Drs Silverberg and Propst).

Department of OB/GYN, University of Rochester, Rochester, NY (Dr Bhagavath).

Department of Gynecology, INOVA Health Care, Falls Church, VA (Dr Shobeiri).

Department of OB/GYN, Henry Ford Medical Center, Troy, MI (Dr Eisenstein).

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Address correspondence to: Dr. David Eisenstein, Henry Ford Hospital, 2825 Livernois, Troy, MI, 48083, USA, Telephone: 248-661-7381, Fax: 248-528-2299, E-mail: DEISENS1@hfhs.org

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minimally invasive treatment that can be used in outpatient or inpatient settings to treat intramural, transmural, subserosal, and submucosal fibroids.[4,5] In a pivotal prospective, multicenter clinical trial (n = 137), Lap-RFA effectively decreased fibroid symptom severity, reduced menstrual blood loss, and enhanced health-related quality of life at 3 months post-treatment, with benefits sustained at 36 months.[6,7] Since approval, > 3000 Lap-RFA procedures have been performed, primarily in the U.S. and Canada.[4]

In June 2013, the FDA noted that standard gynecologic training does not include laparoscopic ultrasound instruction. Laparoscopic ultrasound is an integral part of the Lap-RFA procedure, and failure to appropriately evaluate real-time images of the radiofrequency probe (including the tip and electrode needles) could result in patient injury.[8] To ensure that the post-market Lap-RFA training program was as robust as the training provided during the pivotal trial, this study compares the rate of acute and near-term serious adverse events (SAEs) in patients receiving Lap-RFA for symptomatic uterine fibroids versus identical SAE outcomes in the pivotal (premarket) study.

MATERIALS AND METHODS

This was a post-market, prospective, single-arm, multicenter analysis of acute and near-term safety outcomes over 4 to 8 weeks following Lap-RFA of symptomatic fibroids in premenopausal women, performed by minimally invasive gynecologic surgeons new to Lap-RFA. The study was developed in accordance with FDA post-market surveillance requirements[8] and took place at 14 clinical sites (community and university hospitals) across the U.S. and Canada between February 2014 and October 2017.

In addition to FDA approval of the protocol, consent form, and case report forms, sites obtained prior local institutional review board approval for the ongoing Treatment Results of Uterine Sparing Technologies (TRUST) randomized controlled trial protocol, in which the present study was nested. TRUST is a registered clinical trial in the U.S. (NCT02163525) and Canada (NCT01563783). The study was carried out according to the general ethical principles described in the Declaration of Helsinki and FDA regulations concerning the rights and welfare of human subjects in medical research.

Participating surgeons were a subset of minimally invasive gynecologic surgeons who learned the Lap-RFA procedure during the run-in (training/prerandomization) phase of TRUST. Surgeons were employed at TRUST study sites ranging from ambulatory surgery centers to large university hospitals, had basic laparoscopic and ultrasound training, were comfortable performing laparoscopic surgery, and had minimal to no prior experience with Lap-RFA.

All enrolled women were part of the TRUST study and subject to that trial's inclusion/exclusion criteria.[9–11] Participants were aged ≥ 18 years, menstruating, with symptomatic uterine fibroids ≤ 10 cm in greatest diameter (as assessed with transvaginal ultrasound), and desiring uterine-sparing fibroid treatment. Total allowable uterine volume was ≤ 16 gestational weeks (determined by pelvic examination). Women were required to have a normal Papanicolaou test and no untreated cervical dysplasia or malignancy within the past 36 months. Women were excluded if they: were contraindicated for laparoscopic surgery and/or general anesthesia; were at high risk for, or known to have, significant intra-abdominal adhesion; required major elective concomitant procedures; were pregnant or lactating; used any depot gonadotropin-releasing hormone agonist within 3 months of screening; had an implanted fallopian tube or intrauterine contraceptive device not removed within 10 days of treatment; had chronic pelvic pain known to not be caused by uterine fibroids; had or were suspected of having adenomyosis (as suggested in ultrasound or magnetic resonance images) or stage 3 or 4 endometriosis; had a history (within 5 years) or evidence of gynecologic malignancy or premalignancy; underwent previous pelvic radiation; or, had cervical fibroid(s), ≥ 1 completely intracavitary fibroid (type 0), or only type 0/1 submucosal fibroids.

Surgeons were oriented to the Lap-RFA system and procedure in a sequential, 3-step training model. First, surgeons received didactic instruction, including the principles of laparoscopic ultrasound, procedural concepts, specific techniques, and practical steps. Next, surgeons practiced using intra-abdominal ultrasound and Lap-RFA in a simulated laboratory environment. The final step was the actual performance of operative cases under the observation of a trained proctor, until both surgeon and proctor felt the surgeon was competent and comfortable performing the procedure unsupervised.

Percutaneous Lap-RFA of fibroids was performed on an outpatient basis using a disposable 3.4 mm probe coupled to a dual-function monopolar radiofrequency generator. The device has been previously described in detail (**Figure 1**).[6] For the procedure, patients were supine, and a laparoscope was introduced through a 5 or 10 mm umbilical trocar (based on the surgeon's standard practice). Using a laparoscopic

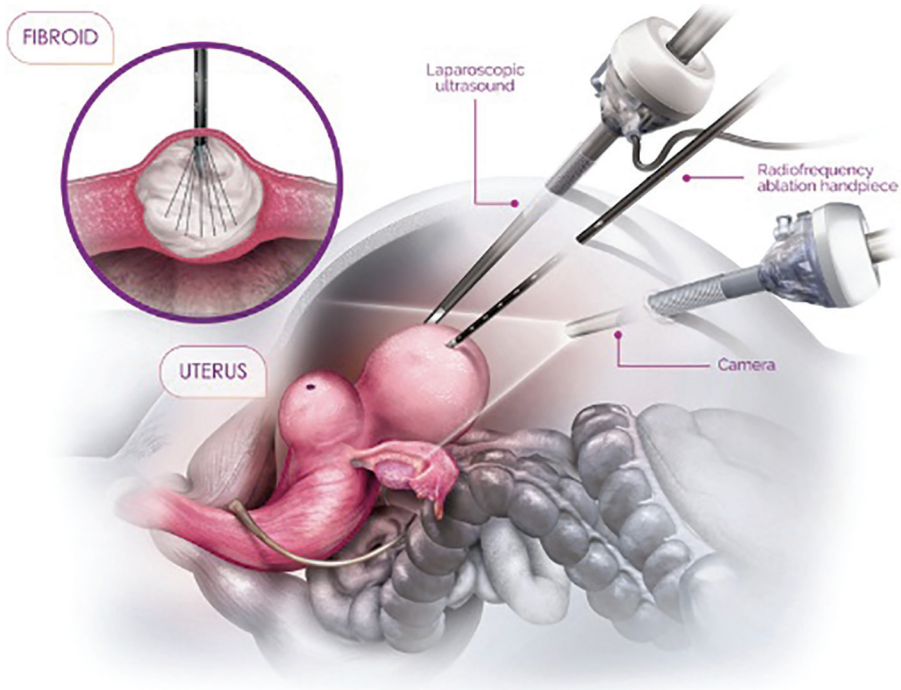

Figure 1. The acessa Laparoscopic Intra-abdominal Ultrasound-guided Radiofrequency Ablation Procedure.

ultrasound transducer (placed through a standard 10 or 12 mm suprapubic trocar), the surgeon identified the size, location, and number of all fibroids. Under laparoscopic ultrasound guidance, the handpiece was inserted percutaneously and advanced into the first target fibroid. Dependent on fibroid size and shape, the electrode array was deployed according to a proprietary treatment algorithm;[12] deployment of the needle array was not required for myomas < 1.5 cm in diameter. If deployed, the array's correct position within the fibroid capsule was verified with 3-dimensional ultrasound transducer, and then the surgeon initiated ablation. A current delivered via the electrode tip and array (if deployed) was used to ablate the targeted and localized fibroid tissue. Continuous real-time temperature feedback was provided on the generator screen via a thermocouple in each electrode needle in the array. Large, temperature-monitored, dispersive pads, placed on the patient's thighs, were used to safely disperse electrical current. For larger or irregularly-shaped fibroids, the needle array was retracted, the probe repositioned within the same fibroid under ultrasound guidance, and the ablation repeated. When required, overlapping ablations were performed (**Figure 2**). After each fibroid was fully treated, the surgeon withdrew the probe from the fibroid with concurrent monopolar coagulation of the probe track and confirmed hemostasis. Depending on fibroid size and location, multiple fibroids could be ablated using a single serosal puncture.[6]

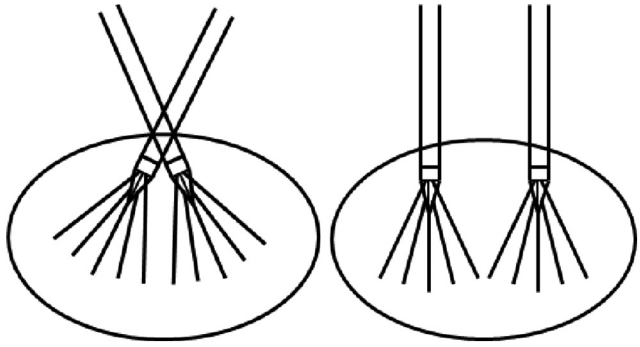

Figure 2. Graphic demonstrating two methods of producing overlapping ablations in oval or irregular fibroids.

After treatment was completed, the trocar fascial and skin sites were repaired according to standard surgical practice. No serosal or myometrial suturing was required. Postoperatively, patients were followed for safety and recovery at 48 hours (window 24 – 72 hours), 1 week (window 5 – 12 days), and 30 days (window 4 – 8 weeks).

The primary study endpoint was the overall rate of acute and near-term SAEs in all evaluated Lap-RFA patients,

Site: _____ **Surgeon:** _____ **Today's Date:** _____
Print Site Name — Print Surgeon's Name — DD/MM/YY

Description of Product: ACESSA RADIOFREQUENCY VOLUMETRIC THERMAL ABLATION
Intended Use of Product: Percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance.

Place a check mark in appropriate column below:

	0–5	6–15	>15	Comments (optional)
1. Years of postgraduate laparoscopic surgery experience (excluding years in residency or fellowship):				
	1–3	**4–6**	**7–10**	**>10**
2. Number of Acessa procedures performed to date				
Factors affecting the efficiency of the procedure:	**Superior/better than expected**	**Average/acceptable/ as expected**	**Inferior/needs improvement**	**Comments (optional)**
3. Ability to view Acessa probe and electrode tips on the laparoscopic ultrasound image				
4. Ability to assess distance between the Handpiece tip/electrode tips and fibroid capsule				
5. Need for assistant to handle instrumentation				
6. Overall Ease of use				

7. Were there any problems experienced with the Acessa procedure? __No __Yes
If yes, please explain: _____
8. Do you have any suggestions for improving the Acessa procedure? __No __Yes
If yes, please explain: _____

Figure 3. Laparoscopic Intra-abdominal Ultrasound-guided Radiofrequency Ablation Procedure, Surgeon Evaluation Form.

compared to the rate of acute and near-term SAEs of Lap-RFA patients in the pivotal study.[6] In both studies, acute and near-term SAEs were ultimately defined as occurring ≤ 48 hours or between 2 and 30 days post-procedure. Serious complications were categorized as related to anesthesia, abdominal entry, or uterine entry/uterine manipulation. SAEs were further categorized as anticipated or unanticipated, and the relationship of the event to the device was determined (either related or unrelated). All complications were reviewed and adjudicated by an independent Clinical Events Committee (CEC). Secondary endpoints included per-surgeon incidence of serious complications during training.

Surgeons also assessed their training and performance using the Acessa™ Procedure Evaluation Form (**Figure 3**). Surgeons completed these feedback forms regarding Lap-RFA training once they had performed ≥ 2 surgical cases.

The sample size was calculated using the SAE rate from the pivotal study, which was considered successful from a safety perspective if the device-related adverse event (AE) rate within 12 months post-procedure did not exceed 10% (regardless of seriousness). The device-related AE rate in the pivotal study was 3.8% (5/135), and the upper limit of the 95% confidence interval (CI) was 8.4%.[6] Of these device-related AEs, 4 occurred within 30 days post-procedure and 1 AE occurred 33 days post-procedure.[4] Therefore, it was reasonable to assume that a device-related AE would occur within 30 days post-procedure. In the TRUST study, the device-related AE rate observed within 30 days post-procedure was considered comparable to the rate observed in the pivotal study if the exact upper limit of the 95% CI did not exceed 10%. Based on this, 100 subjects were required to achieve an adequate sample size for both the acute and near-term time points.

For both acute and near-term SAEs, the null hypothesis was that the rate for the Lap-RFA procedure would be no different than the observed rate in the pivotal study, while the alternative hypothesis was that acute or near-term SAE complication rates were different. Setting a 2-sided alpha level to 0.05 and the sample size to 100, the power to detect a difference in the acute SAE rate was at least 0.80 if the true acute SAE rate was at least 6.7%.

Descriptive statistics and exploratory analyses (conducted using SAS v9.3 [SAS Institute, Cary, NC, USA]) were employed to describe patient outcomes and surgeon feedback.

Preliminary results were published in 2016;[9] below, we report complete results through September 2017.

RESULTS

A total of 29 practicing minimally invasive gynecologic surgeons were recruited to treat 110 subjects; 5 subjects withdrew or were withdrawn prior to treatment, leaving 105 subjects treated per protocol, of which 72 were proctored cases. A total of 101 and 104 subjects completed the

48-hour and 30-day follow-up visits, respectively; 100 completed both study visits. Mean (SD) follow-up time to the last visit was 40.0 (13.8) days.

Based on background data obtained from 26/29 surgeons, and excluding laparoscopic experience gained during residency or fellowship, participating surgeons provided the following information: 4 (15.4%) had 0 – 5 years of post-graduate laparoscopic surgery experience, 8 (30.8%) had 6 – 15 years of experience, and 14 (53.8%) had >15 years of experience. The mean number of proctored cases per surgeon was 2.48. In terms of patients, mean (SD) age was 40.5 (6.9) years, and 41.0% and 37.1% were Caucasian and Black, respectively (Table 1).

Table 2 provides a summary of the incidence of overall (primary endpoint) and per-surgeon (secondary endpoint) acute and near-term serious complications. There were no acute SAEs and only 1 near-term SAE (1/105, 0.95%). This event was a patient readmitted on post-operative day 3 with fever and tachycardia. During her four-day hospitalization, she received parenteral antibiotics, imaging and blood cultures were negative, and she was discharged on seven-day regimen of oral antibiotics. Review by the CEC determined this SAE to be "related to uterine entry/manipulation/treatment, anticipated, and probably device-related." A documentation review of the lot history of the specific device used did not indicate any manufacturing or sterilization-related cause.

Table 3 summarizes SAEs observed in both the premarket and post-market studies. In the premarket, pivotal study, there were 2 acute SAEs (2/137, 1.46%)[6] compared to no acute SAEs in the current post-market study (0/105, 0.0%). Both studies reported 1 serious complication in near-term follow up (~30 days), for a rate of < 1% in each study.

There were two other non-serious complications in the current study: a small laceration of the uterine serosa during manipulation and a laceration of adhesions that required suturing for hemostasis. No transfusions or overnight observation were required.

A total of 26 (89.7%) surgeons completed evaluation forms after performing ≥ 2 procedures. At the time the form was completed, 19 (73.1%) had performed ≤ 6 procedures and 7 (26.9%) had performed ≥ 7 procedures. Table 4 provides a summary of surgeon feedback from the Surgeon Evaluation Form. No surgeons reported experiencing any problems with the procedure. Two surgeons indicated that a factor affecting the efficiency of the procedure was inferior or needed improvement: the ability to view the Lap-RFA probe and electrode tips on the laparoscopic ultrasound image.

Table 1.
Baseline Patient Characteristics

Variable	n = 105
Age (years)	
Mean (SD)	40.5 (6.88)
Median	40.0
Min	21
Max	54
BMI	
Mean (SD)	28.9
Median	29.1
Min	22.4
Max	40.0
Ethnicity	
Caucasian	43 (41.0%)
Chinese	2 (1.9%)
Korean	1 (1.0%)
Black	39 (37.1%)
Latin American	4 (3.8%)
Japanese	0 (0.0%)
Filipino	3 (2.9%)
Aboriginal	2 (1.9%)
South Asian	2 (1.9%)
SE Asian	0 (0.0%)
West Asian	0 (0.0%)
Other	9 (8.6%)

DISCUSSION

In the present study, the acute and near-term serious complication rate among premenopausal women receiving Lap-RFA for symptomatic fibroids was low (0% and 0.96%, respectively) and not different from that observed in the pivotal study (1.46% and 0.73%, respectively). Thus, both null hypotheses, positing no difference between the acute and near-term serious complication rates for the Lap-RFA procedure compared with that observed in the pivotal study, are accepted. Similarly, the incidence of SAEs per surgeon during proctored training and post-training was low (3.4%). As these procedures were primarily performed by surgeons new to Lap-RFA, these results indicate that the

Table 2.
Overall Summary of Serious Complications[1] Related to Patient Safety, Timing of Serious Complications, and Incidence by Surgeons Trained

Category	Number (%)
Patients reporting ≥ 1 serious complication (subsets below)	1/105 (0.95%)
≥ 1 serious anesthesia-related complication	0/105 (0.0%)
≥ 1 serious abdominal entry related complication	0/105 (0.0%)
≥ 1 serious uterine-related complication	1/105 (0.95%)
Rate of acute serious complications (occurring < 48 hours post-procedure)	0/101 (0.0%)[2]
Rate of near-term serious complications (occurring > 48 hours to ≤ 30 days post-procedure)	1/104 (0.96%)[2]

[1]Serious complications are serious adverse events that are treatment related, i.e., anesthesia, abdominal entry, or uterine entry, manipulation, or treatment during the procedure.
[2]Percentages are based on the number of subjects who participated in that follow-up visit.

Table 3.
Serious Events with Laparoscopic Intra-abdominal Ultrasound-guided Radiofrequency Ablation Procedure Compared: Premarket vs Post-market Data (Primary Endpoint)[4,6]

Serious Events/Complications Related To Device Or Procedure	Pivotal Study, Safety Group (n = 137)			Post-market Study, Safety Group (n = 105)		
	N	Event	Rate	N	Event	Rate
Acute/48 h (window 24 – 72 h)						
Related to anesthesia	1	Atelectasis	0.73%	0	N/A	0%
Related to abdominal entry during procedure	0	N/A	0%	0	N/A	0%
Related to uterine entry/ manipulation/treatment	1	Colon laceration	0.73%	0	N/A	0%
Near-term/30 d (window 4 – 8 weeks)						
Related to anesthesia	0	N/A	0%	0	N/A	0%
Related to abdominal entry during procedure	0	N/A	0%	0	N/A	0%
Related to uterine entry/ manipulation/treatment	1	Pelvic abscess	0.73%	1	Fever of unknown origin	0.9-5%

post-market surgeon training model was adequately robust and that minimally invasive gynecologic surgeons can perform the Lap-RFA procedure safely with low complication rates after ≥ 2 proctored cases.

Surgeons also provided overall positive feedback on the procedure using the Acessa™ Procedure Evaluation Form. A majority (61.5% – 73.1%) found the Lap-RFA system functioned as expected, while 26.9% – 42.3% indicated the system exceeded their expectations. Only 7.7% reported that the system needed improvement. In particular, these surgeons were concerned about their ability to view the probe and electrode tips on the laparoscopic ultrasound image. In response to this feedback, the Acessa System was upgraded to include built-in electromagnetic guidance (ProVu™ System) that enhances the image, provides a trajectory for tip placement, and outlines the projected treatment volume.

New technologies may pose an increased risk to patients when first introduced to the market, unless manufacturers provide adequate training.[13] It is incumbent on manufacturers to ensure that their training programs are as robust in the post-market setting as they are in premarket clinical trials. The FDA also cites several unavoidable disadvantages to studying medical products in the premarket clinical phase, such as the size or narrowness of the population studied.[14] In the Lap-RFA pivotal study, for example, the population was limited to women with moderate to severe menstrual blood loss, ≤ 6 fibroids per subject,

Table 4.
Summary of Surgeon Feedback from the Acessa™ Procedure Evaluation Form

Factors affecting the efficiency of the procedure	Superior/Better than expected	Average/acceptable/ as expected Number of Surgeons (n = 26)*	Inferior/Needs Improvement
Ability to view probe and electrode tips on the laparoscopic ultrasound image	7	17	2
Ability to assess distance between the handpiece tip/electrode tips and fibroid capsule	7	19	0
Need for assistant to handle instrumentation	11	16	0
Overall ease of use	7	19	0

*Three surgeons, all from the same site, did not complete the forms as requested.

and with fibroids only ≤ 7 cm in diameter. In this post-market surveillance study of the Lap-RFA system and procedure, the population size was similar, but was expanded to include women with more and larger fibroids and lower levels of menstrual bleeding, making it more representative of the commercial population.

This study has several strengths and weaknesses. Strengths include: a large and diverse group of gynecologic surgeons in terms of post-graduate laparoscopic experience; the use of a Lap-RFA surgical training method consistent with training procedures defined in the literature; and, a relatively large sample in terms of patient location, clinical history, and range of symptoms.[15,16] This patient population more accurately reflects the commercial population than did participants in the premarket trial.[6] The primary limitation of this safety study is a lack of long-term patient follow-up for treatment efficacy, although this was not the study goal. However, long-term data on randomized patients in the TRUST study will be provided in the future.[10,11] Additionally, it would have been ideal to collect more case data per surgeon, but the focus of this study was to determine patient safety and surgeon confidence after training (usually consisting of two or three cases).

CONCLUSION

The acute and near-term safety results from this post-market surgeon training surveillance study are comparable to those of the premarket, pivotal trial, indicating that the Lap-RFA training model contributes to successful skill acquisition and performance of Lap-RFA, and that this procedure can be safely adopted by minimally invasive gynecologic surgeons after 2 proctored cases. Results of the ongoing, post-market TRUST study will provide more information on long-term, device-related events.

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