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Original Article

Laparoscopic Radiofrequency Ablation of Uterine Leiomyomas: Clinical Outcomes during Early Adoption into Surgical Practice

Vanessa L. Jacoby, MD, MAS, Ram Parvataneni, MD, MPH, Erica Oberman, MD, Naghmeh Salamat Saberi, MD, Shira Varon, MD, Michael Schembri, BS, and L. Elaine Waetjen, MD

From the Department of Obstetrics, Gynecology, and Reproductive Sciences, University of California San Francisco, San Francisco, California (Dr. Jacoby and M. Schembri), Department of Obstetrics and Gynecology, University of California Los Angeles, Los Angeles, California (Drs. Parvataneni and Oberman), Department of Obstetrics and Gynecology, University of California Irvine, Irvine, California (Dr. Salamat Saberi), Department of Obstetrics and Gynecology, University of California San Diego, La Jolla, California (Dr. Varon), Department of Obstetrics and Gynecology, University of California Davis, Davis, California (Dr. Waetjen), and University of California Fibroid Network (Drs. Jacoby, Parvataneni, Oberman, Varon, Schembri, and Waetjen)

ABSTRACT **Study Objective:** To assess surgical outcomes, clinical effectiveness, and gynecologist experience of introducing laparoscopic radiofrequency ablation (RFA) of leiomyomas into surgical practice.

Design: Uncontrolled clinical trial.

Setting: Five academic medical centers across California.

Patients: Premenopausal women with symptomatic uterine leiomyomas, uterus size ≤16 weeks size, and all leiomyomas ≤10 cm with no more than 6 total leiomyomas.

Interventions: Laparoscopic RFA of leiomyomas.

Measurements and Main Results: We assessed intraoperative complications, blood loss, operative time, and adverse events. Gynecologists reported the operative difficulty and need for further training after each case. Participants reported leiomyoma symptoms preoperatively and at 6 and 12 weeks after surgery. We analyzed all outcome data from the first case performed by gynecologists with no previous RFA experience. Patient demand for RFA was high, but poor insurance authorization prevented 74% of eligible women from trial participation; 26 women underwent surgery and were enrolled. The mean age of the participants was 41.5 ± 4.9 years. The mean operating time was 153 ± 51 minutes, and mean estimated blood loss was 24 ± 40 cc. There were no intraoperative complications and no major adverse events. Menstrual bleeding, sexual function, and quality of life symptoms improved significantly from baseline to 12 weeks, with a 25 ± 18-point, or 47%, decrease in the Leiomyoma Symptom Severity Score. After the first procedure, the mean difficulty score was 6 (95% confidence interval [CI], 4−7.5) on a 10-point scale, and 89% of surgeons felt "very or somewhat" confident in performing laparoscopic RFA. The difficulty score decreased to 4.25 (95% CI, 1.2−6) after the fourth procedure, with all gynecologists reporting surgical confidence.

Conclusion: Laparoscopic RFA of leiomyomas can be introduced into surgical practice with good clinical outcomes for patients. Gynecologists with no previous experience are able to gain confidence and skill with the procedure in fewer than 5 cases. Journal of Minimally Invasive Gynecology (2020) 27, 915−925. © 2019 Published by Elsevier Inc. on behalf of AAGL.

Keywords: Leiomyomas; Laparoscopy; Radiofrequency ablation

Uterine leiomyomas occur in up to 80% of premenopausal women and are the most common indication for major gynecologic surgery in the United States. The estimated annual cost of care for women with leiomyomas is $34 billion, with 50% of the cost related to lost work and disability related to surgical hospitalization and recovery time [1]. Many women with leiomyomas seek new minimally invasive uterine-sparing treatments with rapid recovery and durable symptom relief, which may decrease the

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Corresponding author: Vanessa L. Jacoby, MD, MAS, Department of Obstetrics, Gynecology, and Reproductive Sciences, University of California San Francisco, 550 16th Street, San Francisco, CA 94158

E-mail: Vanessa.Jacoby@ucsf.edu

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cost and prolonged disability associated with traditional leiomyoma surgeries.

Laparoscopic radiofrequency ablation (RFA) of leiomyomas is an outpatient, uterine- preserving, minimally invasive surgery that aims to improve leiomyoma symptoms with minimal operative risks and short recovery time. The pivotal trial of RFA to gain Federal Drug Administration (FDA) device approval enrolled 134 women and demonstrated significant improvement in leiomyoma-related symptoms and a decrease in leiomyoma volume; 11% of patients underwent additional leiomyoma surgery at 3 years of follow-up [2].

Although the device for RFA of leiomyomas was approved by the FDA in November 2012, lack of coverage among major insurance carriers limited the use of this procedure during the initial years of market availability. However, in January 2017, RFA was assigned a Current Procedural Terminology code by the American Medical Association, which has increased coverage authorization by commercial payers and allowed greater uptake of RFA into gynecologic surgical practice. Therefore, there is an urgent need to understand the learning curve, surgical outcomes, and clinical effectiveness of RFA during the startup phase of gynecologic surgeons adopting this new leiomyoma treatment into clinical practice.

Materials and Methods

The Uterine Leiomyoma Treatment with Radiofrequency Ablation (ULTRA) trial is an investigator-initiated single-arm clinical trial of laparoscopic RFA of uterine leiomyomas. Women were recruited from September 1, 2013, through December 31, 2015 from 5 academic medical center sites across California within the University of California (UC) health system: UC Davis, UC San Francisco, UC Los Angeles, UC Irvine, and UC San Diego. The general public was also targeted for recruitment through social media campaigns, newspaper ads, and publicly posted flyers. The study was registered on ClinicalTrials.gov (identifier NCT01840124) on April 25, 2013, and was approved for all UC sites by the UC San Francisco Institutional Review Board (IRB no. 13-11026; approval date: May 2, 2013). All participants provided written informed consent for study enrollment. An independent Data and Safety Monitoring Board (DSMB) composed of 2 gynecologists and 1 biostatistician not employed by the UC system approved the study protocol and met every 6 months to assess patient safety and data quality.

Women were eligible to participate who were 21 years or older, premenopausal (at least 1 period in the last 3 months), and seeking uterine-sparing surgical treatment of leiomyomas for heavy bleeding, pelvic pressure or discomfort, urinary or bowel symptoms, or dyspareunia. Eligible participants had to have undergone a pelvic exam and imaging with ultrasound or magnetic resonance imaging within the last year to assess leiomyoma characteristics. We defined a leiomyoma as any mass $\geq$2 cm on pelvic imaging consistent with the typical appearance of a uterine leiomyoma. Women were included who had a uterus $\leq$16 weeks in size, all leiomyomas $\leq$10 cm in maximum diameter, and no more than 6 leiomyomas. Eligible participants had to have a negative pregnancy test, normal cervical cancer screening result within the previous 3 years, and, for those age >45 with heavy or irregular bleeding, normal endometrial biopsy findings. We excluded women who were planning treatment for infertility, had the need for a concomitant surgical procedure (e.g., hernia repair or cystectomy), had a pelvic infection within the last 3 months, or had a history of pelvic malignancy or radiation or any implantable metallic device. We also excluded women with a high suspicion for dense pelvic adhesions and any surgical or procedural treatment for leiomyomas within the last 3 months, as well as women with leiomyoma characteristics not amenable to laparoscopic RFA treatment: pedunculated leiomyomas with a stalk <25% of the maximum leiomyoma diameter, intracavitary leiomyoma (FIGO type 0), or a sole submucosal leiomyoma $\geq$50% intracavitary (FIGO type 1). Women who desired future fertility were included in the trial after being informed by their physician that the treatment is not FDA-approved for women who desire future pregnancy, and that there are insufficient data to determine the impact of treatment on fertility and pregnancy outcomes. The consent form also listed a possible increase in the risk of adverse pregnancy outcomes, including miscarriage, placental abnormalities, uterine rupture, and fetal demise. The treating physician also discussed the risks and benefits of all other leiomyoma treatment options, including all medical and procedural therapies available at their clinical site.

At the time of study enrollment, laparoscopic RFA of leiomyomas was a new procedure with unknown coverage among commercial insurance companies. Therefore, after all women interested in laparoscopic RFA were screened for eligibility and counseled about the risks and benefits of surgery and the availability of other leiomyoma treatments, we sent a request for surgery preauthorization to their insurance carrier. If coverage was denied, we presented interested women with the opportunity to undergo an appeal process with their insurance carrier. If authorization for coverage was received, surgery was scheduled, and the patient completed informed consent and was enrolled in the study.

The laparoscopic RFA procedures were performed at each site by an attending gynecologist with assistance from a resident physician. The 7 treating gynecologic surgeons underwent a 1-day didactic and surgical simulation training course provided by the RFA device manufacturer. For the first 5 procedures performed by each gynecologist, a physician trainer and a device technician were present in the operating room to answer questions and provide guidance, but they did not scrub into the cases. There were no run-in procedures for the trial; we collected data on safety and

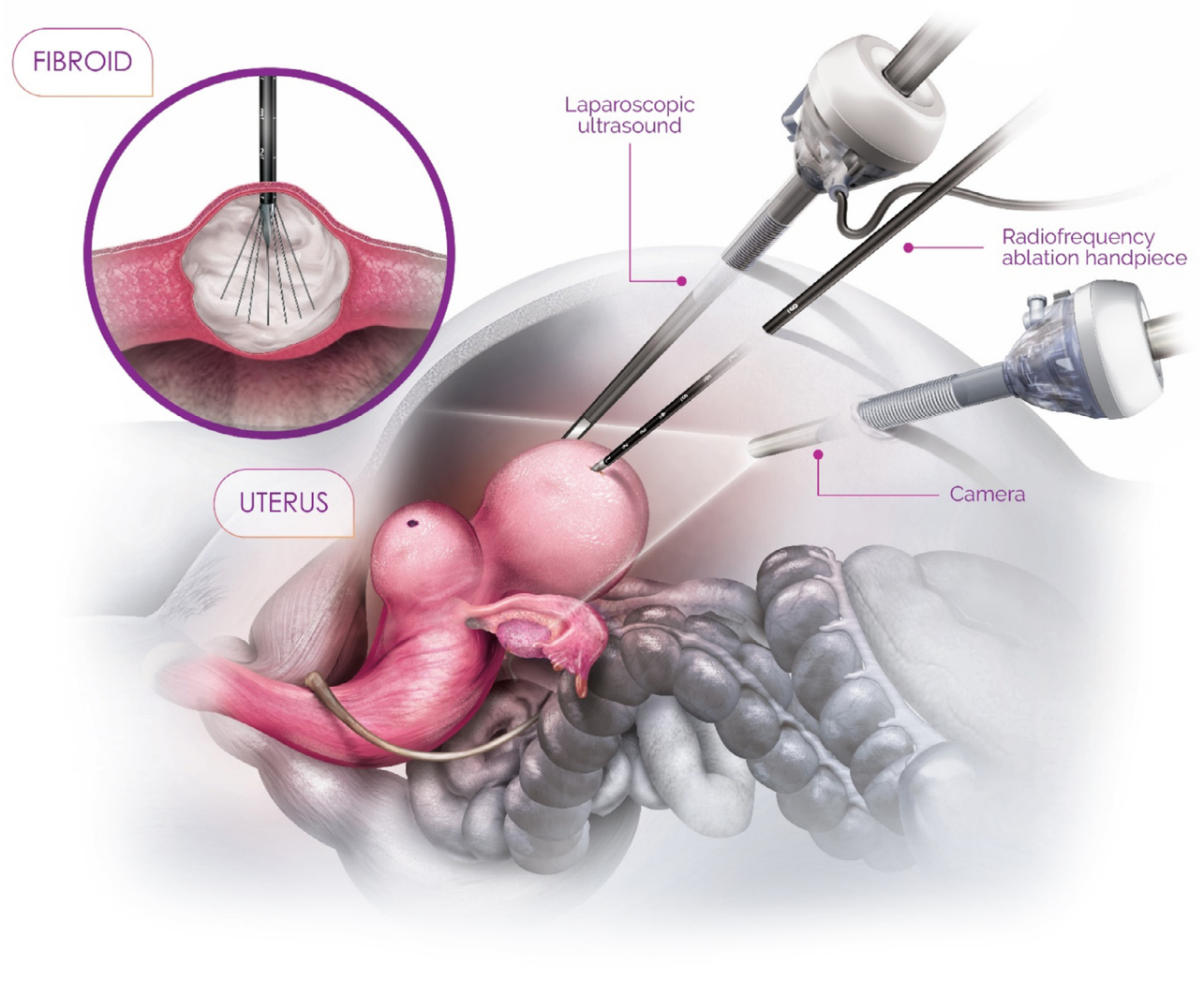
effectiveness beginning with the first case performed. None of the treating gynecologists had previous experience with intraoperative ultrasound or use of radiofrequency energy to treat leiomyomas or any other condition. All surgeons were general gynecologists except 1 who had completed an advanced fellowship in minimally invasive gynecologic surgery.

The gynecologic surgeons performed all RFA procedures under general anesthesia using standard sterile laparoscopic technique. A single-toothed tenaculum was placed on the anterior lip of the cervix for uterine manipulation, and the patient was placed in the dorsal supine position. After wiping the area with an alcohol swipe, the surgeon placed dispersive electrode pads designed specifically for the RFA procedure on each thigh 1 cm superior to the patella. A 5-mm laparoscope was placed at the umbilicus, and a 10-mm port was placed at the uterine fundus for the rigid laparoscopic ultrasound transducer. The surgeon then surveyed the entire uterus by ultrasound to measure and document the visualized leiomyomas.

The Acessa RFA device (Acessa Health, Austin, TX) is a 3.4-mm disposable handpiece with an electrode array that consists of 7 deployable needles to deliver radiofrequency energy from an external generator (Fig. 1). The surgeon can control the radiofrequency energy delivered through the handpiece and monitor the temperature surrounding each needle during treatment on a monitor connected to the generator. To treat each leiomyoma, the surgeon places the handpiece in the pelvis through a small stab incision and passes it through the uterine serosa to deploy it into the leiomyoma tissue using ultrasound guidance. After correct needle array placement is verified, the duration of treatment for

Fig. 1

Laparoscopic radiofrequency ablation of uterine leiomyomas.



each leiomyoma is determined based on its size, using an algorithm that aims to treat the entire leiomyoma volume within 1 cm of the leiomyoma capsule. A continuous, alternating current with a maximum output of 200 W is used during each deployment to bring the leiomyoma temperature to 95 ˚C. For larger leiomyomas, multiple passes are needed to complete a full ablation. Monopolar coagulation is then used to create hemostasis along the track of the handpiece as it is removed from the uterus. After all leiomyomas are treated, the surgeon closes the skin incisions with standard laparoscopic procedures according to standard local practice. All procedures are planned as outpatient surgeries.

The primary outcome for ULTRA was the change in leiomyoma symptoms measured by the Uterine Leiomyoma Symptoms and Quality of Life (UFS-QOL) questionnaire [3] from baseline to 6 weeks and 12 weeks following treatment. We used additional self-reported questionnaires to assess changes in other leiomyoma-related symptoms, including the Menstrual Impact Questionnaire (MIQ) for heavy bleeding [4], the Short-Form Health Survey (SF-36) for overall quality of life [5,6], and the Sexual Outcomes in Women Questionnaire (SHOW-Q) for sexual function [7]. We collected data on operative outcomes, including duration of surgery, estimated blood loss, and complications. Immediately following the procedure, each attending gynecologist rated the difficulty of the procedure on a scale of 0 to 10 and noted whether they would be comfortable performing the surgery without assistance from a device manufacturer representative in the operating room.

Participants reported postoperative outcomes during phone and online interviews at 2 days and 1, 3, 6, and 12 weeks following surgery. Each participant received a $20 gift card after completing the baseline and 6-week questionnaires. To assess postoperative recovery, we asked participants to rate their postoperative pain on a scale of 0 to 10 and to report their use of pain medication and when they returned to their usual activities and/or work. We queried participants about prespecified adverse events (i.e., infection of the incision, urinary tract, or uterus; deep vein thrombosis; blood transfusion; incisional hernia; or abnormal vaginal discharge) as well as unanticipated complications ("Have there been any other adverse changes to your health that impacted your ability to perform your normal activities or resulted in an unplanned or unscheduled doctor visit?").

We assessed changes from baseline to the follow-up time points using the t test for means and the χ^2 test for proportions. Assuming a 5% type 1 error and 90% power, the initial sample size was set at 100 participants, with the aim of collecting data on the first 20 cases at each of the 5 clinical sites. In addition, with 100 participants, we could detect a minimal change of 7.2 in the UFS-QOL from baseline to 12 weeks. This is a clinically significant change, because meaningful improvements in quality of life are generally felt to occur with a minimum of a 10-point change in the UFS-QOL. However, the study investigators faced significant unanticipated challenges in gaining commercial insurance authorization to perform the surgery despite frequent appeals to a diverse range of payers. Therefore, after 2 years, the Data and Safety Monitoring Board and study investigators decided to close study enrollment because the target sample size would not be achieved during the specified and funded recruitment time frame.

Results

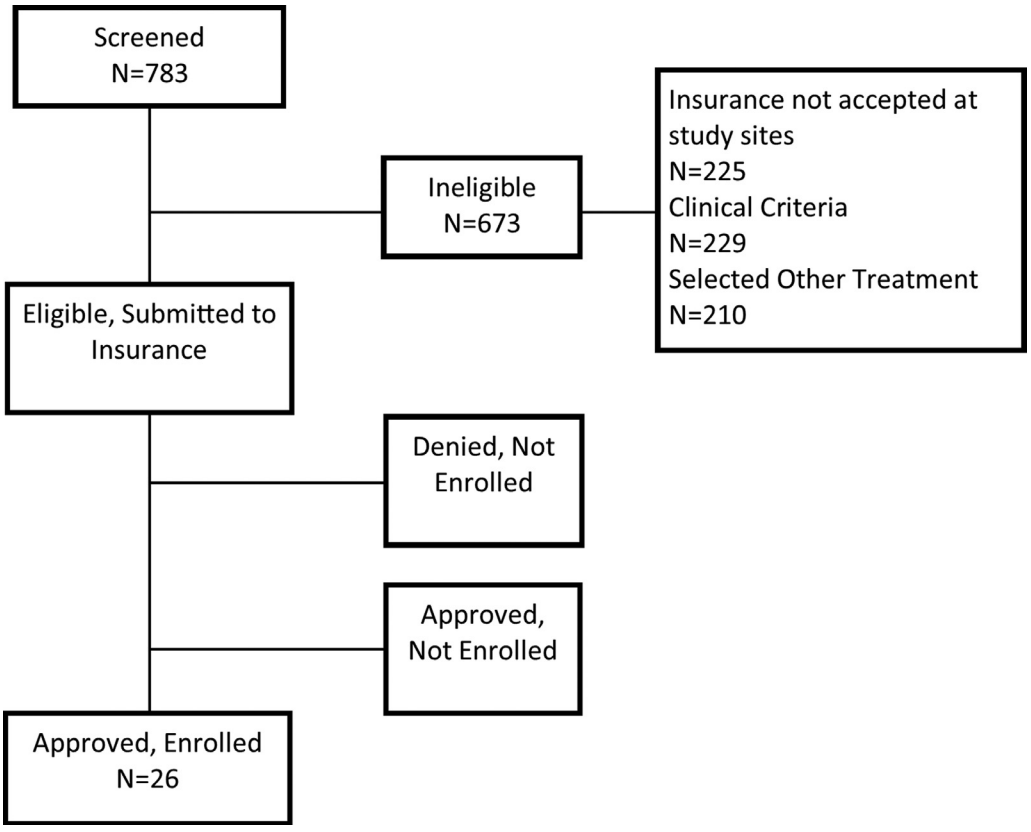
Across the 5 study sites, a total of 783 women were screened for study participation (Fig. 2). After counseling about the procedure, including the potential for insurance companies to deny authorization for coverage and the long wait times to manage appeals to insurance coverage decisions, 210 (27%) of these women elected to undergo other treatment for leiomyomas. Lack of any insurance coverage or a carrier that was accepted at our study sites excluded 225 women (29%), and 229 (29%) were deemed ineligible based on clinical inclusion criteria, such as pregnancy, menopause status, or large leiomyoma size and/or number. A total of 110 women were deemed eligible and agreed to undergo the RFA surgery; however, 70 (64%) were denied insurance coverage. Although 40 women (36%) ultimately received insurance approval for coverage, 14 (13%) decided not to undergo surgery because of symptom improvement either spontaneously or with medical management. Finally, 26 women received insurance approval, enrolled in the study, and underwent the RFA treatment.

The study population was racially and ethnically diverse, with a mean age of 41.5 years (Table 1). Almost one-half (46%) of the participants worked full time, and 19% were covered by Medicaid. The mean uterine size as determined by bimanual examination was 12 ± 2.6 weeks, with an average of 2 ± 1.2 leiomyomas, a mean total leiomyoma volume of 150 ± 114 cc, and a mean diameter of the largest leiomyoma of 5.6 ± 1.6 cm. At the time of study enrollment, 24% of participants reported prior leiomyoma surgery, and 38% were using medication to control leiomyoma symptoms. Leiomyoma symptoms had a significant impact on all activities of study participants, with 38% reporting taking time off work due to leiomyomas and 77% reporting avoiding usual activities due to menstrual symptoms.

The RFA surgery had a low average blood loss of 24 ± 40 cc and a mean operative (skin to skin) time of 153 ± 51 minutes (Table 2). All procedures were completed successfully, with no intraoperative complications or conversion to laparotomy. Attending gynecologists quickly gained comfort with the procedure (Fig. 3). After 4 cases, 50% of treating surgeons reported feeling comfortable performing the procedure without assistance from a company trainer in the operating room. Confidence in performing the procedure was also high, with 100% of gynecologists reporting feeling somewhat or very confident in performing the procedure after 4 cases. On a scale of 0 to 10, the mean difficulty rating by gynecologists after the first case was 6 ±

Fig. 2

Screening and enrollment of study participants.



2.35 and it decreased with each case, to a nadir of 4.25 ± 2.22 after 4 cases.

Postoperative recovery was less than 2 weeks on average (Fig. 4). At 2 days after surgery, the mean pain score was 3.7 (95% CI, 2.97−4.47), and 56% of participants were using opioid pain medication. Pain scores decreased over the next several weeks, with a nadir of 1.0 (95% CI, 0.42−1.57) at the 3-week follow-up, when no participants reported using pain medication. The average time taken off of work was 10.8 ± 7.1 days, and return to usual activities occurred at an average of 9.2 ± 6.5 days. At 5 days after surgery, 34% of participants were back to their usual activities and 50% had returned to work; these percentages increased to 69% and 73% by 10 days after surgery.

In the 6 weeks following surgery, there were no major adverse events (Table 3). During follow-up, 1 participant reported abnormal vaginal discharge and 2 participants experienced urinary tract infection at 3 or more weeks after surgery. Participants reported a wide range of minor symptoms, including gastrointestinal events (bloating, constipation, pain), fatigue, sore throat, musculoskeletal pain, and rash, most of which were reported within the first week following surgery. Overall, 8 participants (32%) reported at least 1 minor adverse event at the 2-day and 1-week visits.

Leiomyoma-related symptoms were significantly improved from baseline to 6 weeks and 12 weeks after surgery (Table 4). UFS-QOL symptom scores improved by 25 points at 12 weeks ($p < .01$), with a corresponding increase in quality of life scores by 22 points ($p < .01$). All of the domains in the Menstrual Impact Questionnaire improved significantly by 12 weeks after treatment, including the overall report of menstrual blood loss and the impact of menstrual bleeding on work and physical and social activities. At 12 weeks, the average score for all domains that measure bleeding impact was 1, which indicates no impact of menstrual bleeding on quality of life. Sexual health also improved in several domains after treatment, with a decrease in the mean score for reporting that pelvic problems interfere with sex, increased sexual desire, and improved satisfaction with sex at 12 weeks after treatment. Overall quality of life also improved in the SF-36 Physical Component Scale, but not the Mental Component Scale, at 12 weeks. At 6 and 12 weeks of follow-up, no participants reported use of medications to control leiomyoma symptoms or any new leiomyoma procedures or surgeries.

Table 1

Baseline characteristics of the study group (N = 26)

Characteristic	Value
Demographic characteristics	
Age, yr, mean ± SD	41.5 ± 4.9
Race/ethnicity, n (%)	
Asian	1 (4)
Black/African American	6 (23)
Latina/Hispanic	4 (15)
White	15 (58)
Other	4 (15)
Education, n (%)	
High school diploma or less	2 (8)
College degree or more	19 (73)
Some college	5 (19)
Employment, n (%)	
Full time	12 (46)
Homemaker/childcare	4 (15)
Seeking/other	4 (15)
Part time/student	7 (27)
Insurance, n (%)	
Medicaid	5 (19)
Medicare	1 (4)
Other	2 (8)
Private insurance (HMO or PPO)	18 (69)
Clinical characteristics	
Body mass index, mean ± SD	27.0 ± 4.6
Parity, n (%)	
0	18 (69)
1 or 2	8 (31)
Current sexual partner, n (%)	21 (81)
Previous surgical treatment for leiomyoma, n (%)	6 (24)
Current use of medication for leiomyoma symptoms, n (%)	10 (38)
Days of menstrual bleeding, mean ± SD	7.0 ± 3.7
Days of heavy menstrual bleeding, n (%)	3.2 (1.9)
Anemia, n (%)	8 (31)
Need to take time off work due to leiomyomas, n (%)	10 (38)
Avoidance of usual activities due to heavy menses, n (%)	20 (77)
Hormonal therapy for leiomyoma symptoms, n (%)	6 (23)
Leiomyoma characteristics	
Uterine size, wk, mean ± SD	12.0 ± 2.6
Number of leiomyomas	2.0 ± 1.2
Largest leiomyoma diameter, cm, mean ± SD	5.6 ± 1.6
Leiomyoma volume, cc, mean ± SD	150.2 ± 114.0

Table 2

Intraoperative outcomes (N = 26)

Outcome	Value
Total operating room time, min, mean ± SD	211± 54
Operating time, skin to skin, min, mean ± SD	153 ± 51
Blood loss, cc, mean ± SD	24 ± 40
RF ablation completed, n (%)	100 (100)
Intraoperative complications, n (%)	0 (0)

Discussion

In this analysis of the ULTRA study, we report key clinical outcomes and operator experience during the initial adoption of laparoscopic RFA into leiomyoma surgical practice. A previous study of 40 RFA cases during the run-in period of a randomized trial reported surgeon experience, but gynecologists were only assessed after they "felt comfortable" with the procedure, had completed 2 to 5 cases, and could complete the procedure "safely" [8]. In contrast, our trial included surgical outcomes beginning with the very first case completed among gynecologists with no prior experience using RFA. Therefore, our study provides a unique opportunity to assess the learning curve and clinical outcomes during the initial cases completed. Our results can serve to guide and inform gynecologists considering adopting this new surgical treatment and improve patient counseling about the risks and benefits as it is introduced into practice.

The learning curve for new surgical techniques has garnered much attention in the last 15 years as new minimally invasive laparoscopic surgical techniques have grown in popularity and availability. For laparoscopic hysterectomy, a total of 25 to 40 completed cases has been cited as the threshold for reaching surgical proficiency [9−13]. Newer techniques, such as robotic-assisted laparoscopic hysterectomy and single-port laparoscopic myomectomy, have also been shown to require 45 to 50 cases to minimize adverse events [14,15]. In contrast to this high volume of cases, 89% of gynecologists in our study reported being somewhat or very confident in performing the procedure after the very first case of RFA. This confidence level rose to 100% after 4 procedures, when one-half of the surgeons felt they no longer required the physician trainer in the operating room. After the first case, gynecologists reported that the procedure was moderately difficult, with a score of 6.0 ± 2.35, but the score dropped quickly to 4.25 ± 2.22 by the fourth case. RFA for leiomyomas does not require laparoscopic suturing; in ULTRA, general gynecologists were able to learn the procedure quickly and gain confidence and skill in fewer than 5 cases.

With the introduction of new surgical techniques, case volume has also been linked to operative outcomes and the rate of adverse events. In large case series of gynecologists learning laparoscopic hysterectomy, the rate of surgical complications was found to decrease over time as the surgeon's case volume increased [16−18]. In the first 26 cases of RFA performed in our trial, there were no intraoperative complications, conversion to laparotomy, or serious adverse events in the 6 weeks following surgery. However, this is a very small sample size that is underpowered to adequately assess surgical complications.

Fig. 3

Gynecologist rating of surgical difficulty.

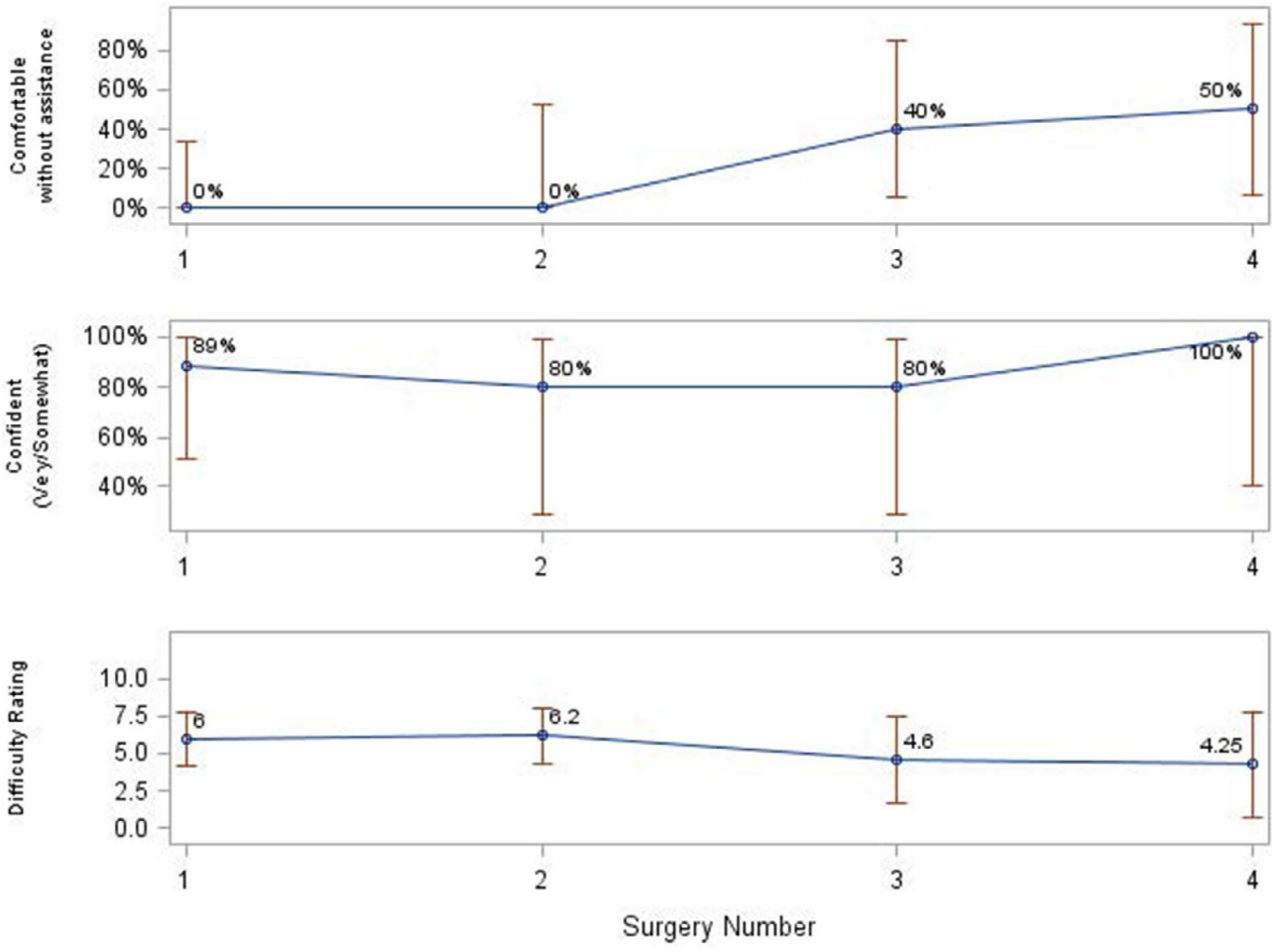
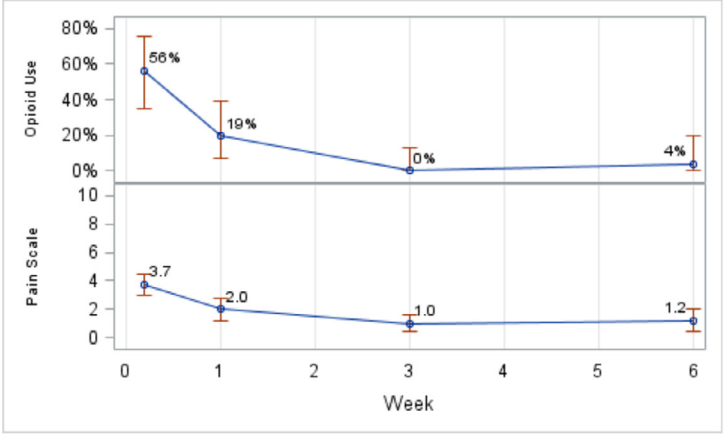
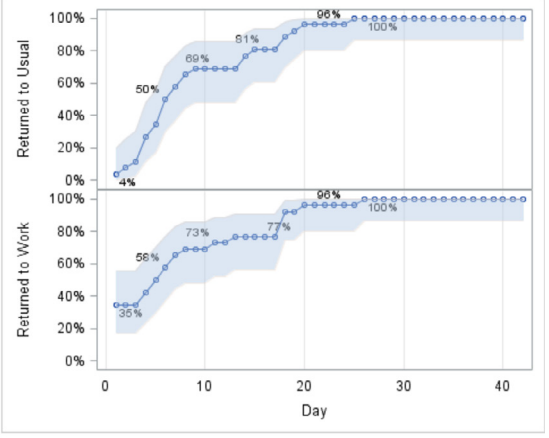


Fig. 4

Postoperative recovery measures.



a. Pain scale and use of opiods



b. Return to work and usual activities

Table 3

Postoperative adverse events

Adverse event	Day 2 visit (N = 25)	Week 1 visit (N = 25)	Week 3 visit (N = 26)	Week 6 visit (N = 26)
Prespecified*				
Abnormal vaginal discharge	1 (4.0)	1 (4.0)	1 (3.8)	1 (3.8)
Bladder/kidney infection			1 (3.8)	1 (3.8)
Skin infection		1 (4.0)		
Gastrointestinal disorders				
Abdominal pain	1 (4.0)			
Bloating	1 (4.0)	1 (4.0)		
Constipation	1 (4.0)	1 (4.0)		
Intestinal inflammation		1 (4.0)		
General disorders				
Fatigue	1 (4.0)			
Flu-like symptoms		1 (4.0)		
Infections and infestations				
Sinus infection		1 (4.0)		
Mouth and throat disorders				
Sore gums		1 (4.0)		
Sore throat	2 (8.0)			
Swollen throat gland		1 (4.0)		
Musculoskeletal and connective tissue disorders				
Arthritis	1 (4.0)			
Chest/rib cage pain			1 (3.8)	
Pain in both arms (elbow joint)			1 (3.8)	
Nervous system disorders				
Migraine	1 (4.0)			1 (3.8)
Renal and urinary disorders				
Urethral pain	1 (4.0)			
Urinary retention	1 (4.0)			
Urinary urgency	1 (4.0)			
Reproductive system				
Ovarian cyst				
Postop vaginal bleeding	1 (4.0)	1 (4.0)		
Uterine cramping	1 (4.0)			1 (3.8)
Skin and subcutaneous tissue disorders				
Adhesive irritation		1 (4.0)		
Belly button bleeding	1 (4.0)			
Rash	1 (4.0)			
Skin blistering		1 (4.0)		
Skin irritation		1 (4.0)		
Skin irritation at site of incision				1 (3.8)
Subjects with 1 or more event	8 (32.0)	8 (32.0)	3 (11.5)	3 (11.5)

Data are n (%). Percentage is based on the total number of subjects indicated (N); for each column, each AE or AE group is counted only once per subject.

* Includes skin infection at the incision site; infection of bladder or kidneys; infection of uterus; blood transfusion; pulmonary embolus or deep vein thrombosis; abnormal vaginal discharge; skin burn on leg at site of grounding pad; injury to superficial blood vessels; injury to bowel or gastrointestinal tract; injury to bladder, ureter, or urethra; injury to pelvic abdominal blood vessels; and problems with intubation or ventilation.

The average operative time in our trial was 2.5 hours, approximately 40 minutes longer than that reported in the run-in phase of 40 cases in a previous randomized trial of RFA (114 ± 60 minutes) [8]. The longer operative time in our trial may be related in part to the skill of the surgical assistants. At 4 of our clinical centers, residents in obstetrics and gynecology served as surgical assistants, whereas cases in the run-in phase of the randomized trial were completed by 2 attending gynecologists who had completed the RFA training course [8]. With our small total number of cases, our trial is underpowered to adequately assess whether changes in operative time occur as RFA volume increases; however, there were no statistically significant differences in the duration of surgery between the first and fourth cases performed by the study gynecologists. We did not query surgeons about what part of the RFA procedure has the greatest impact on overall operative time; however, surgical time may vary by the number, size, and location of leiomyomas to be treated, because surgeons aim to treat all myomas during the RFA procedure. The time required to deliver radiofrequency energy increases as total myoma tissue volume increases,

Table 4

Changes in leiomyoma-related symptoms from baseline to 6 and 12 weeks

Instrument	Baseline	6 weeks	Change over 6 weeks	p value	12 weeks	Change over 12 weeks	p value
Uterine Leiomyoma Symptom and Quality of Life (UFS-QoL)							
Symptom severity	53.73 ± 20.41	42.43 ± 13.78	-11.30 ± 17.10	<.01	27.25 ± 15.24	-25.13 ± 17.83	<.0001
Quality of life	50.06 ± 24.10	63.95 ± 23.12	13.89 ± 18.51	<.01	73.43 ± 20.92	22.51 ± 23.86	<.0001
Menorrhagia Impact Questionnaire (MIQ)							
Blood loss*	3.12 ± 0.71	2.81 ± 0.94	-0.31 ± 0.97	.1060	2.40 ± 0.71	-0.68 ± 0.95	<.01
Limit work†	2.69 ± 1.52	2.08 ± 1.20	-0.62 ± 1.50	.0596	1.60 ± 0.71	-1.04 ± 1.49	<.01
Limit physical activity†	3.00 ± 1.44	2.35 ± 1.20	-0.65 ± 1.50	<.05	1.80 ± 0.58	-1.12 ± 1.33	<.01
Limit social activity†	2.77 ± 1.45	1.92 ± 1.13	-0.85 ± 1.26	<.01	1.60 ± 0.76	-1.08 ± 1.26	<.01
Sexual Health Outcomes in Women Questionnaire (SHOW-Q) ‡							
Orgasm frequency and quality	65.32 ± 24.65	66.28 ± 28.83	-2.83 ± 32.56	.9868	72.26 ± 22.99	3.78 ± 21.32	.5314
Pelvic problem interference with sex	56.52 ± 33.99	30.33 ± 28.45	-25.00 ± 28.65	<.01	19.79 ± 23.42	-33.33 ± 29.43	<.0001
Sexual desire or interest	43.23 ± 26.66	49.67 ± 32.59	6.77 ± 25.80	.2687	53.47 ± 30.34	11.05 ± 24.48	<.05
Satisfaction with sex	35.94 ± 19.61	52.50 ± 25.77	17.71 ± 28.77	<.01	56.25 ± 30.62	21.20 ± 34.63	<.01
Short-Form Health Survey (SF-36)							
Mental Component Scale	45.83 ± 8.70	49.60 ± 8.04	3.78 ± 7.21	<.05	48.41 ± 10.52	2.05 ± 11.41	.1620
Physical Component Scale	46.57 ± 9.30	49.16 ± 8.42	2.59 ± 7.53	<.05	52.52 ± 8.94	5.51 ± 7.84	<.01

* Scores on the Menorrhagia Impact Questionnaire blood loss domain scale range from 1 to 4; higher scores indicate greater blood loss.

† Scores on each of the Menorrhagia Impact Questionnaire domain scales range from 1 to 5; higher scores indicate greater limitation on work, physical activities, and social activities.

‡ Scores on each of the Sexual Health Outcomes in Women Questionnaire domain scales range from 0 to 100; higher scores indicate greater pelvic problem interference, orgasm frequency and quality, sexual desire or interest, and satisfaction with sex.

either with a larger size of 1 myoma or a higher number of total myomas. Further study is needed to understand how these variables and other factors may impact overall operative time.

In addition to safety and ease of performing the surgery, patient-reported outcomes were favorable during this early use of RFA. Recovery time was rapid; 35% of participants had returned to work 2 days after surgery and 73% had done so by 10 days. At baseline, study participants were highly symptomatic, but by 12 weeks after surgery, all patient-reported outcomes had improved significantly, including overall leiomyoma symptoms, heavy bleeding, and sexual health. The 25-point improvement in the UFS-QOL Symptom Severity score is similar to changes in this symptom scale reported in the pivotal trial of laparoscopic RFA [19] and other trials of uterine-preserving leiomyoma procedures 12 weeks after treatment [20,21].

The ULTRA trial highlights the strong demand for new minimally invasive uterine sparing leiomyoma treatments. In a 2-year period, 783 women expressed interest in the trial and were screened for study eligibility. Many of these women were planning future pregnancy and seeking alternatives to myomectomy. Currently, the RFA device has not been approved by the FDA for women who desire future fertility, because of limited pregnancy outcome data. The largest case series reported 30 pregnancies in 28 women who had undergone RFA of leiomyomas in clinical trials or postmarket practice settings [22], Among these pregnancies, 26 (86.7%) resulted in term delivery of a healthy infant, 50% by cesarean section and 50% by vaginal delivery. Obstetric complications were noted in 2 patients, 1 with placenta previa and 1 with postpartum hemorrhage, in which a degenerated myoma was expelled from the vagina 2 days after cesarean section, necessitating endometrial curettage and 6 units of transfused blood. Additional studies with much larger sample sizes are needed to further evaluate pregnancy outcomes and determine the safety of RFA for women who seek future fertility.

In conclusion, our results suggest that unlike many other new laparoscopic procedures, laparoscopic RFA may be quickly adopted into leiomyoma surgical practice. Although our sample size is small, we found statistically significant improvements in leiomyoma-related symptoms from baseline to 6 and 12 weeks following surgery, even in the first cases performed by each surgeon. Since the close of the trial, a new visual guidance system has been introduced to assist gynecologists in correctly targeting the RF probe into the leiomyoma. This support may further decrease the difficulty score, even after the first procedure. One limitation of this study is the single-arm unblinded design, which might have biased patient-reported outcomes, such as changes in leiomyoma symptoms, but likely had no effect on surgeon difficulty rating or the rate of complications. Future studies should focus on comparative effectiveness studies to provide more definitive conclusions about how RFA outcomes compare with other available surgeries and procedures for treating leiomyomas.

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