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Authors

Jacoby, Vanessa L
Parvataneni, Ram
Oberman, Erica
et al.

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

AUTHORS AND AFFILIATIONS Vanessa L JACOBY, MD, MAS[1, 6], Ram PARVATANENI, MD, MPH[2, 6], Erica OBERMAN, MD[2, 6], Naghmeh SALAMAT SABERI, MD[3, 6] , Shira VARON, MD[4, 6], Michael SCHEMBRI, B.S. [1], L. Elaine WAETJEN, MD[5,6]

Department of Obstetrics, Gynecology, and Reproductive Sciences, University of California, San Francisco[1]; Department of Obstetrics and Gynecology, University of California, Los Angeles[2]; Department of Obstetrics and Gynecology, University of California, Irvine[3]; Department of Obstetrics and Gynecology, University of California, San Diego[4]; Department of Obstetrics and Gynecology, University of California, Davis[5]; University of California Fibroid Network[6]

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CORRESPONDING AUTHOR
Vanessa L. Jacoby, M.D., M.A.S.
Department of Obstetrics, Gynecology, and Reproductive Sciences University of California, San Francisco
550 16th St., San Francisco, CA 94158
Phone: 415.885.7788
e-mail: Vanessa.Jacoby@ucsf.edu

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Leiomyomas; Laparoscopy; Radiofrequency Ablation

PRECIS

Among gynecologists with no prior training, the initial cases of laparoscopic radiofrequency ablation of leiomyomas can be performed with rapid onset of surgical confidence and favorable clinical outcomes.

ABSTRACT

Study Objective

To assess surgical outcomes, clinical effectiveness, and gynecologist's experience of introducing laparoscopic radiofrequency ablation (RFA) of leiomyomas into surgical practice.

Design Uncontrolled clinical trial

Setting 5 academic medical centers across California

Patients

Premenopausal women with symptomatic uterine leiomyomas, uterus ≤16 week 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 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 prior 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 enrolled. The mean age of participants was 41.5 years (standard deviation (SD) 4.9). Mean operating time was 153 minutes (SD 51) and estimated blood loss was 24cc (SD 40). 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 point (SD 18), or 47%

decrease in the leiomyoma Symptom Severity Score. After the first procedure performed, 6 was the mean difficulty score (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 score decreased to 4.25 (CI 1.2, 6) after the fourth procedure with all gynecologists reporting surgical confidence.

Conclusions

Laparoscopic RFA of leiomyomas can be introduced into surgical practice with good clinical outcomes for patients. Gynecologists with no prior experience are able to gain confidence and skill with the procedure quickly in <5 cases

Uterine Leiomyoma Treatment With Radiofrequency Ablation (ULTRA)
https://clinicaltrials.gov/ct2/show/NCT01840124
ClinicalTrials.gov Identifier: NCT01840124
Date registered: April 25, 2013

INTRODUCTION

Uterine leiomyomas occur in up to 80% of premenopausal women and are the most common indication for major gynecological surgery in the United States. The estimated annual cost of care for women with leiomyomas is $34 billion, with 50% of the cost from 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 that may defray the cost and prolonged disability of 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 FDA approved 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 CPT 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 during the start-up phase of gynecologic surgeons adopting this new leiomyoma treatment into clinical practice.

MATERIALS and METHODS

The Uterine Leioleiomyoma 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 patients at five 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 (#NCT01840124) on April 25, 2013, approved for all UC sites by the UC San Francisco Institutional Review Board (IRB number: 13-11026 Approval Date: 05/02/2013) and all participants gave written informed consent for study enrollment. An independent Data Safety and Monitoring Board (DSMB) of two gynecologists and one biostatistician not employed by UC approved the study protocol and met every 6 months to assess patient safety and data quality.

Women were eligible to participate if they were 21 years or older, premenopausal (at least one period in the last three 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 (MRI) within the last year to assess leiomyoma characteristics. We defined a leiomyoma as any mass on pelvic imaging ≥2cm consistent with the typical appearance of a uterine leiomyoma. Women were

included if the uterus was ≤16 week size, all leiomyomas ≤10 cm in maximum diameter, and they had no more than six leiomyomas. Eligible participants had to have a negative pregnancy test, normal cervical cancer screening within the previous 3 years and, for those over 45 with heavy or irregular bleeding, a normal endometrial biopsy. We excluded women if they were planning treatment for infertility, had need for a concomitant surgical procedure (e.g. hernia repair or cystectomy), had pelvic infection within the last three months, 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 three months. We also excluded women with leiomyoma characteristics that are not amenable to laparoscopic RFA treatment: pedunculated leiomyomas with stalk <25% of the maximum leiomyoma diameter, intracavitary leiomyoma (FIGO Type 0), or the only leiomyoma is submucosal ≥50% intracavitary (FIGO Type 1). Women who desired future fertility were included in the trial after detailed counseling by their physician that the treatment is not FDA approved for women who desire future pregnancy and there is 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 the opportunity to undergo an appeal process with their insurance carrier. If authorization for coverage was received, a surgery date was scheduled to undergo the procedure 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 seven treating gynecologic surgeons underwent a one day didactic and surgical simulation training course provided by the RFA device manufacturer. For the first five 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 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 one 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 then the patient was placed in the dorsal supine position. The surgeon placed dispersive electrode pads designed specifically for the RFA procedure (Acessa™) on each thigh 1cm superior to the patella after wiping the area with

an alcohol swipe. A 5mm laparoscope was placed at the umbilicus and a 10mm port was placed at the uterine fundus for the rigid laparoscopic ultrasound transducer. The surgeons then surveyed the entire uterus by ultrasound to measure and document the visualized leiomyomas.

The RFA device (Acessa™) is a 3.4mm disposable handpiece with an electrode array that consists of 7 deployable needles to deliver radiofrequency energy from an external generator (Figure 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 placed the handpiece in the pelvis through a small stab incision and passed it through the uterine serosa to deploy it into the leiomyoma tissue using ultrasound guidance. After correct needle array placement was verified, the duration of treatment for each leiomyoma was determined by its size using an algorithm that aims to treat the entire leiomyoma volume within 1cm of the leiomyoma capsule. A continuous, alternating current with a maximum output of 200W was used during each deployment to bring the leiomyoma temperature to 95^0C. For larger leiomyomas, multiple passes were needed to complete a full ablation. Monopolar coagulation was then used to create hemostasis along the track of the handpiece as it is removed from the uterus. After all leiomyomas were treated, the surgeon closed the skin incisions with standard laparoscopic procedures according to standard local practice. All procedures were planned as outpatient surgeries.

The primary outcome for ULTRA was change in leiomyoma symptoms measured by the Uterine Leiomyoma Symptoms-Quality of Life (UFS-QOL)

questionnaire[3] from baseline to 6 and 12 weeks following treatment. We used additional self-reported questionnaires to assess change in other leiomyoma-related symptoms including: 1) the Menstrual Impact Questionnaire (MIQ) for heavy bleeding[4], 2) the Short Form Health Survey (SF-36) for quality of life[5,6], 3) and the Sexual Outcomes in Women Questionnaire (SHOW-Q) for sexual function.[7] We collected data on operative outcomes including surgery duration, estimated blood loss, and complications. Immediately following the procedure, each attending gynecologist rated the difficulty of the procedure on a scale from 0 to 10 and 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 on-line interviews at 2 days and 1, 3, 6, and 12 weeks following surgery. Participants received gift cards of $20 after completing the baseline and 6 week questionnaires. To assess postoperative recovery, we asked participants to rate their post-operative pain on a scale from 0 to 10, to report their use of pain medication, and when they returned to their usual activities and/or work. We queried participants about pre-specified adverse events (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 follow-up time points using t tests for means and chi-squared 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 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 two years, the DSMB and study investigators decided to close study enrollment because the target sample size would not be reached during the specified, funded recruitment timeframe.

RESULTS

Across all five study sites, there were 783 women screened for study participation (Figure 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 leiomyoma treatment. Lack of any insurance coverage or a carrier that was accepted at our study sites excluded 225 (29%) of women; 229 (29%) were deemed ineligible based on clinical inclusion criteria such as pregnancy, menopause status, a large leiomyoma size and/or number. One hundred ten women were eligible and agreed to undergo the RFA surgery; 70 (64%) were denied insurance coverage. Although 40 (36%) women ultimately gained insurance approval for coverage, 14 (13%) decided not to undergo surgery because substantial time had passed and symptoms had improved spontaneously or with medical management. Twenty-six women

gained 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). Most of the participants (46%) worked full time and 19% were covered by Medicaid. The mean uterine size by bimanual exam was 12 weeks (standard deviation (SD) 2.6) with an average of two leiomyomas (SD 1.2) , a total leiomyoma volume of 150cc (SD 114), and the mean diameter of the largest leiomyoma of 5.6cm (SD 1.6cm). 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 they had taken time off work due to leiomyomas and 77% reporting that they avoided their usual activities due to menstrual symptoms.

The RFA surgery had a low average blood loss of 24 cc (SD ±40) and a mean operative (skin to skin) time of 153 minutes (Table 2, SD ±51). All procedures were completed successfully with no intraoperative complications or conversion to laparotomy. Attending gynecologists gained comfort with the procedure quickly (Figure 3). After four cases, 50% of treating surgeons reported that they felt 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 that they felt somewhat or very confident in performing the procedure after 4 cases. On a scale from 0 to 10, the mean difficulty rating by gynecologists after the first case was 6 (SD ±2.35) and decreased each case to a nadir of 4.25 (SD ±2.22) after four cases.

Postoperative recovery was, on average, less than two weeks (Figure 4).

Two days after surgery, the mean pain score was 3.7 (95% CI 2.97,4.47) and 56% of participants were using opoid 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 days (SD ±7.1) and return to usual activities was 9.2 days (SD ±6.5). Five days after surgery, 34% of participants were back to their usual activities and 50% had returned to work with an increase to 69% return to usual activities and 73% returned to work by 10 days after surgery.

In the 6 weeks following surgery, there were no major adverse events (Table 3). During follow up, one participant reported abnormal vaginal discharge and two had urinary tract infections three 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 (32%) participants reported at least one minor adverse event at the 2 day and 1 week visit.

Leiomyoma-related symptoms significantly improved from baseline to 6 and 12 weeks after surgery (Table 4). UFS-QOL symptom scores improved by 25 points at 12 weeks ($p<0.01$) a corresponding increase in quality of life scores by 22 points ($P<0.01$). All of the domains in the Menstrual Impact Questionnaire improved significantly 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 12 weeks after treatment. Overall quality of life also improved in the Physical Component Scale of the SF-36 at 12 weeks but not the Mental Component Scale. 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.

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 prior 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 2-5 cases, and could complete the procedure "safely".[8] In contrast, our trial includes surgical outcomes beginning with the very first case completed among gynecologists with no prior experience using RFA. Therefore, we provide a unique opportunity to assess the learning curve and clinical outcomes during the initial cases completed. These results 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 fifteen years as new minimally invasive laparoscopic surgical techniques have grown in popularity and availability. For laparoscopic hysterectomy, 25-40 completed cases is reported as the threshold to reach surgical proficiency.[9-13] Newer techniques such as robot-assistance with

laparoscopic hysterectomy or single-port laparoscopic myomectomy have also been shown to require 45-50 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% of gynecologists after four procedures, when 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 (SD ±2.35), but the score dropped quickly to 4.25 (SD ±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 less than five 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 decreases over time as the volume of cases increases for each surgeon.[16-18] In the first 26 cases of RFA performed in our trial, there were no intra-operative complications, conversions 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.

Operative time in our trial was 2.5 hours, about 40 minutes longer than in the “run-in” phase of 40 cases in a RFA randomized trial (114 min, SD 60 min).[8] The longer operative time in our trial may in part be related to the skill of the surgical assistant. At four of our clinical centers, residents in obstetrics and gynecology served as surgical assists, while cases in the “run-in” phase of the

randomized trial were completed by two attending gynecologists who had both completed the RFA training course.[8] With a small overall number of cases, our trial is underpowered to adequately assess if changes in operative time occur as RFA volume increases. However, there were no statistically significant differences in the duration of surgery between the 1st and 4th case performed by the study gynecologists. We did not query surgeons about what part of the RFA procedure most impacts 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 fibroids during the RFA procedure. The time required to deliver radiofrequency energy increases as total fibroid tissue volume increases, either with larger size within one fibroid or higher number of total fibroids. 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% 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 two-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 leiomyoma in clinical trials or post-market practice settings[22], Among these pregnancies, 26 (86.7%) delivered at term with healthy infants; 50% by cesarean section and 50% by vaginal delivery. Obstetric complications were noted in 2 patients; one had placenta previa and one had a post-partum hemorrhage in which she expelled a degenerated fibroid per vagina 2 days after cesarean section and required endometrial curettage and 6 units of transfused blood. Additional data is needed with much larger sample size to further evaluate pregnancy outcomes and determine the safety of RFA for women who seek future fertility.

CONCLUSION

Unlike many other new laparoscopic procedures, our results suggest that laparoscopic RFA may be adopted quickly into leiomyoma surgical practice. Although the 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 initial cases performed by each provider. 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 the study is the single-arm unblinded design which may bias patient-reported outcomes such as changes in leiomyoma symptoms,

but is unlikely to have an 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 compared with other available leiomyoma surgeries and procedures.

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446None.
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Figure 1 Legend. Laparoscopic Radiofrequency Ablation of Uterine Leiomyoma

Figure 2 Legend. Screening and Enrollment of Study Participants

Figure 3 Legend. Gynecologist Rating of Surgical Difficulty

Figure 4 Legend. Post-Operative Recovery Measure

Table 1. Baseline Characteristics

Total N=26 **Number (%)** **or** **Characteristic** **Mean (SD)**	
Demographic Characteristics	
Age, Mean±SD	41.5±4.9
Race/Ethnicity	
Asian	1 (4)
Black/African American	6 (23)
Latina/Hispanic	4 (15)
White	15 (58)
Other	4 (15)
Education	
<=High School	2 (8)
College Degree or more	19 (73)
Some College	5 (19)
Employment	
Full time	12 (46)
Homemaker/Child care	4 (15)
Seeking/Other	4 (15)
Part time/Student	7 (27)
Insurance	
Medi-Caid	5 (19)
Medicare	1 (4)
Other	2 (8)
Private insurance (HMO or PPO)	18 (69)
Clinical Characteristics	
Body mass index	27.0 (4.6)
Parity	
0	18 (69)

1-2	8 (31)
Current Sexual Partner	21 (81)
Prior leiomyoma surgical treatment	6 (24)
Current use of medication for leiomyoma	10 (38)
Days of Menstrual Bleeding, Mean±SD	7.0±3.7
Days of Heavy Menstrual Bleeding	3.2 (1.9)
Anemia	8 (31)
Had to take time off work due to leiomyomas	10 (38)
Avoids usual activities due to heavy menses	20 (77)
Use hormonal treatments for leiomyoma	6 (23)
Leiomyoma Characteristics	
Uterine Size (in weeks)	12.0±2.6
Number of Leiomyomas	2.0±1.2
Largest leiomyoma diameter (cm)	5.6 (1.6)
Leiomyoma Volume (in cc)	150.2±114.0

Table 2. Intraoperative Outcomes

Characteristic	Total N=26
Total Operating room time (minutes)	211±54
Operating Time (minutes)--skin to skin	153±51
Blood loss (cc)	24±40
RF ablation completed	100 (100)
Intraoperative Complications	0 (0)

542 **Table 3. Post-Operative Adverse Events**
543

	Number (% of Subjects*)			
Adverse Event	**Day 2 Visit**	**Week 1 Visit**	**Week 3 Visit**	**6 Week Posto p**
Pre-Specified†				
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				
Gums sore		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				
Urethra soreness	1 (4.0)			
Urinary retention	1 (4.0)			

Adverse Event	Number of (%) Subjects*			
	Day 2 Visit	Week 1 Visit	Week 3 Visit	6 Week Postop Visit
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 blister		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)

*Percent based on the total number of subjects indicated (n); for each column, each AE or AE group is counted only once per subject.

†Includes: Infection of skin at incision; 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 GI tract; injury to bladder, ureter, or urethra; injury to pelvic abdominal blood vessels; problems with intubation or ventilation.

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555 **Table 4. Changes in leiomyoma related symptoms from baseline to 6 and 12 weeks**
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Score	Baseline	6 Week	Change over 6 weeks	P-value	12 Week	Change over 12 weeks	P-value
The Uterine Leiomyoma Symptom and Quality of Life (UFS-QoL) scores							
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	0.1060	2.40±0.71	-0.68±0.95	<.01
Limit Work†	2.69±1.52	2.08±1.20	-0.62±1.50	0.0596	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) scores ‡							
Orgasm frequency and quality	65.32±24.65	66.28±28.83	-2.83±32.56	0.9868	72.26±22.99	3.78±21.32	0.5314
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	0.2687	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)							

Score	Baseline	6 Week	Change over 6 weeks	P-value	12 Week	Change over 12 weeks	P-value
Mental Component Scale	45.83±8.70	49.60±8.04	3.78±7.21	<.05	48.41±10.52	2.05±11.41	0.1620
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, respectively.

‡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, respectively.