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10
11 **Precis**

12 In our 49 participants undergoing combined lap-RFA and lap-MYO there were few peri-
13 operative events, a satisfactory recovery time, and significant improvement in quality of life
14 measures with high patient satisfaction through 12 months after surgery.

15
16 **Abstract**

17 **Background and Objectives**

18 Uterine fibroids are common in women and can lead to symptoms of abnormal uterine bleeding,
19 pelvic pain and bulk symptoms. Treatment can be medical or surgical. This study aims to
20 describe characteristics and outcomes of women undergoing combined laparoscopic
21 radiofrequency ablation (lap-RFA) and laparoscopic myomectomy (lap-MYO) to treat
22 symptomatic uterine fibroids.

23
24 **Methods**

This is a multi-center prospective cohort study including both academic centers and private practices. Women in the Uterine Leiomyoma Treatment by Radiofrequency Ablation (ULTRA) Study who were scheduled to undergo surgical management of fibroids underwent a combined laparoscopic radiofrequency ablation (lap-RFA) and laparoscopic myomectomy (lap-MYO). We assessed quality of life and sexual function changes from before to 12 months after surgery using validated questionnaires.

Results

Of the 480 participants in ULTRA, 49 underwent a combined lap-RFA and lap-MYO procedure between 2014-2022. The mean number of fibroids treated was 3.6 (SD 2.0). The mean number of days to return to usual activities was 12.7 (SD 10.1). The Uterine Fibroid Symptom and Health-Related Quality of Life Questionnaire symptom severity score (0-100 points) improved by 36.4 points (SD 27.0, $p<0.001$) at 12 months and the Sexual Health Outcomes in Women Questionnaire (0-100 points) assessment of pelvic problems interference with sex improved by 13 points (SD 34.4 $p=0.02$) as early as 6 weeks. About 75% of women were satisfied with the surgery at 12 months.

Conclusion

Combining lap-RFA and lap-MYO is associated with few peri-operative events, satisfactory recovery time, and significant improvement in quality-of-life measures with high patient satisfaction through 12 months after surgery.

48 **Manuscript Text**

49 **Introduction**

50 Uterine fibroids are benign smooth muscle tumors estimated to occur in 70-80% of
51 women.¹ Despite being common, they can cause debilitating symptoms and have a significant
52 impact on quality of life.² Symptoms of fibroids include irregular and or heavy bleeding,
53 abdominal pain and bulk symptoms such as constipation, pelvic pressure and urinary frequency.³
54 The treatment of fibroids can be medical, interventional and surgical. Myomectomy is the gold
55 standard uterine preserving surgical option, and whenever possible, a minimally invasive
56 approach requires less pain medication, faster recovery, decreased intraoperative blood loss and
57 shorter hospital stay compared to open myomectomy.⁴

58 Laparoscopic radiofrequency ablation of fibroids (lap-RFA) has gained popularity in
59 recent years as another uterine preserving option for management of fibroids. It is an outpatient
60 procedure that was FDA approved in 2012 for the treatment of fibroid related symptoms.⁵ The
61 treatment is delivered laparoscopically and guided by intra-abdominal ultrasound allowing most
62 women returning to normal activities in 3-4 days.⁶

63 The heterogeneity of fibroid symptoms and disease burden necessitate individualized,
64 tailored approach to treatment. Combining laparoscopic myomectomy (lap-MYO) and lap-RFA
65 offers surgeons the possibility to optimize outcomes and successful symptom management
66 without the constraints of a single technique. However, there is little information on outcomes
67 after this combined approach. The aim of this study was to describe participant characteristics,
68 surgical complications and quality of life outcomes after combined lap-RFA and lap-MYO.

69

70 **Methodology**

The Uterine Leiomyoma Treatment with Radiofrequency Ablation (ULTRA) study is an IRB approved multicenter longitudinal study of lap-RFA. Starting in 2014, ULTRA enrolled women undergoing lap-RFA procedures at a single academic center and then expanded the study to other sites. In 2020, ULTRA also enrolled women undergoing planned laparoscopic or abdominal myomectomy to develop a uterine sparing surgical comparison group for lap-RFA. We describe a subgroup of ULTRA participants who underwent combined, simultaneous minimally invasive procedures of lap-RFA and lap-MYO.

Eligibility criteria for the ULTRA cohort included women who spoke English or Spanish who were scheduled to undergo lap-RFA ablation of fibroids or, starting in 2020, abdominal or laparoscopic myomectomy. Exclusion criteria included women less than 21 years old or those scheduled to undergo hysteroscopic myomectomy.

Participants of the study completed a baseline, pre-operative assessment including questions regarding reproductive health, demographics, medical history and medication use. Pre-operative imaging with ultrasound (US) or magnetic resonance imaging (MRI) was used to document fibroid characteristics including size and number. We estimated total leiomyoma volume by summing the estimated spherical volume of each fibroid based on the available report dimensions using the following formula $V = (4/3) * 3.14159 * (\text{mean}(\text{fibroidsize A, fibroidsize B, fibroidsize C, etc.}) / 2)^3$.⁷ For uterine volume, we used the following formula $V = 0.52 * (L * AP * T)$.⁸ Medical records provided peri-operative details including estimate blood loss, intraoperative complications, and length of hospital stay. The decision behind which fibroids were removed by lap-RFA and which were removed by lap-MYO was determined by each individual surgeon. To assess postoperative complications and recovery, ULTRA asked participants at two days, one week, three weeks and six weeks about pre-specified or other

adverse events (incisional, urinary tract or intraabdominal infections, deep vein thrombosis, blood transfusion, incisional hernia, or abnormal vaginal discharge) and to rate their post-operative pain on a scale from 0 to 10, report their use of pain medication and when they returned to their usual activities and work. At baseline and then at six weeks, three months, six months and 12 months after surgery, ULTRA assessed fibroid-related symptom impact and quality of life impact with the Uterine Fibroid Symptom and Health-Related Quality of Life Questionnaire (UFS-QOL) and sexual functioning with the Sexual Health Outcomes in Women (SHOW-Q) questionnaire. The UFS-QOL measures the domains of symptoms severity (higher scores indicated greater severity) and health related quality of life including activities, concern, control, energy/mood, self-consciousness, sexual function and overall (higher scores indicate better quality of life) and scores them from 0 to 100.^{9,10} The SHOW-Q measures four domains with scores ranging from 0-100.¹¹ Orgasm frequency and quality was measured only in sexually active women and higher scores indicate better frequency and quality. Measured in all women, higher scores for pelvic problems interference with sex indicate worse interference whereas higher scores for sexual desire and satisfaction with sex indicate better sexual function. Finally, women were asked whether they were satisfied with their surgery and would recommend it to a friend at six weeks and 12 months.

We used descriptive statistics to report demographic and clinical characteristics of participants. Categorical variables were reported as counts and percentages. To assess, change from baseline in outcome measures, we used the Wilcoxon signed rank test. All statistical analyses were performed using SAS 9.4 (SAS Institute Inc, Cary, NC), with p value of <0.05 considered statistically significant.

Results

Demographics and Clinical Characteristics: Forty-nine participants enrolled in ULTRA (N = 480) underwent combined lap-RFA and lap-MYO between April 2015 to May 2022. Of the 49 participants, 45 (92%) contributed follow-up observations at 6 weeks and 41 (84%) contributed follow up observations at 12 months. The mean age at enrollment was 40.3 (SD 4.3) years with an average body mass index (BMI) of 30.0 (SD 7.2). Most women self-reported race as Black (N=37, 76%) and White (N=8,16%). Most women worked full time (N=42, 86%) and had completed a college degree or higher education (N=38, 78%). Most of the participants either had never given birth (N=22, 45%), or had had 1-2 live births (N=20, 40%). Preoperative imaging revealed an average of 3.5 (SD 2.0) fibroids with an average total fibroid volume of 161.2 (SD 150.4) cm³ and uterine volume of 519.5 (SD 345.4) cm³. Meanwhile, the average number and volume of fibroids noted with intraoperative laparoscopic ultrasound (LUS) was higher at 6.1 (SD 3.6) and a fibroid volume of 178.1 cm³ (SD 190.6).

Perioperative outcomes and complications: The median estimated blood loss was 54.9 (SD 63.8) cc. One participant reported an intraoperative blood transfusion and five reported overnight hospitalization for observation. No women reported complications at two days after their surgery. One participant reported a wound infection at seven days. Three participants reported minor infections (one bladder and two uterine infections) necessitating the use of antibiotics. One participant reported heavy vaginal bleeding with anemia at six weeks requiring surgical intervention of a myomectomy. The most commonly reported symptom in the six weeks after surgery was vaginal discharge and spotting.

Pain and reported opioid use: The mean self-reported pain score (0-10) fell from 5.4 at 2 days to 1.9 at 3 weeks and 1.4 at 6 weeks. Mirroring this, reported opioid use fell from 60% at 2 days to 7% at 3 weeks and 5% at 6 weeks (Figure 1).

Return to usual activities and work: Return to work and usual activities were similar across time from baseline to 6 weeks following surgery (Figure 2). By 20 days, 85% of participants reported returning to usual activities and 83% reported returning to work. The mean number of days for returning to usual activities was 12.4 (SD 10.1) and returning to work was 13.7 (SD 9.8).

Quality of life: The mean USF-QOL symptom severity score improved from baseline (-9.9, SD 24.4) starting as early as six weeks after the combined procedure. For all other domains of the UFS-QOL, improvement started at the three-month post-operative evaluation and was greatest at 12 months after the combined procedure (Table 2). For example, mean reduction in symptom severity was -37.7 (SD 26.3) points and increase in overall quality of life was 36.6 (SD 29.8) points from before to 12 months after surgery.

Satisfaction: By six weeks after surgery, 37 (82%) patients expressed that they were satisfied with the combined lap-RFA and lap-MYO procedure, 41 (91%) would recommend it to friends, and 42 (93%) felt it was effective in eliminating fibroid symptoms. When considering longevity of satisfaction, 32 (78%) patients remained satisfied, 31 (76%) would recommend it to friends, and 30 (73%) felt it was effective in eliminating symptoms at 12 months.

Sexual function: Overall, SHOW-Q scores in the domains of interference with sex, sexual desire, and satisfaction with sex improved from baseline at 3, 6 and 12 months of follow up (Table 3). However, perceptions of pelvic problem interfering with sex was the only domain to significantly improve by 6 weeks after treatment with a mean change of -13.0 (SD 34.4, $p=0.02$).

The only domain that did not demonstrate significant improvement by 12 months post-procedure for women who were sexually active was orgasm frequency and quality.

Discussion/Conclusions

Treatment options offered by gynecological surgeons available to women with fibroids have long been limited to hysterectomy, myomectomy, and endometrial ablation. With the more recent addition of lap-RFA, women who desire uterine sparing procedures have an additional option, but there may be times when combined treatments will allow better control of symptoms. Our prospective cohort study over 12 months demonstrates that combining lap-RFA and lap-MYO simultaneously had few peri-operative events, satisfactory recovery, as well as improved symptom severity, quality of life and sexual functioning by three months that was durable through 12 months postoperatively.

One of the great benefits of minimally invasive surgery is fewer complications, less postoperative pain and a faster return to work and normal activities compared to open surgery. In our 49 women, we identified few complications and found that our participants reported satisfactory recovery times. For example, the trajectory of opioid medication use was similar to other benign gynecological procedures; a little more than half used opioid pain medication in the first few days of surgery but dropped rapidly to 5% after 6 weeks similar to previous studies of benign hysterectomy.¹² Full return to usual activities and work by 3 weeks in our study was similar to that reported for lap-MYO alone, suggesting that the addition of lap-RFA did not considerably increase recovery time in our 49 participants.¹³

Absolute fibroid reduction can be difficult to achieve during lap-MYO due to reduced tactile feedback and visualization when compared to open abdominal approaches. While pre-

operative imaging is customary prior to myomectomy, not all fibroids may be detected, even with MRI. For example, there may be as much as a 65% increase in the number of fibroids detected on LUS compared to pre-operative ultrasound and MRI.^{14, 15, 16} We report similar findings as total fibroid burden was higher when LUS was used compared to those reported on pre-operative imaging. As RFA utilizes LUS, combining this procedure with lap-MYO may allow surgeons to have the benefit of increasing the number fibroids treated during surgery, leading to greater effectiveness and durability of treatment.

We found that women who underwent combined lap-RFA and lap-MYO reported improvement in many aspects of their lives as early as three months including symptom severity, quality of life and sexual functioning. These improvements persisted through the 12 months of follow up. While we are not able to report objective results of the treatment nor able to compare effectiveness with other treatments, improvement on validated questionnaires combined with subjective reporting of high satisfaction with the surgery that our participants would recommend to friends suggests that treating fibroids with a combined procedure is effective for symptom improvement and emotional satisfaction. The most likely explanation is that reducing fibroid volume through shrinkage and excision together were important for these quality of life improvements and procedural satisfaction.

Our study has a number of strengths. First, over 60% of the women recruited were Black, representing an understudied population who is more impacted by uterine fibroids than other racial or ethnic groups.¹⁷ Similarly, ULTRA had a high representation of nulliparous women, likely because of the study's focus on uterine sparing procedures. Second, we prospectively followed women across multiple time points from before their fibroid procedure to one year after with good retention (84%), thus reducing recall and attrition bias that are often associated with

207 overestimating satisfaction and effectiveness. Third, ULTRA was multi-center study, including
208 both academic centers and private practices making our results generalizable to multiple types of
209 clinical practice.

210 Our study also had a few limitations. First, this is a small study without a comparison arm
211 to assess effectiveness of combining lap-RFA and lap-MYO to each alone or other uterine sparing
212 procedures. However, there is little data on this combined approach and the indications for
213 combining the procedures in the same surgery--such as a unique type of fibroid burden--likely
214 make our participants different from those undergoing lap-RFA or lap-MYO alone. Second, we
215 have few objective measures of operative outcomes (e.g. follow up imaging and records of health
216 care utilization after the procedure), however, our use of standardized quality of life and sexual
217 function measures for fibroids surgery provides comparability with many other fibroid outcome
218 studies.

219 In conclusion, combining lap-RFA and lap-MYO appears to be associated with few peri-
220 operative events, satisfactory recovery time, and significant improvement in quality of life
221 measures with high patient satisfaction through 12 months after surgery.

222

223 **References**

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276 **Tables**

Table 1: Characteristics of women undergoing combined laparoscopic radiofrequency ablation of fibroids and laparoscopic myomectomy in the Uterine Leiomyoma Treatment by Radiofrequency Ablation (ULTRA) Study (2014-2022)		
Variable		
Age at enrollment,	<i>Mean (SD)</i> <i>Median [IQR]</i> <i>Range</i>	40.3 (4.3) 40.0 [38.0 - 43.0] 31.0 - 50.0

Body Mass Index (BMI),	<i>Mean (SD)</i> <i>Median [IQR]</i> <i>Range</i>	30.0 (7.2) 28.3 [24.1 - 34.3] 18.6 - 48.6
Race or Ethnicity, N (%)		
Black		37 (76)
White		8 (16)
Hispanic		4 (9)
Asian		2 (4)
Highest Level of Education, N (%)		
Some college or less		10 (20)
College graduate (4 years BA or equivalent)		15 (31)
Advanced degree		23 (47)
Full time employment, N (%)		42 (86)
Current relationship status		
Married or domestic partner		15 (31)
Divorced/Widowed/Separated		5 (10)
In a significant relationship		12 (24)
Single		17 (35)
Parity, N (%)		
0		22 (45)
1		10 (20)
2		10 (20)
3+		7 (14)
Symptoms reported as indications for surgery, N (%)		
Bleeding		41 (85)
Pelvic Pain/Pressure/Bloating		41 (85)
Painful Sex		20 (42)
Urinary Symptoms		30 (63)
Constipation		19 (40)
Fibroid Characteristics - Preoperative		
Number of fibroids,	<i>Mean (SD)</i> <i>Median [IQR]</i> <i>Range</i>	3.5 (2.0) 3.0 [2.0 - 5.0] 1.0 - 9.0
Fibroid volume (cm ³),	<i>Mean (SD)</i> <i>Median [IQR]</i> <i>Range</i>	161.2 (150.4) 112.5 [65.4 - 199.0] 5.5 - 661.9
Uterine volume (cm ³),	<i>Mean (SD)</i> <i>Median [IQR]</i> <i>Range</i>	519.5 (345.4) 477.9 [314.0 - 714.8] 87.9 - 2226.1
Fibroid Characteristics – Intraoperative		
Number of fibroids,	<i>Mean (SD)</i> <i>Median [IQR]</i> <i>Range</i>	6.1 (3.6) 5.0 [3.0 - 8.0] 1.0 - 17.0
Fibroid volume (cm ³),	<i>Mean (SD)</i> <i>Median [IQR]</i>	178.1 (190.6) 94.1 [64.2 - 233.5]

<i>Range</i>	7.6 - 988.6
N = 49 contributed characteristic data for all variables except as follows: preoperative uterine fibroid number and volume (N = 48) and uterine volume (N = 43). SD = Standard deviation IQR = Intraquartile range	

277

278 **Table 1:** Characteristics of women undergoing combined laparoscopic radiofrequency ablation

279 of fibroids and laparoscopic myomectomy in the Uterine Leiomyoma Treatment by

280 Radiofrequency Ablation (ULTRA) Study (2014-2022)

281

Table 2: Participant survey results from the Uterine Fibroid Symptom & Health-Related Quality of Life Questionnaire (UFS-QOL)* in the Uterine Leiomyoma Treatment by Radiofrequency Ablation (ULTRA) Study (2014-2022)				
Baseline (N=49)				
	Baseline	Follow Up	Change[†]	
Variable	Mean Score (SD[†])	Mean Score (SD[†])	Mean Change (SD[†])	P-Value[§]
Symptom Severity	63.8 (22.1)			
Overall QOL score [¶]	39.9 (25.2)			
Activities	41.9 (29.3)			
Concern	29.9 (30.5)			
Control	41.7 (29.2)			
Energy/mood	43.4 (26.3)			
Self-consciousness	36.2 (31.1)			
Sexual function	46.2 (32.9)			
6 Week Post-Operative Visit (N=45)				
	Baseline	Follow Up	Change[†]	
Variable	Mean Score (SD[†])	Mean Score (SD[†])	Mean Change SD[†]	P-Value[§]
Symptom Severity	63.0 (21.9)	52.1 (24.4)	-10.9 (24.8)	0.01
Overall QOL score [¶]	40.3 (24.8)	44.7 (24.1)	4.3 (20.6)	0.16
Activities	42.5 (29.6)	46.3 (27.0)	3.8 (23.9)	0.39
Concern	30.2 (29.8)	36.6 (28.7)	6.3 (22.0)	0.03
Control	42.6 (28.2)	48.6 (29.0)	6.1 (25.8)	0.04
Energy/mood	43.7 (26.7)	46.5 (27.9)	2.8 (21.9)	0.55
Self-consciousness	36.3 (30.4)	42.2 (27.1)	5.9 (28.0)	0.05

Sexual function	46.7 (33.1)	46.7 (31.8)	0.0 (36.6)	0.76
3 Month Post Operative Visit (N=42)				
	Baseline	Follow Up	Change[†]	
Variable	Mean Score (SD[†])	Mean Score (SD[†])	Mean Change (SD[†])	P-Value[§]
Symptom Severity	61.8 (22.0)	28.9 (22.5)	-33.0 (29.4)	<.0001
Overall QOL score [¶]	41.9 (25.1)	72.5 (28.0)	30.6 (32.0)	<.0001
Activities	43.9 (29.0)	74.6 (29.6)	30.7 (35.0)	<.0001
Concern	33.0 (31.3)	68.5 (33.2)	35.5 (34.0)	<.0001
Control	43.9 (29.1)	75.4 (28.7)	31.4 (36.7)	<.0001
Energy/mood	44.9 (26.8)	74.2 (27.7)	29.3 (31.8)	<.0001
Self-consciousness	38.1 (31.1)	70.0 (30.8)	31.9 (40.3)	<.0001
Sexual function	47.3 (32.4)	65.2 (36.3)	17.9 (41.4)	0.0068
6 Month Post-Operative Visit (N = 41)				
	Baseline	Follow Up	Change[†]	
Variable	Mean Score (SD[†])	Mean Score (SD[†])	Mean Change (SD[†])	P-Value[§]
Symptom Severity	60.7 (22.0)	24.5 (18.5)	-36.3 (27.0)	<.0001
Overall QOL score [¶]	42.7 (26.1)	78.0 (22.7)	35.4 (27.2)	<.0001
Activities	45.2 (30.0)	80.7 (23.7)	35.5 (28.9)	<.0001
Concern	34.3 (31.5)	74.6 (28.0)	40.4 (32.0)	<.0001
Control	44.5 (30.0)	79.9 (23.7)	35.4 (32.6)	<.0001
Energy/mood	44.8 (27.8)	79.9 (22.7)	35.1 (27.7)	<.0001
Self-consciousness	40.0 (32.0)	73.0 (25.3)	32.9 (34.9)	<.0001
Sexual function	47.0 (34.1)	73.8 (28.8)	26.8 (39.7)	<.0001
12 Month Post-Operative Visit (N = 41)				
	Baseline	Follow Up	Change[†]	
Variable	Mean Score (SD[†])	Mean Score (SD[†])	Mean Change (SD[†])	P-Value[§]
Symptom Severity	61.0 (22.2)	24.6 (19.7)	-36.4 (24.7)	<.0001
Overall QOL score [¶]	41.5 (25.2)	76.5 (23.7)	35.0 (29.4)	<.0001
Activities	44.3 (28.8)	80.9 (24.0)	36.6 (31.2)	<.0001
Concern	31.6 (31.0)	72.0 (30.3)	40.4 (31.5)	<.0001
Control	43.7 (29.3)	79.8 (23.8)	36.1 (33.8)	<.0001
Energy/mood	44.3 (27.1)	77.3 (24.1)	33.0 (31.2)	<.0001
Self-consciousness	38.6 (30.5)	70.7 (26.9)	32.1 (37.5)	<.0001
Sexual function	45.1 (33.2)	70.4 (28.2)	25.3 (38.7)	0.0001
* Harding, G., Coyne, K. S., Thompson, C. L., & Spies, J. B. (2008). The responsiveness of the				

uterine fibroid symptom and health-related quality of life questionnaire (UFS-QOL). *Health and Quality of Life Outcomes*, 6, 99.

† Change is calculated as follow-up value minus baseline value.

‡ SD = standard deviation

§ Signed Rank test

|| Symptom severity: scores range from 0 to 100, higher scores indicate greater severity.

¶ UFS-QOL Overall score and domain scores (concern, activities, energy/mood, control, self-consciousness, sexual function): range from 0 to 100, higher score indicates better quality of life.

282
283 **Table 2:** Participant survey results from the Uterine Fibroid Symptom & Health-Related Quality
284 of Life Questionnaire (UFS-QOL)* in the Uterine Leiomyoma Treatment by Radiofrequency
285 Ablation (ULTRA) Study (2014-2022)

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Table 3. Participant survey results from the Sexual Health Outcomes in Women Questionnaire (SHOW-Q)* in the Uterine Leiomyoma Treatment by Radiofrequency Ablation (ULTRA) Study (2014-2022)					
Variable	N	Baseline Mean[†] (SD[§])	Follow-up Mean[†] (SD[§])	Change[†] Mean[†] (SD[§])	P- Value
Baseline					
Orgasm frequency and quality scale¶	38	55.2 (28.0)			
Pelvic problem interference with sex [#]	48	38.5 (32.5)			
Sexual desire**	48	45.7 (33.1)			
Satisfaction with sex**	47	49.5 (32.8)			
6 Week Post Operative Visit					
Orgasm frequency and quality scale¶	22	58.5 (22.7)	62.6 (26.3)	4.1 (17.1)	0.21
Pelvic problem interference with sex [#]	43	40.1 (31.4)	27.1 (29.3)	-13.0 (34.4)	0.02
Sexual desire**	43	48.1 (32.4)	52.1 (29.6)	4.1 (31.6)	0.33
Satisfaction with sex**	41	49.4 (31.9)	56.7 (29.7)	7.3 (31.4)	0.20
3 Month Post Operative Visit					
Orgasm frequency and quality	30	55.9 (26.3)	65.0 (25.2)	9.1 (21.4)	0.02

scale [¶]					
Pelvic problem interference with sex [#]	41	40.4 (30.8)	14.8 (20.7)	-25.6 (33.7)	<.0001
Sexual desire ^{**}	41	49.7 (30.8)	57.6 (25.5)	7.9 (32.3)	0.15
Satisfaction with sex ^{**}	40	50.9 (32.7)	67.8 (28.0)	16.9 (35.9)	0.0026
6 Month Post Operative Visit					
Orgasm frequency and quality scale [¶]	28	60.7 (22.6)	66.4 (22.5)	5.7 (23.7)	0.22
Pelvic problem interference with sex [#]	39	37.2 (32.2)	12.0 (15.9)	-25.2 (33.6)	<.0001
Sexual desire ^{**}	39	48.6 (31.1)	62.4 (26.8)	13.8 (29.4)	0.0079
Satisfaction with sex ^{**}	38	52.0 (33.6)	70.4 (23.0)	18.4 (35.0)	0.0029
12 Month Post Operative Visit					
Orgasm frequency and quality scale [¶]	30	60.2 (22.2)	62.9 (24.9)	2.7 (21.8)	0.57
Pelvic problem interference with sex [¶]	40	36.0 (31.4)	15.0 (16.5)	-21.0 (33.2)	<.0001
Sexual desire [#]	40	47.5 (31.9)	64.0 (29.5)	16.5 (33.3)	0.0046
Satisfaction with sex ^{**}	39	51.0 (32.9)	69.2 (25.0)	18.3 (36.6)	0.0031
* Learman, L. A., Huang, A. J., Nakagawa, S., Gregorich, S. E., & Kuppermann, M. (2008). Development and validation of a sexual functioning measure for use in diverse women's health outcome studies. <i>American Journal of Obstetrics and Gynecology</i>, 198(6), 710.e1-8; discussion 710.e8-9. † Change calculated as follow-up value minus baseline value. ‡ SHOW-Q scores range from 0 to 100. § SD = standard deviation Signed Rank test ¶ Orgasm measured only in sexually active women: higher scores indicate better orgasm frequency and quality. # Pelvic problem interference with sex: higher scores indicate worse interference. ** Sexual desire and satisfaction: higher scores indicate better sexual function.					

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289 **Table 3.** Participant survey results from the Sexual Health Outcomes in Women Questionnaire

290 (SHOW-Q)* in the Uterine Leiomyoma Treatment by Radiofrequency Ablation (ULTRA) Study

291 (2014-2022)

292

293 **Figure Legends**

294 **Figure 1:** Percent of Women Using Opioid Pain Medication and Average Self-Reported Pain
295 Score with 95% Confidence Intervals* by Weeks After Combined Laparoscopic Radio-
296 Frequency Ablation and Myomectomy Surgery in the Uterine Leiomyoma Treatment by
297 Radiofrequency Ablation (ULTRA) Study (2014-2022)

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299 **Figure 2.** Percent of Women Reporting Return to Usual Activities and Work with 95%
300 Confidence Intervals* by Days After Combined Laparoscopic Radio-Frequency Ablation and
301 Myomectomy Surgery in the Uterine Leiomyoma Treatment by Radiofrequency Ablation
302 (ULTRA) Study (2014-2022)

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