Long-term results of transcervical, intrauterine ultrasound-guided radiofrequency ablation of uterine fibroids with the Sonata System: a retrospective follow-up study

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BACKGROUND: The Sonata System is a new minimally invasive, transcervical, uterine-sparing treatment option for fibroids with a mainly intramural location. The device combines intrauterine ultrasonography with radiofrequency ablation. Long-term follow-up data are still lacking.

OBJECTIVE: This study aimed to evaluate long-term outcomes of the Sonata System in terms of surgical reintervention and to identify factors predicting surgical reintervention. Moreover, patient satisfaction, fibroid size reduction, and complication rate were evaluated.

STUDY DESIGN: We performed a retrospective single-center cohort study of 53 women who underwent Sonata treatment between December 2011 and April 2019. Medical chart review was conducted to collect data on surgical reintervention and patient, fibroid, and surgery characteristics. The follow-up period lasted from date of initial surgery until April 2020. In addition, women filled out a questionnaire at a single time point (April 2020) containing questions about surgical reintervention and patient satisfaction. Kaplan–Meier analysis was used to determine cumulative reintervention rates and median time without reintervention. Univariate Cox regression analyses were performed to identify factors predicting surgical reintervention.

RESULTS: Median follow-up period was 36 months (interquartile range, 22–58). Twenty-four women (45.3%) underwent a surgical reintervention, of which most were hysteroscopic myomectomies (45.8%). Surgical reintervention rates as determined by Kaplan–Meier analysis at 1-year and 2-year follow-up were 24.5% and 39.8%, respectively. Eventually, 7 women (13.2%) underwent a hysterectomy after the Sonata treatment. Univariate Cox regression analyses were performed, but did not show a significant association between surgical reintervention and age, preoperative fibroid size, type of ablated fibroid, number of ablated fibroids, and presence of other fibroids that could not be ablated during the Sonata procedure. Median fibroid diameter was 41 mm (interquartile range, 29–50) before and 29 mm (interquartile range, 20–40) after treatment ($Z=−5.01; P<.001; 95\%$ confidence interval, $−13.0$ to $7.0$). Thirty-four women (69.4%) were satisfied with the treatment effect, and 42 women (85.7%) would recommend the Sonata treatment to other women. No device-related complications occurred.

CONCLUSION: The Sonata System is a safe and minimally invasive treatment option for women suffering from (partly) intramural fibroids. The findings of this long-term follow-up study support counseling women for treatment with the Sonata System. More prospective studies with long-term follow-up are needed to investigate for which type and size of uterine fibroid the Sonata System is of most value.

Keywords: radiofrequency ablation, Sonata, transcervical, uterine fibroids
Introduction

Uterine fibroids—also called leiomyomata—are a common gynecologic problem in premenopausal women, with an estimated cumulative incidence of 70% to 80% by the age of 50. They can cause symptoms of heavy menstrual bleeding, dysmenorrhea, and pelvic pain, which have a negative impact on women’s quality of life.²,³ There are several treatment options for fibroids. Although hysteroscopic removal is a good minimally invasive treatment option and remains the gold standard for submucosal fibroids,⁴ few minimally invasive treatment options for fibroids without an intracavitary component exist. Hysterectomy remains the most commonly performed fibroid-related surgery.⁵ However, most women with fibroids express a preference for uterine-preserving treatment options without invasive surgery.⁶ Radiofrequency ablation (RFA) is an emerging minimally invasive treatment targeting fibroid-related symptoms by inducing coagulative necrosis and depressing estrogen and progesterone receptor expression in the ablated tissue.⁷ RFA can be performed through a transvaginal, transcervical, and laparoscopic route.⁸ The Sonata System (Gynesonics, Redwood City, CA) integrates RFA with intrauterine ultrasonography. This medical device combines an RFA handpiece with an intrauterine ultrasound probe, which is inserted transcervically. This enables incisionless and minimally invasive treatment of intramural fibroids (International Federation of Gynecology and Obstetrics [FIGO] types 3, 4, 5, and 2−5), although treatment of type-1 and -2 fibroids is also possible.⁹ The first 2 prospective cohort studies evaluating the Sonata System in respectively 50 and 147 women showed significant reduction in total fibroid volume and fibroid-related complaints, with low surgical reintervention rates.¹⁰−¹³ However, these study populations were followed up for a short time, and evaluation of large cohorts with a long follow-up period is still lacking.

In the Máxima Medical Center, treatment with the Sonata System has been performed since 2011. Because of the lack of long-term results, we decided to perform a retrospective cohort study to evaluate the surgical reintervention rate and patient satisfaction in women treated with the Sonata System. In addition, we aimed to identify factors predicting surgical reintervention.

Material and Methods

A single-center retrospective cohort study was performed. All women who underwent Sonata treatment between December 2011 and April 2019 were identified. The follow-up period lasted from the date of initial surgery until April 2020, to ensure a minimum follow-up period of 12 months. Data were collected through medical chart review, and a questionnaire was sent at a single time point.

All Sonata procedures were performed by a single surgeon (M.B.) under general anesthesia, spinal anesthesia, or procedural sedation and analgesia. An extensive explanation of the Sonata procedure was described elsewhere.¹⁰,¹⁴ Sonata procedures were performed on FIGO type 2, 3, 4, 5, and 2-5 fibroids. Determination of the FIGO classification of the fibroids was performed by transvaginal ultrasound or magnetic resonance imaging (MRI) if available. In case of any uncertainty on the classification, an additional hysteroscopy or a saline infusion sonohysterography was used.

Women were discharged the same day, and follow-up appointments were planned at our outpatient clinic at approximately 6 weeks, 3 months, 6 months, and occasionally 12 months. Transvaginal ultrasonography or MRI was used for fibroid size evaluation. During the period of this retrospective cohort study, our clinic participated in international prospective cohort studies on the Sonata treatment. Hence, some of the women were included in these studies as well.¹⁰,¹⁵ Our primary outcome measure of surgical reintervention was defined as the need for a new surgical intervention because of fibroid-related symptoms and/or abnormal uterine bleeding. Secondary outcomes were fibroid size reduction, patient satisfaction, presence of peri- and postoperative complications, and potential factors predicting surgical reintervention.

Data on patient, fibroid, and surgery characteristics were retrieved from medical files. In addition, follow-up data were collected on surgical reintervention, hormonal reintervention, postoperative complications, and fibroid size.

Fibroid types were categorized into FIGO type 2, type 2-5, and other (types 3, 4, 5, 6).⁹ For fibroid size evaluation, fibroids’ maximum diameters were used. To evaluate the Sonata treatment effect on fibroid size, fibroid measurements from a follow-up visit approximately 6 months after the Sonata treatment were used.

When MRI was available for size evaluation, these measurements were used for analysis.

Patients received a self-tailored, standardized, nonvalidated questionnaire at a single time point (April 2020) by post or email, to avoid missing surgical reinterventions performed in another hospital and to evaluate patient satisfaction. In addition to surgical and hormonal reintervention, women were asked whether they were satisfied with the treatment effect, whether they would recommend the Sonata treatment to other women with comparable symptoms, to what extent they experienced fibroid-related symptoms before Sonata treatment (on a 5-point Likert scale, in which the top 2 choices were considered relevant), and whether their fibroid-related symptoms had improved (and if not, whether they had remained the same or had deteriorated). This questionnaire can be found in Supplemental Files 1 and 2.

Statistical analysis

Data were analyzed using IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp, Armonk, NY). Categorical variables were described as numbers with percentages, and the chi square test was used for testing significance. Continuous data were described as means with standard deviation (SD) if normally distributed, or medians with...
interquartile ranges (IQRs) when data were skewed. A Wilcoxon signed-rank test was used for testing significance, with the use of the Hodges–Lehmann estimator to calculate the corresponding confidence interval (CI). A Kaplan–Meier analysis was used to determine cumulative reintervention rates and median time without reintervention, with standard errors (SEs) and CIs. Univariate Cox regression analyses were performed to identify factors that were associated with surgical reintervention. When multiple fibroids were ablated in women, the largest fibroid was used for these analyses.

**Ethical approval**

The medical ethical committee of Máxima Medical Center reviewed the study protocol (reference number N19.053) and confirmed that the Medical Research Involving Human Subjects Act did not apply to our study.

**Results**

**Patients**

Between December 2011 and April 2019, 62 women underwent treatment with the Sonata device. After assessment of eligibility, 9 women were excluded. Reasons for exclusion are shown in Figure 1. Forty-seven women gave informed consent for both chart review and survey, 4 allowed only chart review, and 2 agreed to participate in the survey only. Hence, follow-up data were available for 53 women. Among them were 7 women who underwent Sonata treatment as part of the Fibroid Ablation Study-EU (FAST-EU) trial and 6 women who were enrolled in a study evaluating uterine patency after Sonata treatment. Results of these studies are presented elsewhere.10,15

Baseline characteristics are shown in Table 1. Mean age at the time of surgery was 45.1 years (SD, 5.3). Preoperatively, 35 women (66.0%) used hormonal medication or tranexamic acid for reduction of fibroid-related complaints. Seven women (13.2%) had a previous hysteroscopic myomectomy.

Perioperative fibroid characteristics are shown in Table 2. In 51 women for whom chart review was allowed, 75 fibroids were ablated. Median procedure time was 31 minutes (IQR, 25–39).

Median number of ablated fibroids per woman was 1 (IQR, 1–2), with a range of 1 to 5. Most ablated fibroids were type-2 (45.8%). The group of fibroids categorized as “other” consisted of 9 type-3 fibroids (45.0%), 7 type-4 fibroids (35.0%), 3 type-5 fibroids (15.0%), and 1 type-6 fibroid (5.0%). Among 20 women (39.2%), in addition to the fibroids that were ablated during the procedure, there were other fibroids present that could not be treated with the Sonata device.

At baseline the median maximum diameter of the fibroids was 41 mm (IQR, 29–50), and for type-2 fibroids specifically the diameter was 41.5 mm (IQR, 30.8–50).

Of the Sonata patients who completed the questionnaires, before Sonata treatment, 93.5% (n=43) suffered from heavy menstrual bleeding, 45.7% (n=21) from pain in the lower abdomen, 45.2% (n=19) from bulging symptoms, 31.7% (n=13) from leg pain, 23.9% (n=11) from back pain, and 15.4% from pain during sexual intercourse (n=6). Of the patients, 68.9% (n=31) experienced multiple symptoms simultaneously.

**Follow-up**

Median follow-up time was 36 months (IQR, 22–58), with a range of 13 to 101 months. All 49 women who gave informed consent to participate in our survey answered the questionnaires, resulting in a response rate of 100%.

**Reintervention**

Surgical reintervention occurred in 24 women (45.3%). Nine women (17.0%) underwent a second reintervention and 1 woman (1.9%) a third reintervention. Data on type and number of reinterventions are presented in Table 3. Median time until first surgical reintervention was 11 months (IQR, 8–16). A Kaplan–Meier survival analysis was performed, showing that at 12 months 75.5% of women were free from surgical reintervention (SE, 0.059; 95% CI, 0.64–0.87). At 24 months, this percentage was 60.2% (SE, 0.070; 95% CI, 0.46–0.74) (Figure 2). Median time without
reintervention was 61 months (SE, 24.16; 95% CI, 13.64−108.36).

In the first surgical reintervention group, a hysteroscopic myomectomy was the most performed reintervention (45.8%). In this “additional hysteroscopic myomectomy” group, the initial Sonata treatment was performed on 6 women with a type-2 fibroid (54.5%), 2 women with a type-2–5 fibroid (18.2%), 2 women with a type-3 fibroid (18.2%), and 1 woman with a type-4 fibroid (9.1%). Median time until additional hysteroscopic myomectomy was 8 months (IQR, 6−15).

Univariate Cox regression analyses were performed but did not show a significant association between surgical reintervention and age, preoperative fibroid size, type of ablated fibroid, number of ablated fibroids, and presence of other fibroids that could not be ablated during the Sonata procedure (Table 4).

Hormonal reintervention occurred in 12 women (22.6%); this included oral contraception (n=4; 7.5%), levonorgestrel intrauterine device (n=4; 7.5%), ulipristal acetate (n=3; 5.7%), and a gonadotropin-releasing hormone analog (n=1; 1.9%).

**Patient satisfaction**

Thirty-four women (69.4%) were satisfied with the treatment effect and 35 (71.4%) indicated that their fibroid-related symptoms had improved. Of the remaining 14 women, 13 (92.9%) stated that their symptoms remained unchanged, and 1 (7.1%) indicated that her symptoms had deteriorated. Surgical reintervention was associated with lower patient satisfaction (χ² (1)=20.50; P<.001) (Table 5). Forty-two women (85.7%) would recommend the Sonata treatment to other women experiencing similar symptoms. From the 24 women undergoing surgical reintervention, 16 (66.7%) would recommend the Sonata treatment to other women.

**Complications**

No perioperative complications occurred. Three minor postoperative complications (5.7%) were observed. First, 1 woman had a urinary tract infection 5 days postoperatively that was successfully treated with oral antibiotics. Second, 1 woman presented with a superficial thrombophlebitis in her left calf 1 week postoperatively. She was treated with compression stockings and analgesics for 7 days, after which she recovered well. Finally, 1 woman complained of severe headache for 4 days after the procedure (performed under spinal anesthesia), which was managed conservatively, and full recovery was observed.

**Fibroid size reduction**

Fibroid size was evaluated by transvaginal ultrasonography in 39 women (83%) and by MRI in 8 women (17%). Mean interval between Sonata treatment and fibroid size evaluation was 4.3 months (SD, 2.5). Preoperatively, median maximum fibroid diameter was 41 mm (IQR, 29−50). Postoperatively, this diameter was 29 mm (IQR, 20

![FIGURE 1](https://example.com/image1.png)

Flowchart of study selection for women undergoing Sonata treatment in Máxima Medical Center from December 2011 until April 2019.

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**TABLE 1**

Baseline characteristics of women undergoing Sonata treatment

| Baseline characteristics | n=51 |
|--------------------------|------|
| Age (y; mean, SD)        | 45.1 (5.3) |
| BMI (kg/m²; median, IQR) | 24.1 (21.4−29.4) |
| Parity (median, IQR)     | 1.0 (0.0−2.0) |

Use of preoperative fibroid-related medication (n, %)

| Medication         | n  |
|--------------------|----|
| None               | 16 (31.4) |
| Oral contraception| 15 (29.4) |
| Levonorgestrel IUD | 7 (15.7) |
| Ulipristal acetate | 8 (13.7) |
| GnRH analog        | 1 (2.0) |
| Tranexamic acid    | 4 (7.8) |

Baseline characteristics of 51 women who underwent Sonata treatment and consented to medical chart review. Percentages are column percentages based on the number of observations available.

BMI, body mass index; GnRH, gonadotropin-releasing hormone; IQR, interquartile range; IUD, intrauterine device; SD, standard deviation.

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Sonata treatment had led to a significant fibroid size reduction ($Z = -5.01; P < 0.001; 95\% \text{ CI}, -13.0$ to $-7.0$). Median fibroid diameter reduction was 8.5 mm (IQR, 4.0–16.3). The amount of fibroid size reduction was not significantly associated with surgical reintervention.

### TABLE 2

Pre- and perioperative fibroid characteristics of women undergoing Sonata treatment

| Fibroid characteristics                   | n=75 |
|-------------------------------------------|------|
| Number of ablated fibroids per women (median, IQR) | 1 (1–2) |
| Fibroid ablation time (min; median, IQR)    | 4.7 (4–6.8) |
| Preoperative fibroid size (max diameter in mm; median, IQR) | 41 (29–50) |
| Type 2                                     | 41.5 (30.8–50) |
| Type 2-5                                   | 45 (40–54) |
| Other                                      | 30 (20–49) |
| Type 2 (%)                                 | 33 (45.8) |
| Type 2-5 (%)                               | 19 (26.4) |
| Other (%)                                  | 20 (27.8) |
| Location of fibroid (%)                    |      |
| Anterior wall                              | 22 (31.9) |
| Posterior wall                             | 21 (30.4) |
| Right wall                                 | 1 (1.4)  |
| Left wall                                  | 6 (8.7)  |
| Fundal                                     | 19 (27.5) |

Characteristics of 75 fibroids ablated in 51 women who consented to medical chart review. Percentages are column percentages based on the number of observations available.

IQR, interquartile range.

The group of fibroids categorized as “other” consisted of 9 type-3 fibroids (45.0%), 7 type-4 fibroids (35.0%), 3 type-5 fibroids (15.0%), and 1 type-6 fibroid (5.0%).

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### TABLE 3

Surgical reintervention after Sonata treatment

| Surgical reintervention | First reintervention | Second reintervention | Third reintervention |
|-------------------------|----------------------|-----------------------|----------------------|
| Yes                     | 24 (45.3)            | 9 (17.0)              | 1 (1.9)              |
| Hysteroscopic myomectomy| 11 (45.8)            | 2 (22.2)              | 1 (100.0)            |
| Endometrial ablation    | 2 (8.3)              |                       |                      |
| Sonata                  | 3 (12.5)             | 1 (11.1)              |                      |
| Laparoscopic myomectomy | 3 (12.5)             |                       |                      |
| Uterine artery embolization | 1 (4.2)        | 2 (22.2)              |                      |
| Hysterecomy             | 3 (12.5)             | 4 (44.4)              |                      |
| Hysteroscopic endometrial resection | 1 (4.2) |                      |                      |

Data on surgical reintervention for 53 women (medical chart review and questionnaires combined). Data are presented as numbers of patients and percentages.

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Comment

**Principal findings**

This retrospective cohort study provides a long-term evaluation of uterine fibroid treatment by transcervical, intrauterine ultrasound-guided RFA with the Sonata System in 53 women. Median follow-up time was 36 months (IQR, 22–58), and surgical reintervention occurred in 24 women (45.3%). Thirty-four women (69.4%) were satisfied with the treatment effect, and 42 women (85.7%) would recommend the Sonata treatment to others. Three minor postoperative complications and no perioperative complications occurred. Fibroid size was significantly reduced.

**Clinical implications**

Data on long-term results of the Sonata System are still limited. However, Christopher et al. published an article in 2021 providing the first preliminary results of the SAGE ongoing postmarket worldwide registry, in which they investigated long-term outcomes up to 5 years after Sonata treatment. Currently, only safety data and no long-term reintervention data have been published.16 Thus far, 2 (manufacturer-initiated and sponsored) prospective cohort studies have presented data on surgical reintervention after Sonata treatment: the FAST-EU study (n=50) and the Sonography Guided Transcervical Ablation of Uterine Fibroids (SONATA) pivotal trial (n=147). Surgical reintervention rates at 12-month follow-up were 8.0% and 0.7%, respectively.10,11 In the SONATA trial, this percentage was 5.5% at 24 months and 9.2% at 36 months (n=132).12,13 In addition, a retrospective cohort study of 17 women who underwent Sonata treatment as part of the FAST-EU study in Mexico published 5-year follow-up data and found a reintervention rate of 11.8%.17 Our study found a reintervention rate of 24.5% at 1-year and 39.8% at 2-year follow-up.

There could be several explanations for the differences in reintervention rates. First, the FAST-EU trial and the SONATA pivotal trial used strict selection criteria. In our study, we also included women who underwent Sonata...
treatment outside of a clinical trial. This might have led to a more heterogeneous study population, possibly resulting in a higher reintervention rate.

Second, in our study most ablated fibroids were type-2 or type-2-5 (72.2%). In the other studies, most ablated fibroids were type-3 or -4 (48.8% in the SONATA trial and 45.7% in the FAST-EU trial). A hysteroscopic myomectomy remains the standard treatment for FIGO type-2 fibroids. However, when a type-2 fibroid is >3 cm, the probability of complete resection within a single procedure is low. When a type-2 fibroid is not suitable for hysteroscopic myomectomy because of its size, Sonata treatment is a convenient alternative.

Third, the ablated fibroids in our study had a bigger size. In the other studies, the mean ablated fibroid diameters were 2.5±1.2 cm and 3.2±1.4 cm. However, in our study the mean fibroid diameter was 4.0±1.6 cm, and for type-2 fibroids specifically it was 4.1±1.6 cm. Type-2 fibroids of this diameter are not suitable for a single hysteroscopic myomectomy. For this reason, a single Sonata treatment was preferred over a hysteroscopic myomectomy in multiple sessions.

In our experience, women choosing the Sonata treatment often have a strong desire to preserve their uterus but need a solution for their fibroid-related symptoms, resulting in lower quality of life. In our study, most women who underwent a first surgical reintervention underwent hysteroscopic myomectomy (45.8%). We noticed that a larger portion of the previously ablated fibroid was positioned intracavitarily after Sonata treatment. Thus, a 2-step approach (Sonata treatment followed by hysteroscopic myomectomy) resulted in complete fibroid removal for some patients. Although the surgical reintervention rate after the Sonata treatment is high, this is a risk that these women are often willing to take to preserve their uterus. After all, 66.7% of women who underwent surgical reintervention would still recommend the treatment to others, which is an important finding that should be considered when counseling patients on Sonata treatment. In this long-term follow-up period, only 7 women (13.2%) underwent a hysterectomy.

To establish appropriate expectations, counseling women properly is highly important. The possible need for an additional hysteroscopic myomectomy—as a 2-step approach to fibroid removal—or another surgical reintervention should be discussed. Furthermore, women should be informed about the possibility that it may take some time to achieve the optimal treatment effect because of the long-term ablation effect on fibroid tissue, resulting in continuation of total fibroid volume reduction (as shown by the study of Bröllman et al).

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**TABLE 4**

| Factor (n=51)                        | HR surgical reintervention | 95% CI     | P value |
|-------------------------------------|---------------------------|------------|---------|
| Presence of other fibroids (no/yes) | 0.806                     | (0.34–1.92)| .627    |
| Number of ablated fibroids (1/≥1)   | 0.590                     | (0.22–1.60)| .300    |
| Age                                 | 0.967                     | (0.90–1.04)| .364    |
| Preoperative fibroid size (<50mm/≥50mm) | 1.623                   | (0.68–3.90)| .278    |
| Fibroid type                         |                           |            |         |
| Other Ref                           | 0.567                     | (0.22–1.49)| .250    |
| Type 2                              |                           | 0.376      | (0.12–1.20)| .098    |
| Type 2-5                            |                           |            |         |

Univariate Cox regression analysis for risk of surgical reintervention after Sonata treatment for 51 women who consented to medical chart review.

CI, confidence interval; HR, hazard ratio; Ref, fibroid type used as control.

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Alternative uterine-sparing treatment options for intramural fibroids that can be discussed are abdominal myomectomy and uterine artery embolization, for which surgical re-intervention rates of 12.2% and 14.4% have been described at 60-month follow-up. Although these are lower than the rates in our study, it should be considered that these treatment options are associated with other risks and side effects, such as risk of abdominal scars, bleeding, longer recovery, and pain. In addition, Sonata treatment is associated with lower total payer cost at 12-month follow-up compared with hysterectomy and myomectomy.

**Strengths and limitations**

This study has several strengths. First, it had a long follow-up period; thus far only 1 other study presented 3-year follow-up data. Second, this study combined retrospective chart review with standardized questionnaires to not miss reinterventions performed in other hospitals. Third, we performed the Sonata treatment in a more heterogeneous population. Because this study was not part of an industry-sponsored cohort study with strict inclusion criteria, a wide variety of types and sizes of fibroids were treated, leading to more realistic and generalizable results.

An important limitation of this study is its retrospective nature, resulting in risk of recall bias when answering the questionnaires. In addition, although similar to those of other studies, the sample size was relatively small, which could be a reason that we did not find factors significantly associated with surgical re-intervention in our Cox regression analyses. All Sonata procedures were performed by a single surgeon; therefore, generalizability is limited. However, given the novelty of the procedure, 1 surgeon was chosen to perform the Sonata treatment, which benefits the learning curve and thus the effectiveness of the treatment.

**Conclusions**

The Sonata System is a safe and minimally invasive treatment option for fibroids, for which few minimally invasive treatment alternatives exist. This long-term follow-up study showed a high surgical re-intervention rate in patients undergoing Sonata treatment. Despite this, women still recommended the treatment to other women, and most women did not undergo hysterectomy. It is important when counseling patients to discuss the differences in re-intervention rates and risks between the different treatment options, so that decisions can be made on the basis of patients’ individual preferences. The lack of large follow-up studies stresses the need for more prospective studies with larger patient cohorts with long-term follow-up to determine the uterine fibroid type and size for which the Sonata System is most valuable.

**TABLE 5**

| Surgical reintervention | Satisfied with treatment effect | n=49 | χ² | P value |
|-------------------------|--------------------------------|------|-----|---------|
|                         | No (n, %)                      | Yes (n, %) | Total (n, %) |       |         |
| No                      | 1                              | 2.0  | 26  | 53.1    | 27     | 55.1    | 20.50 | <.001 |
| Yes                     | 14                             | 28.6 | 8   | 16.3    | 22     | 44.9    |       |       |
| Total                   | 15                             | 30.6 | 34  | 69.4    | 49     | 100.0   |       |       |

Patient satisfaction and surgical re-intervention after Sonata treatment for 49 women who consented to participate in the survey. Data are presented as number of patients and percentages. χ² and P value for chi-square test.

*Because 2 reinterventions occurred in women who did not consent to survey participation, the total number of surgical re-intervention presented here is 22 instead of 24 (the total number of surgical reinterventions) as presented in the main text and Table 3.

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**Supplementary materials**

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.xagr.2022.100087.

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