

Laparoscopy vs. Robotic Surgery for Endometriosis (LAROSE): a multicenter, randomized, controlled trial

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Objective: To determine whether the use of the robot for surgical treatment of endometriosis is better than traditional laparoscopy in terms of operative length, perioperative parameters, and quality of life outcomes.

Design: Multicenter, randomized clinical trial.

Setting: University teaching hospitals.

Patient(s): Women aged >18 years with suspected endometriosis who elected to undergo surgical management.

Intervention(s): Randomization to conventional or robot-assisted laparoscopic removal of endometriosis.

Main Outcome Measure(s): The primary outcome measured was operative time. Secondary outcomes were perioperative complications and quality of life.

Result(s): The mean operative time for robotic vs. laparoscopic surgery for endometriosis was 106.6 ± 48.4 minutes vs. 101.6 ± 63.2 minutes. There were no differences in blood loss, intraoperative or postoperative complications, or rates of conversion to laparotomy in the two arms. Both groups reported significant improvement on condition-specific quality of life outcomes at 6 weeks and 6 months.

Conclusion(s): There were no differences in perioperative outcomes between robotic and conventional laparoscopy.

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Key Words: Endometriosis, laparoscopy, perioperative outcomes, quality of life, robot-assisted surgery

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Endometriosis is a common disease, with an estimated incidence of 11% in the population (1). Although patients with endometriosis may be asymptomatic, symptoms that are frequently associated with endometriosis include severe

dysmenorrhea, dyspareunia, pelvic pain, and infertility. It is estimated that approximately 35%–50% of women with pelvic pain, infertility, or both have endometriosis (2, 3). Health care costs for endometriosis are substantial, with 29% of the cost

attributed to the surgical procedure and 18% to hospitalization (4). Endometriosis can be treated by laparotomy, but a minimally invasive approach has been the preferred method since the initial reports of the application of laparoscopy for the diagnosis and treatment of endometriosis (5, 6).

There are limited data describing the use of robotic surgery for endometriosis. The initial reports consisted of cases in which the robotic platform was used for resection of endometriosis located in the bladder, ureter, or rectum, with favorable outcomes (7–11). Two more-recent case series also

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suggested that surgical management of deep infiltrating endometriosis is feasible using robotic assistance (12, 13). These studies included postoperative follow-up questionnaires that suggested clinical improvement but lacked a control group (12, 13).

There are fewer studies comparing robotic surgery with conventional laparoscopy for the treatment of endometriosis (14–16). In these studies both surgical approaches seem to have similar perioperative outcomes, with longer operative times reported in the robotic approach. However, another comparison study reported a 16% shorter operating time for robotics as compared with laparoscopy for patients with deep infiltrating endometriosis (stage III/IV), with operative time as an independent risk factor for postoperative complications and hospital stay (17). Importantly, these studies are retrospective, and long-term postoperative outcomes, such as quality of life and pain scores, have not been investigated. The observed differences in these retrospective studies may be explained by patient selection or surgeon experience. Therefore a randomized clinical trial is needed to assess surgical outcomes.

The objective of this study was to investigate robotic-assisted vs. conventional laparoscopy for the treatment of endometriosis in a prospective fashion, to compare operative times between surgical approaches. Operative time was the primary outcome in all other studies comparing laparoscopy with robotic surgery for endometriosis discussed previously. Additionally, operative time is intrinsically linked to cost, and therefore of significant interest. Secondary outcomes were perioperative and intermediate-term quality of life outcomes.

MATERIALS AND METHODS

This is a multi-institutional randomized control trial that received institutional review board approval at all sites and was registered at clinicaltrials.gov (NCT01556204). Participating institutions included the Cleveland Clinic, Cleveland, Ohio; Mayo Clinic, Scottsdale, Arizona; and Brigham and Women's Hospital, Boston, Massachusetts. Study subjects were recruited from patients who presented to participating surgeons' clinics if they were planning an operation for endometriosis and who were symptomatic with pain or infertility from March 2012 to July 2015. Subjects were randomized for mode of surgery type and followed postoperatively at 6 weeks and 6 months after the date of surgery (Supplemental Fig. 1, available online at www.redjournal.org).

Our primary outcome was operating time, defined as incision to closure time. Secondary outcomes included perioperative data, postoperative pain, and quality of life as measured by the 12-Item Short Form Health Survey (SF-12) and the Endometriosis Health Profile-30 (EHP-30) questionnaire at baseline and 6 weeks and 6 months after surgery (18, 19).

Inclusion Criteria

Women were included if they were aged ≥ 18 years and were undergoing laparoscopic treatment of pain or infertility with

presumed endometriosis as determined by the operating surgeon and/or ultrasound finding of endometrioma(s).

Exclusion Criteria

Exclusion criteria were suspected malignancy, medical illness precluding laparoscopy, inability to give informed consent, morbid obesity (body mass index >44 kg/m²), or need for concomitant bowel resection and/or ureteral reanastomosis. Patients preoperatively known to require bowel resection and/or ureteral reanastomosis were not included, given that these events impact operating time significantly and might not have been distributed equally between both arms.

Randomization

Participants were randomized preoperatively at each site (at the time of surgery scheduling) according to a computer-generated randomization schedule with random number table. Randomization was performed by a research nurse or research fellow. T.F., J.F.M., and M.N.W. performed both conventional and robotic surgery, S.L.C. performed robotic surgery, and J.I.E. performed laparoscopic surgery. All patients were blinded to their assignment until the day of surgery.

Data Collection

In addition to a standardized evaluation including the history and physical examination, enrolled patients completed validated health-related quality of life questionnaires SF-12 and EHP-30, with additional questions to determine baseline pain and activity scales as well as daily pain medication use. Questionnaires were completed in person at baseline, and follow-up questionnaires were mailed to patients. A research nurse or coordinator completed questionnaires over the telephone when applicable per patient choice.

Operative data included total operating room time and time from incision to closure, surgeon-estimated blood loss, intraoperative and postoperative complications, and number of days in the hospital (in cases that warranted admission). Intraoperative complications collected include any injury to bladder, ureter, rectal/large bowel, small bowel, or major blood vessels, complications due to primary trocar or secondary trocar, unexpected delays due to anesthesiology, surgeon, incorrect count, needle lost, need for x-ray, conversion to laparotomy, indication for conversion, and any other applicable intraoperative complications. Postoperative complications collected include deep vein thrombosis, pulmonary embolism, wound seroma, wound infection, need for postoperative antibiotics, blood transfusion, return to operating room, ileus, small bowel obstruction, cardiac complication or myocardial infarction, pulmonary complications/atelectasis, abscess, urinary tract infection (100,000 colony-forming units/mL on culture), neurologic complications, intractable pain, postoperative hospitalization due to surgery/endometriosis, and postoperative emergency room visits. The standard American Society of Reproductive Medicine (ASRM) intraoperative endometriosis scoring system was documented at the end of each surgery (20). A research nurse, study coordinator, or surgeon collected all the operating room data at each institution.

Operative Methods

Each site had experienced laparoscopic and robotic surgeons. Only the surgeons listed on this article (J.F.M., M.N.W., J.I.E., S.L.C., T.F.) performed the surgery, with assistance from residents or fellows.

Laparoscopic-assisted resection of endometriosis was performed using up to five 5-mm ports, including an umbilical port and additional ports as dictated by each individual surgery. Some surgeons used a 12-mm umbilical port at times. The robotic-assisted resection of endometriosis was performed using the da Vinci Surgical System Si (Intuitive Surgical) using up to five ports as needed. No additional technology, such as Firefly Fluorescence Imaging (Intuitive Surgical), was used to identify the lesion. An umbilical port was placed for the laparoscope (10/12 mm), a 5-mm port for the assistant, and two or three ports (5/8 mm) for the robotic arms. Superficial and deep endometriosis resection was performed in the usual standard fashion. All superficial lesions suspicious for endometriosis (pigmented and nonpigmented) were completely resected until nondiseased peritoneal margins were visualized around the defect; all deep lesions suspicious for endometriosis were completely resected until nondiseased margins were visualized in the tissue surrounding the defect. Cystectomy was performed for endometrioma(s). Additional procedures were performed as needed to completely resect all endometriosis lesions, including hysterectomy in some cases. The fascia of any port ≥ 10 mm was reapproximated. Cystoscopy was performed when deemed appropriate by the surgeon.

Statistical Methods

Demographics, descriptive, and perioperative statistics were compared between groups to demonstrate the similarity of the two groups subsequent to randomization. Comparisons between numerical factors were performed by either the Student *t* test or Wilcoxon's rank sum test, with the appropriate test being determined in accordance with the inspection for normality. Categorical factors were compared using the Pearson χ^2 test or Fisher's exact test when expected frequencies were too low to satisfy the conditions of the χ^2 test. General linear regression was performed to evaluate the relationship between the continuous outcomes, such as estimated blood loss and surgery type, adjusting for ASRM score. Logistic regressions were performed to evaluate the relationship between complications and surgery type, controlling for ASRM score. Linear mixed effects models were performed to assess the association between the summarized survey measures and surgery type, time, and interaction between surgery type and time, where the correlation within the same patient at different time points was taken into consideration using repeated measures. Independent variable significance was examined using *t* and *F* tests. A variable was considered significant if the significance level was $<.05$. Variable significance was tested using either the Tukey-Kramer or Dunnett's test to adjust for the multiple comparisons. SAS 9.4 software (SAS Institute) was used for all analyses.

Sample Size Calculation

Variance estimates for this power analysis were taken from Nezhat et al. (14). We determined that 37 subjects in each arm were needed to detect a difference of ≥ 32 minutes in operating time between conventional and robotic surgery for endometriosis, with 80% power and a significance level of .05.

RESULTS

A total of 73 patients were included in the study: 38 in the laparoscopic group and 35 in the robotic group. The baseline characteristics, including body mass index, racial identification, age of patients, indication for surgery, and history of prior medical therapy and pelvic surgery in each arm, were similar and are depicted in Table 1. The most common indications for surgery in both groups included pelvic pain, dysmenorrhea, and dyspareunia. Of the patients with endometrioma as an indication for surgery, all patients had concurrent pain complaints. Patients in both groups had on average one prior laparoscopic surgery, and few had prior robotic surgery. The majority of patients had prior medical therapy, most commonly oral contraceptive pills.

Primary Outcome

The mean operative time for robotic vs. laparoscopic surgery for endometriosis was 106.6 ± 48.4 minutes vs. $101.6 \pm$

TABLE 1

Baseline demographic characteristics of participants.

Characteristic	Robotic (n = 35)	Laparoscopic (n = 38)
Age (y)	34.3 \pm 7.2	34.5 \pm 8.5
Body mass index (kg/m ²)	26.1 \pm 5.2	24.8 \pm 5.9
Race or ethnicity		
White/Caucasian	22 (64.7)	29 (76.3)
Hispanic	8 (23.5)	5 (13.2)
Black/African American	2 (5.9)	2 (5.3)
Asian/Pacific Islander	0 (0)	2 (5.3)
Other	2 (5.9)	0 (0)
Indication for surgery		
Pelvic pain	27 (77.1)	34 (89.5)
Infertility	4 (11.4)	5 (13.2)
Dysmenorrhea	19 (54.3)	16 (42.1)
Dyspareunia	12 (34.3)	15 (39.5)
Endometrioma	6 (17.1)	5 (13.2)
History of infertility	16 (45.7)	13 (34.2)
Previous pelvic surgery		
Ovarian cystectomy	14 (40)	12 (31.6)
Oophorectomy	5 (14.3)	8 (21.1)
Hysterectomy	3 (8.6)	9 (23.7)
Previous laparoscopies	1.2 \pm 1.3	1.2 \pm 1.4
Previous robotic surgeries	0.1 \pm 0.4	0.1 \pm 0.4
Previous medical treatment		
Oral contraceptive pills	30 (85.7)	29 (76.3)
Leuprolide	14 (40)	8 (21.1)
Depot medroxyprogesterone	11 (31.4)	10 (26.3)
Norethindrone	3 (8.6)	1 (2.6)
Levonorgestrel-releasing intrauterine system	6 (17.1)	3 (7.9)
Letrozole/anastrazole	1 (2.9)	1 (2.6)

Note: Data are mean \pm SD or number (percentage). All comparisons had *P* values $>.05$.

Soto. Laparoscopy vs. robotics for endometriosis. Fertil Steril 2017.

63.2 minutes ($P=.71$) (Table 2). A total of six hysterectomies were performed, with no statistically significant differences between arms (four patients in the robotic arm and two patients in the laparoscopic arm, $P=.42$). Intraoperative staging was significant for lower stage of endometriosis in the robotic arm compared with conventional laparoscopy ($P=.018$), although no differences were found in total ASRM score (Table 2). Multivariable analysis showed that after adjusting for stage of disease, there were no statistical differences in operative time ($P=.28$), blood loss ($P=.11$), or intraoperative complications ($P=.74$) between the two surgical approaches. When adjusted for type of surgery, the operating time for stage I/II/no endometriosis patients was 76 minutes less than the operating time for stage III/IV patients ($P<.001$). There were no differences in rate of endometriosis confirmation by pathology between the two surgical approaches. Patients with lesions not meeting strict pathologic criteria for endometriosis (presence of glands and stroma) had mostly fibrosis (95%), with one borderline tumor reported.

Perioperative Outcomes

There were no differences in intraoperative or postoperative complications, rates of conversion to laparotomy, or type of surgery performed in the two arms (Table 2). Two patients in the robotic group required rehospitalization for pain management: one because of pain associated with pyelonephritis and the other for postoperative pain control because of ileus.

TABLE 2

Perioperative characteristics and postoperative complications.

Variable	Robotic (n = 35)	Laparoscopic (n = 38)
Mean operative time (min)	106.6 ± 48.4	101.6 ± 63.2
Mean anesthesia time (min)	157.1 ± 52.7	151.2 ± 69.7
Mean docking time (min)	4.6 ± 5.9	N/A
Estimated blood loss (mL)	100.9 ± 229.8	43.8 ± 39.8
Total ASRM score		
Stage I/II	19 (54.3)	9 (23.7)
Stage III/IV	10 (28.6)	14 (36.8)
No endometriosis	6 (17.1)	15 (39.5)
Pathology		
Endometriosis	23 (65.7)	18 (48.6)
No endometriosis	12 (34.3)	19 (51.4)
Intraoperative complications		
Ureteral complications	0	2 (5.3)
Rectal/large bowel injury	0	1 (2.6)
Small bowel injury	1 (2.9)	0
Conversion to laparotomy	0	1 (2.6)
Postoperative complications		
Wound infection	3 (8.6)	5 (13.5)
Abscess	0	2 (5.4)
Urinary tract infection	3 (8.6)	5 (13.5)
Intractable pain	4 (11.4)	2 (5.4)
Other: catheter associated pain, superficial wound separation, dyspareunia, myofascial pain, urinary retention, vaginal bleeding	8 (22.9)	13 (35.1)

Note: Data are mean ± standard deviation (SD) or number (percentage). All P values were not statistically significant ($>.05$), with the exception of "Total ASRM score" ($P=.018$).

Soto. Laparoscopy vs. robotics for endometriosis. *Fertil Steril* 2017.

Three patients in the laparoscopic group required rehospitalization: two for pain secondary to ileus and abscess and one patient for postoperative urinary tract infection. Other postoperative complications included wound infection/cellulitis (three patients), urinary retention (one patient), and vaginal bleeding (one patient).

EHP-30

When quality of life scores were analyzed using a linear mixed effects model, all parameters, including pain scores, control/powerlessness, emotions, social support, self-image, work, children, sexual intercourse, medical profession, and treatment improved compared with baseline at 6 weeks and 6 months (Fig. 1). The exception is the parameter "Infertility," defined as feelings of anxiety about ability to conceive, which did not improve at 6 weeks ($P=.11$) or 6 months compared with baseline ($P=.84$). No statistical differences were found between groups when each parameter was compared at baseline, 6 weeks, or 6 months on univariate analysis (Supplemental Table 1).

SF-12

The Mental Health Score was comparable between both arms at each time point, with no significant changes at 6 weeks and 6 months compared with baseline (Fig. 2 and Supplemental Table 2). The Physical Health Score was higher in the laparoscopic group at 6 weeks and reached near statistical significance ($P=.055$) but similar at baseline and at 6 months postoperatively (Supplemental Table 2). Within each group, while taking into account changes over time using a linear mixed model effect, scores at 6 weeks and 6 months compared to baseline were not statistically different (Fig. 2). When compared across all time points using a linear mixed model, there were no differences between groups (Supplemental Table 2).

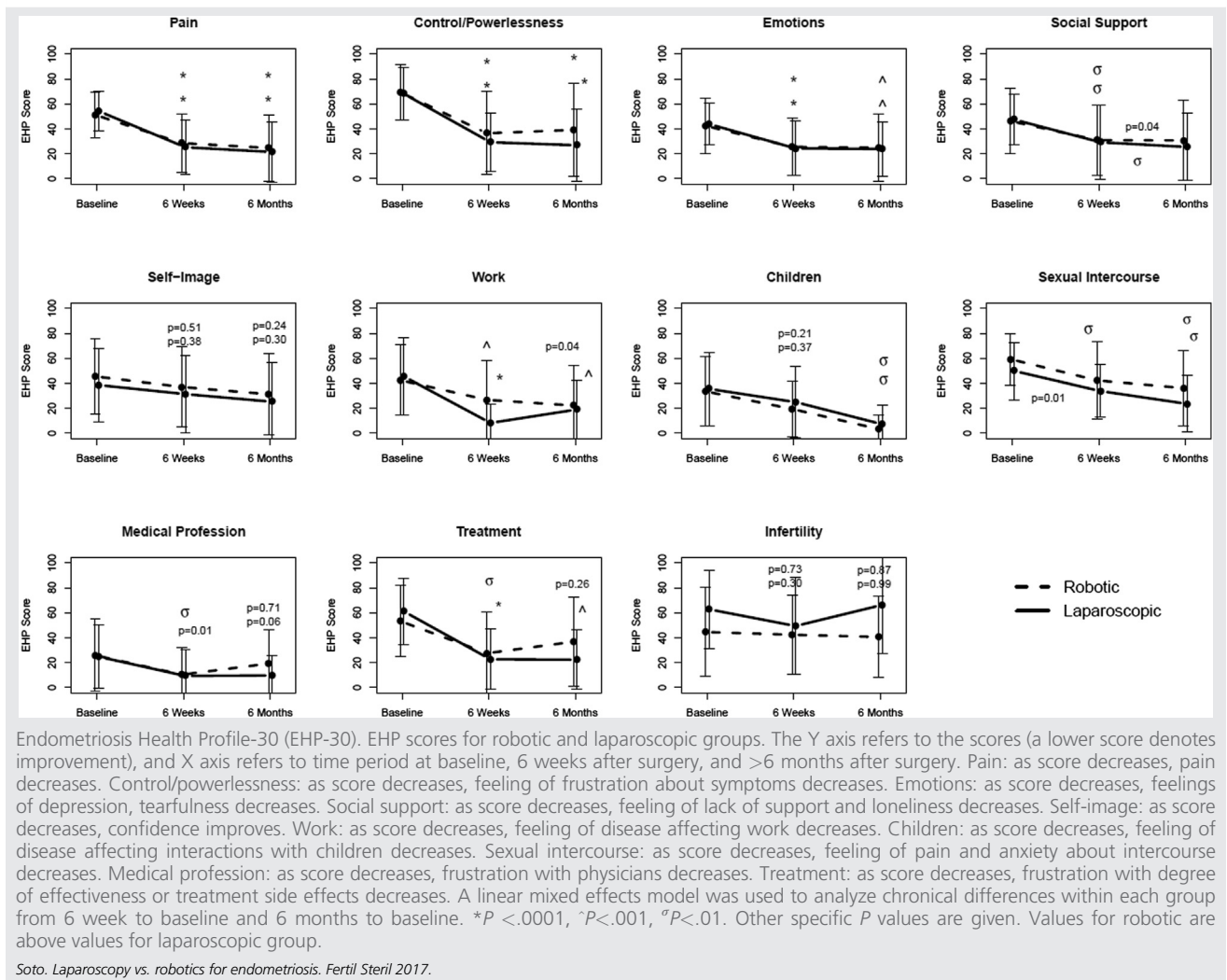
DISCUSSION

This study represents the first multicenter, randomized, controlled trial to compare robotics with laparoscopy for the treatment of endometriosis. No differences were noted in operative time between both groups. The implication of differences in operative time would be cost. However, this study was not designed to assess costs. Additionally, there were no significant clinical differences observed over a 6-month follow-up period with regard to complications or quality of life. Although there were no differences in complications, this study was underpowered to determine a difference.

Notably, the patients in each group improved in all aspects of quality of life scores attesting to the value of surgical intervention in the treatment of endometriosis. It is possible that surgery is so effective in the intermediate term (up to 6 months) that the addition of robotic technology cannot improve on these results.

Although there were no differences in indications for surgery, after randomization, patients in the robotic group were statistically more likely to have a lower stage of endometriosis. This finding confirms the well-known fact that

FIGURE 1



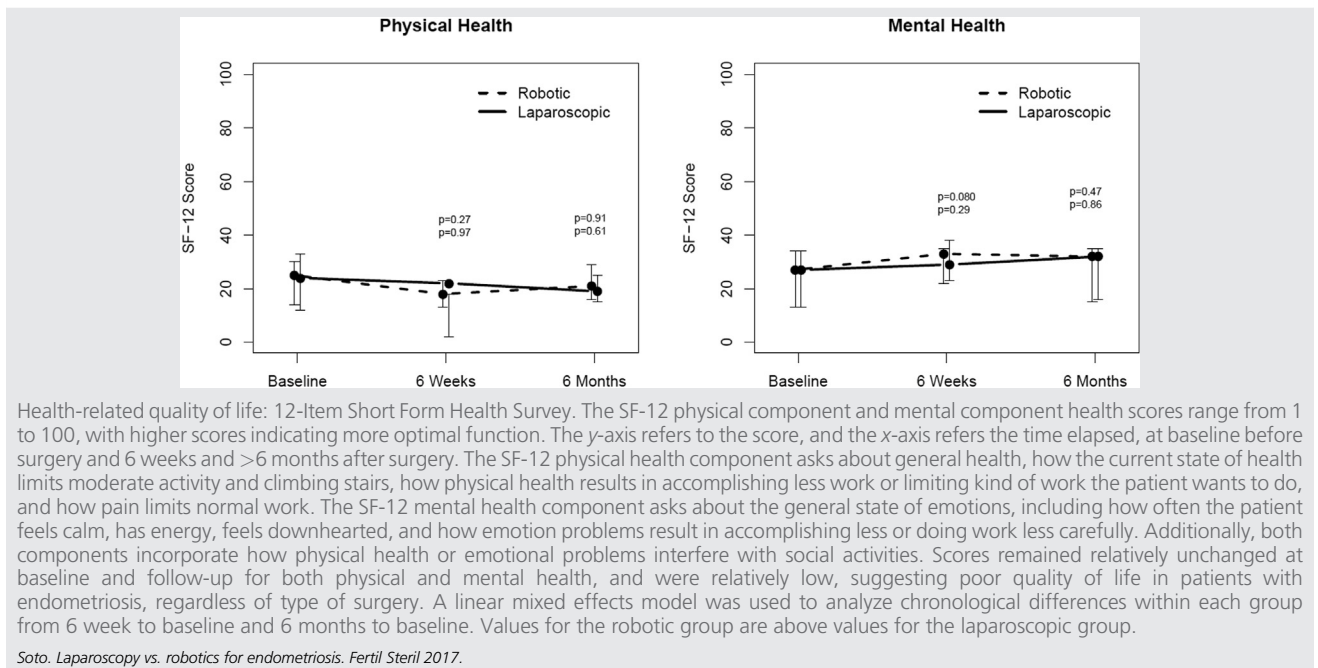
symptoms do not always correlate to stage of disease in endometriosis and underscores the need to consider both operative parameters as well as quality of life outcomes for surgical management of endometriosis. It should be noted that not all patients included in the study had endometriosis. Patients without either intraoperative or histologic confirmation of endometriosis were still included in the study analysis, in keeping with the “intention to treat” concept to avoid crossover effects, which may alter the original randomization. The discrepancy between visual diagnosis of endometriosis and histologic confirmation is well known (21). Pathology reports for patients with no endometriosis revealed mostly chronic inflammation, fibromuscular tissue, fibroadipose tissue, salpingiosis, and fibrous adhesions. One case was significant for a serous borderline tumor. The false-positive rate for endometriosis is 35%; however, most of these patients had low ASRM scores (<15), with the exception of two cases found to have stage IV endometriosis intraoperatively and fibrous adhesions on histology likely due to adhesions from

a completely obliterated cul-de-sac. When adjusted to stage of disease, the operative times were comparable for robotic and laparoscopic surgery. Milder stage of disease, as expected, had a shorter operative time compared with advanced endometriosis, regardless of surgical approach.

The similar operative times demonstrated in this trial stand in contrast to the retrospective studies that have been published to date (14–17). However, it should be noted that mean operative time and blood loss found in this study are within the range of time and volumes previously reported by these other studies, which suggests that our findings are unlikely related to patient selection and surgeon/team experience with the various platforms.

The physical and mental health component of the SF-12 did not change significantly compared with baseline. Interestingly, a recent study assessing the long-term effect of hysterectomy and uterus-preserving surgery on health-related quality of life also observed a flat trend from baseline (22). Additionally, the lack of change indicated by the SF-12 in

FIGURE 2



contrast to the improvements shown by the EHP-30 may suggest that the EHP-30 is a more specific test to assess the nuance of quality of life issues faced by patients with endometriosis.

The strengths of this trial include its multicenter, randomized design and the use of validated questionnaires for endometriosis quality of life. The centers that participated in the trial were similarly experienced in both laparoscopy and robotic surgery. This likely explains the comparable operative times in both arms of the study. Because this trial was performed at three large academic referral centers, the findings may not be applicable to other clinical settings or providers.

There are several weaknesses to the study. We did not standardize postoperative medical therapy. However, this should not affect the short-term quality of life outcomes. A Cochrane review concluded that there was no evidence of short-term benefit for postsurgical hormonal suppression of endometriosis compared with surgery alone for the outcomes of pain, disease recurrence, or pregnancy rates (23). Another potential weakness of this study is the high number of biopsy-negative patients. As discussed above, the observation that many patients with visually identified endometriosis ultimately do not have histologic confirmation has been reported many times (21, 24). However, there was no difference in frequency of occurrence in this randomized study. Another weakness of this study was that less than 100% of the surveys were returned at the end of the follow up period, which is typical of pain surveys. It is unlikely that this influenced the outcome because these were equally distributed between the randomized groups. However, for the primary objective of perioperative outcomes, all patients were included.

Although this clinical trial assessed intermediate-term results up to 6 months, it is possible that robotic technology may improve long-term results more than 1 year. Previous clinical trials with long-term follow-up revealed that recurrence of symptoms is low for the first 1 to 2 years, especially if medical postoperative suppressive therapy is used (25). Additionally, improvement in quality of life can last more than 4 years after surgery, suggesting that a long-term follow-up of more than 5 years may be needed to show a significant difference (26).

To conclude, laparoscopy and robotic surgery for the treatment of endometriosis have comparable perioperative outcomes and significant improvement in quality of life after intervention. Other high-quality clinical trials evaluating clinical outcomes and intermediate- and long-term quality of life are needed to assess the utility of robotic surgery in endometriosis.

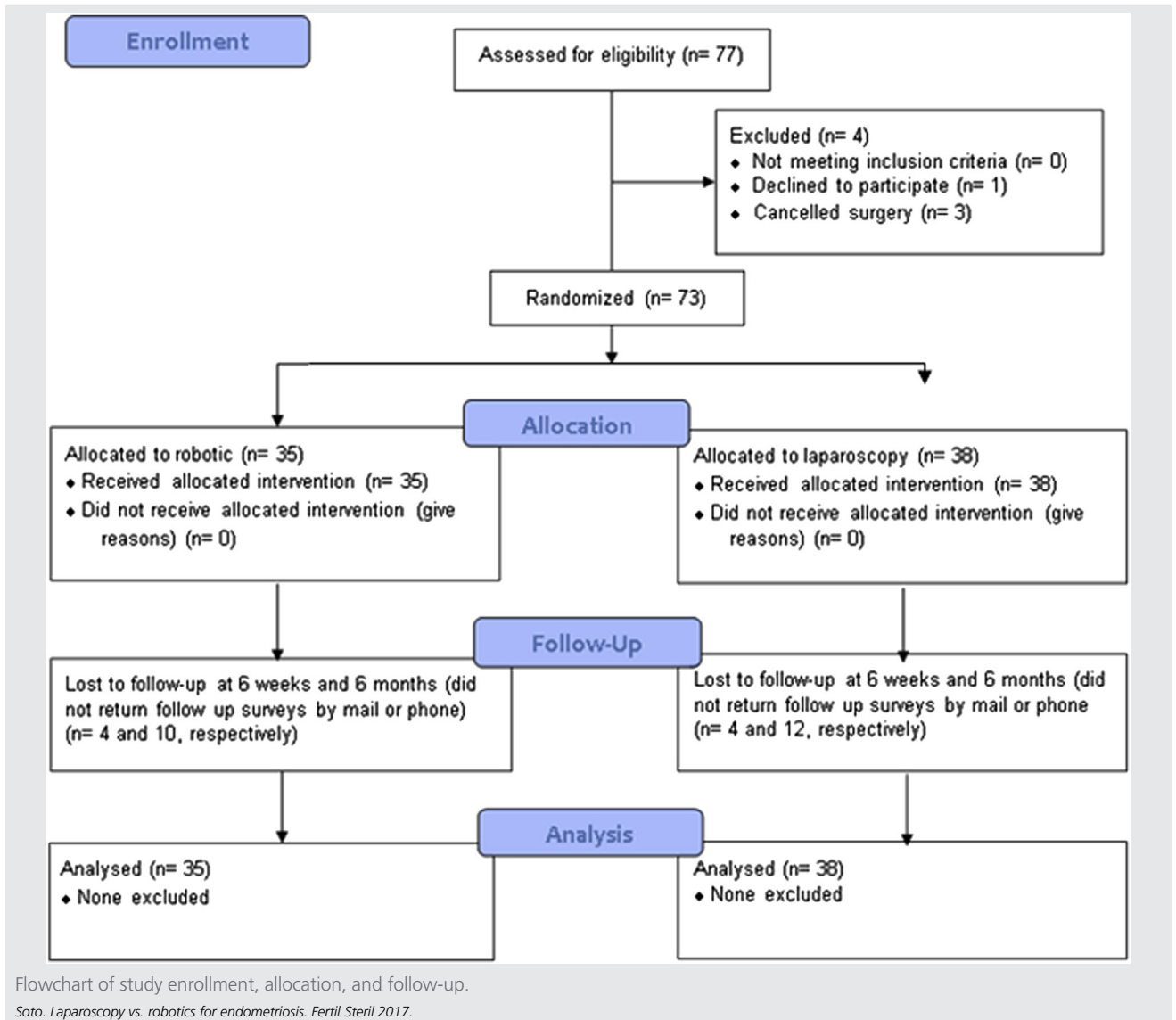
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SUPPLEMENTAL FIGURE 1



SUPPLEMENTAL TABLE 1

Postoperative quality of life outcomes: EHP-30.

Parameter	Robotic (n = 35)	Laparoscopic (n = 38)
Pain		
Baseline	51.2 ± 18.1	54.2 ± 16.0
6 wk	28.6 ± 23.7	25.3 ± 21.6
6 mo	24.8 ± 26.5	21.5 ± 23.9
Control/powerlessness		
Baseline	69.3 ± 21.9	68.1 ± 20.9
6 wk	36.5 ± 33.3	29.3 ± 23.5
6 mo	39.2 ± 37.3	26.9 ± 28.9
Emotions		
Baseline	42.5 ± 22.5	43.9 ± 16.6
6 wk	25.6 ± 23.1	24.4 ± 21.6
6 mo	25.0 ± 26.9	23.9 ± 21.8
Social support		
Baseline	46.3 ± 25.9	47.5 ± 20.1
6 wk	31.0 ± 28.1	29.3 ± 29.6
6 mo	30.8 ± 32.1	25.5 ± 26.9
Self-image		
Baseline	45.5 ± 29.9	38.6 ± 29.5
6 wk	37.1 ± 32.2	31.4 ± 31.0
6 mo	31.3 ± 32.3	25.3 ± 31.6
Work		
Baseline	42.5 ± 28.2	45.5 ± 31.0
6 wk	26.8 ± 31.1	8.3 ± 15.1
6 mo	22.3 ± 32.3	19.1 ± 23.718
Children		
Baseline	33.6 ± 28.0	35.6 ± 29.3
6 wk	19.5 ± 21.9	25.0 ± 28.9
6 mo	3.4 ± 11.3	7.3 ± 15.5
Intercourse		
Baseline	59.3 ± 20.5	49.9 ± 23.0
6 wk	42.3 ± 31.0	33.8 ± 21.1
6 mo	36.2 ± 30.0	23.6 ± 22.6
Feelings about medical professionals		
Baseline	25.9 ± 28.9	24.8 ± 25.2
6 wk	10.4 ± 21.9	9.4 ± 21.5
6 mo	19.3 ± 26.8	9.8 ± 15.8
Feelings about treatment		
Baseline	53.3 ± 28.7	61.1 ± 25.6
6 wk	27.6 ± 32.8	22.7 ± 24.3
6 mo	36.8 ± 35.4	22.4 ± 23.9
Feelings about conception		
Baseline	44.6 ± 35.8	62.8 ± 31.2
6 wk	42.4 ± 31.9	49.4 ± 38.8
6 mo	40.6 ± 32.6	66.3 ± 38.8

Note: Data are mean ± SD. Number at follow-up for robotic and laparoscopic groups at 6 weeks and 6 months: n = 31 and n = 34; n = 25 and n = 26, respectively. All other comparisons using the mixed linear effects models, which looks at the trend in scores over time or score comparisons at individual time points, had *P* values >.05.

Soto. *Laparoscopy vs. robotics for endometriosis. Fertil Steril* 2017.

SUPPLEMENTAL TABLE 2

Quality of life outcomes: SF-12.

SF-12	Robotic	Laparoscopic
Physical Health Score		
Baseline	41.5 ± 4.8	42.7 ± 6.4
6 wk	39.6 ± 3.6	41.9 ± 2.8
6 mo	42.4 ± 3.9	41.1 ± 4.3
Mental Health Score		
Baseline	42.7 ± 7.0	43.2 ± 7.0
6 wk	46.1 ± 6.1	45.8 ± 5.7
6 mo	44.9 ± 7.9	44.7 ± 5.4

Note: Data presented as mean ± SD. Number at follow-up for robotic and laparoscopic groups at 6 weeks and 6 months: n = 31 and n = 34; n = 25 and n = 26, respectively. All comparisons were not statistically significant ($P > .05$). Of note the physical health score at 6 weeks ($P = .055$).

Soto. Laparoscopy vs. robotics for endometriosis. *Fertil Steril* 2017.