



# COMMITTEE OPINION

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## Committee on Gynecologic Practice Society of Gynecologic Surgeons

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## Robotic Surgery in Gynecology

**ABSTRACT:** The field of robotic surgery has developed rapidly, and its use for gynecologic conditions has grown exponentially. Surgeons should be skilled at abdominal and laparoscopic approaches for a specific procedure before undertaking robotic approaches. Surgeon training, competency guidelines, and quality metrics should be developed at the institutional level. Robot-assisted cases should be appropriately selected based on the available data and expert opinion. As with any surgical procedure, repetition drives competency. Ongoing quality assurance is essential to ensure appropriate use of the technology and, most importantly, patient safety. Adoption of new surgical techniques should be driven by what is best for the patient, as determined by evidence-based medicine rather than external pressures. Well-designed randomized controlled trials or comparably rigorous nonrandomized prospective trials are needed to determine which patients are likely to benefit from robot-assisted surgery and to establish the potential risks.

### Recommendations

- Well-designed randomized controlled trials (RCTs) or comparably rigorous nonrandomized prospective trials are needed to determine which patients are likely to benefit from robot-assisted surgery and to establish the potential risks.
- Robot-assisted cases should be appropriately selected based on the available data and expert opinion. As with any surgical procedure, repetition drives competency. In addition to the didactic and hands-on training necessary for any new technology, ongoing quality assurance is essential to ensure appropriate use of the technology and, most importantly, patient safety.
- Adoption of new surgical techniques should be driven by what is best for the patient, as determined by evidence-based medicine rather than external pressures.
- As with any procedure, adequate informed consent should be obtained from patients before surgery. In the case of robotic procedures, this includes a discussion of the indications for surgery and risks and benefits associated with the robotic technique compared with alternative approaches and other therapeutic options.
- Surgeons should describe their experience with robotic-assisted surgery or any new technology when counseling patients regarding these procedures.
- Surgeons should be skilled at abdominal and laparoscopic approaches for a specific procedure before undertaking robotic approaches.
- Surgeon training, competency guidelines, and quality metrics should be developed at the institutional level.
- Reporting of adverse events is currently voluntary and unstandardized, and the true rate of complications is not known. The American College of Obstetricians and Gynecologists (the College) and the Society of Gynecologic Surgeons (SGS) recommend the development of a registry of robot-assisted gynecologic procedures and the use of the Manufacturer and User Facility Device Experience Database to report adverse events.

## Background

The field of robotic surgery has developed rapidly, and its use for gynecologic conditions has grown exponentially (1, 2). Initially developed for battlefield medicine, robot-assisted surgery was approved by the U.S. Food and Drug Administration in 1999 for urologic and cardiac procedures and in 2005 for gynecologic surgery. Today, robot technology is applied widely in gynecology for hysterectomy, sacrocolpopexy, myomectomy, adnexal surgery, and malignancy staging (3).

Robot-assisted surgery currently is performed at more than 2,025 academic and community hospital sites nationwide, with growth in excess of 25% annually (4). Growth in hospital ownership of robotic systems parallels the increase in the volume of robotic-assisted procedures (5). Beyond physician preference, patient fascination with technology, industry pressure, and marketing efforts of hospitals and physicians have fueled the popularity of robot-assisted surgery. Hospitals and physicians actively advertise and promote robotic surgery programs, often with unsubstantiated claims of improved outcomes and patient safety (6, 7). The purpose of this Committee Opinion, developed by the College and SGS, is to provide background information on robot-assisted surgery for gynecologic conditions, review the literature on this topic, and offer practice recommendations.

## Overview of Technology

The current robotic surgical system consists of four components: 1) a console where the surgeon sits, views the screen, and controls the robotic instruments and camera via finger graspers and foot pedals; 2) a robotic cart with three or four interactive arms that hold instruments through trocars attached to the patient; 3) a camera and vision system that allow for a three-dimensional image of the pelvis using image synchronizers and illuminators; and 4) wristed instruments with computer interfaces that translate the mechanical movements of the surgeon's hands into computer algorithms that direct the instruments' movements within the patient (8). During robotic surgery, the primary surgeon sits unscrubbed at the console, away from the operating room table and at some distance from the patient, using finger graspers to control the instruments. Foot pedals and a clutch are used for camera control, activation of energy sources, focusing, and switching the robotic arm. Four to five trocars are used, including one through which a 12-mm or 8-mm three-dimensional endoscope is placed. Instruments are passed through three to four ports, three of which can be controlled by the robotic arms. One additional arm, not controlled by the robot, may be placed as an "assistant" port. Assistant surgical team members pass robotic instruments and sutures through these ports for use by the primary surgeon. These ports also provide suction, irrigation, and countertraction. Instruments for suturing, clamping, endosurgery, and tissue manipulation are

used with the robotic arms. The console provides three-dimensional imaging with improved depth perception, and the surgeon has autonomous control of the camera and instruments. Finally, the robotic arm, with its wristed joint and six degrees of freedom, allows for greater dexterity than unassisted surgery and decreases normal hand tremors.

## Summary of Current Evidence

The rapid adoption of robotic technology for gynecologic surgery is not supported by high-quality patient outcomes, safety, or cost data. A wide array of literature exists, but most studies are retrospective, observational, and non-comparative. Four RCTs compared robot-assisted surgery for benign gynecologic disease with laparoscopy, and none showed any benefit from using the robotic approach (9–12). These and other studies show that robot-assisted gynecologic surgery can be performed safely in centers with experienced surgeons and that this minimally invasive approach could be considered for procedures that might otherwise require laparotomy. For gynecologic oncology surgery, there are no data from RCTs. Well-designed RCTs or comparably rigorous nonrandomized prospective trials are needed to determine which patients are likely to benefit from robot-assisted surgery and to establish the potential risks. Adoption of new surgical techniques should be driven by what is best for the patient, as determined by evidence-based medicine rather than external pressures. As with any procedure, adequate informed consent should be obtained from patients before surgery. In the case of robotic procedures, this includes a discussion of the indications for surgery and risks and benefits associated with the robotic technique compared with alternative approaches and other therapeutic options.

## Benign Hysterectomy

Hysterectomy is the second most common surgical procedure in the United States, with approximately 433,000 inpatient hysterectomies performed annually (13). Although more than 50% of hysterectomies are performed abdominally, there is an increasing trend towards minimally invasive approaches (13–15). In 2010, 30.5% of benign hysterectomies were performed laparoscopically compared with only 14% in 2005 (13, 14). The increase has been even steeper for robotic-assisted hysterectomy, with 0.5% of all hysterectomies performed robotically in 2007 compared with 9.5% in 2010 (13).

Despite this rapid increase, data on outcomes and costs are limited. Two of the four RCTs compared robot-assisted and laparoscopic hysterectomy (9, 11). In these two trials, comprising 148 patients, operative times were significantly longer for robot-assisted hysterectomy (29 minutes and 77 minutes mean difference, respectively). However, no differences in blood loss, length of stay, type or number of complications, postoperative pain levels, analgesic use, or recovery time were found.

A large cohort study analyzed 264,758 women who underwent hysterectomy for benign gynecologic disorders at 441 hospitals across the United States from 2007 to 2010 (16). Compared with conventional laparoscopy, robot-assisted hysterectomy was associated with a significantly lower risk of hospitalization longer than 2 days (24.9% versus 19.6%, although the study did not provide data regarding overall average length of stay) but a significantly higher total cost (\$2,189 more per case). No other differences in rates of transfusion, overall in-hospital complications, or discharges to nursing facilities were found. Another large cohort study that used the 2009 and 2010 Nationwide Inpatient Sample found hospital costs to be \$2,489 higher for robot-assisted hysterectomies compared with laparoscopic hysterectomies (15). Transfusions were decreased and postoperative pneumonia was increased in the robot-assisted group.

The remainder of the current literature consists of single-institution studies of low-to-moderate quality that compare robotic hysterectomy with abdominal and laparoscopic approaches (17–23). These studies show no significant difference in mean operating time or perioperative morbidity compared with traditional laparoscopic procedures. However, compared with laparotomy, robot-assisted approaches had less blood loss, lower complication rates, and shorter hospital stays (18, 19).

Concern has arisen that vaginal cuff dehiscence may be more likely with robotic-assisted hysterectomy. The overall incidence of vaginal cuff dehiscence after any hysterectomy is 0.14–4.1%; however, a recent large cohort study suggested that transvaginal closure of the cuff was associated with a threefold and ninefold reduction in the risk of dehiscence compared with laparoscopic and robotic closure, respectively (24, 25).

Overall, the current literature shows conflicting evidence and is of poor quality. Based on RCTs and two large cohort studies, robot-assisted hysterectomy appears to have similar morbidity profiles to laparoscopic procedures but results in significantly higher costs. Further comparative studies that assess long-term outcomes and patient safety and identify subgroups of patients who would benefit from a robotic approach are warranted. Reporting of adverse events is currently voluntary and unstandardized, and the true rate of complications is not known. The College and SGS recommend the development of a registry of robot-assisted gynecologic procedures and the use of the Manufacturer and User Facility Device Experience Database to report adverse events. Additionally, based on its well-documented advantages and lower complication rates, the College continues to recommend vaginal hysterectomy as the approach of choice for benign disease whenever feasible (26).

### **Sacrocolpopexy**

Sacrocolpopexy is widely used for the management of apical vaginal vault prolapse. Traditionally, it has been performed with an abdominal or laparoscopic approach.

However, adoption of the laparoscopic approach has been limited by a steep learning curve. Robot-assisted sacrocolpopexy is believed to facilitate this technically difficult procedure and allow more surgeons to offer a minimally invasive approach. However, in the two RCTs that compared robot-assisted sacrocolpopexy with laparoscopic sacrocolpopexy, operating time, postoperative pain, and cost were found to be significantly greater in the robot-assisted group (10, 12). Both groups had similar anatomical and functional outcomes 6 months to 1 year after surgery, though the robotic experience of the surgeons was low at the start of the study, which may have affected the results. A retrospective cohort study that compared robot-assisted sacrocolpopexy with the abdominal approach found longer operating times but shorter lengths of stay and less blood loss with the robot-assisted group (27). Overall, the current literature is too scant to adequately indicate which minimally invasive approach should be recommended. Further comparative studies that assess long-term anatomical and functional outcomes and patient safety and that identify subgroups of patients who would benefit from a robotic approach are warranted.

### **Myomectomy**

Uterine leiomyomas are the most common pelvic mass in women and myomectomy often is selected to relieve myoma-related symptoms in women who desire continued fertility or who decline hysterectomy (28–32). Although laparoscopic myomectomy techniques have been shown to decrease postoperative morbidity and allow faster recovery (33, 34), most myomectomies are completed via laparotomy (35). The robotic system may help overcome limitations, such as unfavorable myoma location (36) or patient obesity (37).

Despite the purported benefits of robot assistance, data are limited to observational studies of varying quality and power. Although shown to have significantly shorter postoperative recovery times than abdominal myomectomy, robot-assisted laparoscopic myomectomies have longer operative times and significantly higher costs than abdominal and laparoscopic approaches (38–45). Overall, there was no difference in blood loss, length of stay, and complication profiles for robot-assisted laparoscopic myomectomy compared with either abdominal or laparoscopic procedures. Furthermore, the current literature is insufficient to comment on postprocedure conception rates or pregnancy outcomes. Comparative effectiveness studies are needed to better evaluate outcomes, safety, and cost of robot-assisted myomectomy.

### **Gynecologic Malignancies**

Robot-assisted surgery has been increasingly used for early-stage endometrial cancer. Although randomized prospective trials currently do not exist for the robotic-assisted surgical management of endometrial cancer, there are 13 retrospective trials comparing robot-assisted

hysterectomy with either conventional laparoscopic (46–54) or abdominal hysterectomy (47, 51, 53, 55–59).

In the SGS systematic review, eight studies that compared robotic-assisted surgery with laparoscopy for endometrial cancer were assessed in a total of 1,218 patients (60). Length of stay was significantly reduced among the robotic-assisted cohort. There was a trend toward reduced operating times, but the finding was not consistent among the studies. In most studies, estimated blood loss was significantly less with robotic surgery. The number of lymph nodes retrieved did not differ between groups. Additionally, some studies showed more rapid postsurgical recovery with robot-assisted surgery.

In eight studies that compared robot-assisted surgery with abdominal surgery (642 patients had robotic surgery and 835 patients had abdominal surgery), it was consistently reported that women who had robotic surgery had less estimated blood loss and shorter hospital stays (47, 51, 53, 55–59). Operating room time was longer for the robotic-assisted cohort in most of the studies, and there appear to be no significant differences between the two modalities in relation to the total number of lymph nodes retrieved.

Cost comparisons of robotic and traditional open techniques have been reported by two groups (47, 61). When the total direct and indirect costs were compared, robot-assisted surgery was found to have advantages over open surgery (\$8,212.00 versus \$12,943.60,  $P=.001$ ) in large part because of shorter lengths of stay with minimally invasive surgery.

Although there are no RCTs that compare robotic approaches for endometrial cancer with laparoscopic or open abdominal approaches, there is a body of retrospective literature that suggests a decrease in perioperative morbidity and improvement in surgical variables with the use of robotic approaches. As with benign gynecologic procedures, prospective comparative trials are needed to better define outcomes and identify patients with endometrial cancer who would benefit from robotic surgery.

Robot-assisted surgery is increasingly used for treatment of cervical cancer, but outcome data are limited to retrospective reviews. One study that compared robot-assisted hysterectomy with laparoscopic radical hysterectomy found no advantages to the robotic approach (62). The only area of significance was in a reduced estimate of blood loss among the robotic cohort (115.5 cc versus 171 cc,  $P<.001$ ). Additional studies are necessary to help validate whether robot-assisted and laparoscopic radical hysterectomy have similar outcomes. In six trials that compared robot-assisted radical hysterectomy with abdominal radical hysterectomy, robot-assisted surgery had reduced lengths of stay, less blood loss, and higher total number of lymph nodes retrieved (55, 62–66). There were inconsistent data on which modality had shorter operating times. Data on long-term survival for the various approaches are not currently available.

## Other Gynecologic Procedures

Patients scheduled for gynecologic procedures of short duration and low complexity are unlikely to benefit from robotic-assisted surgery. The College and SGS suggest that there is no advantage, and that there are possible disadvantages, to performing the following procedures with robotic assistance compared with other minimally invasive approaches:

- Tubal ligation
- Simple ovarian cystectomy
- Surgical management of ectopic pregnancy
- Prophylactic bilateral salpingo-oophorectomy

## Learning Curve

For the surgeon, robot-assisted surgery addresses common problems of conventional laparoscopic surgery. Fatigue and muscle strain are minimized because the surgeon sits ergonomically at a console separate from the patient. Some claim that the combination of improved imaging and instrument control allows for a faster surgical learning curve compared with conventional laparoscopy, which includes two-dimensional imaging and counterintuitive hand movements (1). Thus, robotics may permit less experienced laparoscopic surgeons to perform minimally invasive procedures that previously would have required laparotomy. Although the use of robot-assisted technology is believed to shorten the learning curve of complex minimally invasive procedures, this has not been substantiated.

The number of cases required for proficiency is not clear. One retrospective study evaluated robotic learning curves based on time for completion of the index gynecologic procedures. Investigators reported that times plateaued after 50 cases (67). A retrospective review from a single surgeon performing 100 robotic hysterectomies found that improvement in surgical times and complication rates peaked at 20 cases (47). A further small decrease in operative times was noted after each subsequent quintile (20 cases). It is unclear if skill acquisition is prolonged with more complex gynecologic cases. Factors that affect this learning curve include abdominal or laparoscopic experience with procedures being performed, prior laparoscopic skills of the surgeon, and the experience of the robotic surgical team. Training of the surgical team is essential and has been reported to decrease operative time and complication rates (67, 68). One simulator study found that robot implementation hastened skill acquisition for certain tasks in surgeons with less experience but not in experienced surgeons (69). Robot-assisted cases should be appropriately selected based on the available data and expert opinion. As with any surgical procedure, repetition drives competency. Ongoing quality assurance is essential to ensure appropriate use of the technology and, most importantly, patient safety. Adoption of new surgical techniques should be driven by what is best for

the patient, as determined by evidence-based medicine rather than external pressures.

### Credentialing, Privileging, and Training

Credentialing and privileging are conducted by health care institutions, whereas boards, such as the American Board of Obstetrics and Gynecology, provide certification after completion of resident training. Medical specialty organizations, other educational institutions, and the health care industry do not have the authority to certify, credential, or privilege but may educate physicians and document their completion of training.

Although obstetric and gynecologic residencies are increasingly including training in robotic procedures, many practitioners receive privileges to perform robotic procedures as a new skill. Robot-assisted surgery utilizes new technology for commonly indicated procedures. The College and SGS recommend that credentialing and privileging for robotic procedures be based on the following general criteria:

- The practitioner must have completed a didactic educational program. These programs may have been a part of residency or fellowship training and may be offered and accredited by such organizations as the College, SGS, the American Association of Gynecologic Laparoscopists, the Society of Gynecologic Oncology, and the American Urogynecologic Society.
- Individuals must have hands-on training using the new technology. When possible, this should first be provided in a laboratory setting using animal subjects or human cadavers. As simulation capabilities continue to improve, simulation centers will be able to assist greatly in initial training. These programs also may be accredited by the aforementioned medical specialty organizations, as well as university, academic, and didactic centers.
- Robot-assisted cases should be appropriately selected based on the available data and expert opinion. Once initial training has been completed, practitioners should carefully select patients who can benefit from a procedure with robotic assistance; cases should not be selected for the purpose of satisfying a quota. Health care institutions often require practitioners' initial cases to be proctored by a surgeon experienced with this technology. In small institutions where an experienced proctor does not exist, other pathways may need to be considered. The number of procedures needed to demonstrate competence should be determined by the institution.
- As with any surgical procedure, repetition drives competency. In addition to the didactic and hands-on training necessary for any new technology, ongoing quality assurance is essential to ensure appropriate use of the technology and, most importantly, patient safety. Surgeons should describe their experience

with robotic-assisted surgery or any new technology when counseling patients regarding these procedures.

- Residents in obstetric and gynecologic programs approved by the Accreditation Council for Graduate Medical Education are becoming trained in new minimally invasive technologies, with some residency programs instituting robotic training. The Council on Resident Education in Obstetrics and Gynecology is developing criteria for training in robot-assisted surgery. Although robot-assisted surgery is not a specific part of the newly adopted Milestones in obstetric and gynecologic residency training (<http://acgme.org/acgmeweb/Portals/0/PDFs/Milestones/ObstetricsandGynecologyMilestones.pdf>), individual programs and specific residents may well receive training compatible with that outlined previously for the practicing physician. Training also is available at the fellowship level. Whether a graduate has appropriate training in these areas will be validated by the residency or fellowship training program director.

Residency and fellowship programs serve an important role by ensuring their graduates maintain a balanced experience and that the introduction of robotic technology does not limit graduates' competence in performing vaginal, laparoscopic, or abdominal hysterectomies. Surgeons should be skilled at abdominal and laparoscopic approaches for a specific procedure before undertaking robotic approaches. Surgeon training, competency guidelines, and quality metrics should be developed at the institutional level.

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