# Surgery

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# **Robotic-Assisted Surgery**



Ву

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### **Reviewed and Edited by Brian Housman, MD**

This article will discuss the pros and cons of robotic-assisted surgery for various procedures. It will also touch on credentialling issues and the future of robotic-assisted surgery.

#### How Is Robotic-assisted Surgery Performed?



Robotic-assisted surgery uses a console located away from the bedside where the operating surgeon is seated. The console is connected to a robotic cart that is beside the patient. The console typically contains two binocular lenses that magnify and create a three-dimensional image for the surgeon.[1] A dual-camera endoscope on a robotic arm transmits 3-D images to the surgeon[1]. During the surgery, two handpieces transmit the surgeon's hand movements, allowing manipulation of surgical instruments which are attached to robotic arms.[1,2] A motion filtration system minimizes tremor, and foot pedals control different types of monopolar or bipolar energy used to cut and coagulate during the surgery and also control movement of the different robotic instruments including suction, irrigation and stapler devices needed for the procedure.[2] Some robotic systems have the ability to automatically reposition the robotic arms to keep the instruments in the same relative position in the operating field when the patient's stretcher is moved to allow better surgical field exposure. This permits a smooth transition when repositioning a patient, as opposed to needing to undock the robotic platform and then reposition the robotic arms.[3]

An assistant, located at the bedside, can retract, remove specimens, suction and deliver equipment as needed.

Some advantages of robotic-assisted surgery for the surgeon include improved dexterity, allowing the surgeon a better ergonomic operating position with lessened muscle fatigue, and the elimination of the need to stand, possibly for hours.[1]

#### **Robotic-assisted Surgery Procedures**

The first recorded use of robotics was in a brain biopsy procedure in 1985.[4] Since then, the FDA has cleared or approved robotic-assisted surgery for a broad variety of surgery indications across specialties such as cholecystectomy,[5] thoracic surgery[6], hysterectomy, atrial septal defect closure,[7] mitral valve repair,[8] coronary artery anastomosis during cardiac revascularization,[7] spinal pedicle screw insertion,[9] hip replacement, total knee replacements[10], simple and radical prostatectomy,[11,12] transoral otolaryngology procedures,[13] and bronchoscopic lung biopsy[14]. The FDA removed its clearance for robotic-assisted thyroidectomy in 2011 which will be discussed later.[15]

In 2001, doctors in New York City performed a telerobotic-assisted gallbladder removal on a patient located in France.[4]

### **Robotic-Assisted Surgery Complications**

The reported complication rate due to robotic malfunction is approximately 0.1% to 0.5%. When robotic errors do occur, rates of permanent injury reported range from 4.8% to 46.6% in the medical literature. In 2016 less than 800 complications directly attributable to a robotic operating system were reported to the FDA for the previous 10-year period.[2] However, almost 57% of respondents in an internet survey of urologists had experienced an irrecoverable intraoperative malfunction of the robot while performing a robot-assisted radical prostatectomy. The most common issues reported were malfunctioning of the robotic arms, arm joint problems and camera issues, followed by electrical power issues, instrument malfunction, and a broken console handpiece.[2,16]

Some possible disadvantages of robotic-assisted surgery include increased procedure time, human error in operating the apparatus, mechanical failure, accidental burn injuries, lack of tactile feedback, and nerve palsies due to direct nerve compression or extreme body positioning required for some robotic-assisted surgical procedures.[2] It is uncommon for mechanical failure to result in uncontrolled motion of the arms, due to safety protocols now built into modern robotic-assisted systems that prevent instrument use or restrict motion.\*

### **Experience Required to Gain Technical Proficiency**

There is currently no consensus of how many procedures a surgeon would need to perform to gain proficiency in robotic-assisted surgery. While standardized credentialing is gaining attention in the literature, proficiency varies significantly based on the specialty and technical complexity. It has been demonstrated that there is a learning curve when surgeons use these tools.[2,17] A learning curve is the rate of progress in learning a new skill. There are no national standards but it is common practice for hospitals to require certification to perform robotic-assisted surgery. Online and in-person training courses by the manufacturers are typically required, and one reference cited 20 bedside and 50 console procedures for residents and 5 proctored procedures for attendings with 50 tracked procedures as being a common standard.[17] However, an issue that may be problematic is that a hospital's credentialing process relies on the manufacturers of the equipment.[17]

Various studies defining mastery of robotic-assisted colorectal surgery reported that a surgeon needed 15 to 20 cases to overcome the learning curve.[18] However, in one study it was reported that technical competence occurred after 44 cases and expert performance occurred after 75 cases.[19] In another study the initial learning curve was 35 cases but it took 128 cases to reach expert performance.[20]

At one academic center, the failure rate for robotic-assisted mitral valve replacement was 7% for the first 100 cases and fell to 4.5 % in the next 200 cases. The need to convert robotic-assisted to open surgery occurred in 5% to 9.1% during the early part of the learning curve, compared to 0.7% to 1.3% in the later part of the curve.[21,22]

In a study of 3,246 patients who received totally endoscopic coronary artery bypass graft (CABG) surgery, 14% needed a larger incision during the robotic-assisted procedure, which was found to be dependent on where the surgeon was on the learning curve with the equipment.[23]

An appraisal of the robotic-assisted surgery learning curve in the medical literature concluded that there are few guidelines on dealing with the learning curve. The number of cases needed to achieve peak performance varied by type of surgery and the learning curve may have several phases, as surgeons perform more complex cases with growing experience. The literature also lacks a uniform assessment of outcomes and complications that could be used to decide when expertise had been achieved.[24]

#### A Review of Some Robotic-assisted Procedures

#### **Abdominopelvic Surgery**

A systematic review of 50 studies concluded that while robotic-assisted abdominopelvic surgery was safe with slight decreases in complications, it failed to find a significant advantage over traditional open or laparoscopic surgery.[17] In that review, 9% of conventional laparoscopies led to complications requiring further surgical intervention, compared to 8% of robotic-assisted operations. In studies of gastrointestinal surgery,

life-threatening complications ranged from 0 to 2 % for robot-assisted surgery, from 0 to 3% for standard laparoscopy and from 1 to 4 % for open surgeries. In up to 8% of robotic-assisted surgeries and up to 12% in standard laparoscopic surgery the surgeon had to convert to an open surgical procedure. Robotic-assisted surgery was found to have increase costs and time duration compared with standard surgery.[17,25] The authors also point out that in the published literature two-thirds of the authors have received honoraria, speaking or consulting fees from the manufacturer. They also stated that the lack of high-quality data supporting robot-assisted surgery over laparoscopy or open surgery has not affected its rapid growth due in part to aggressive marketing by manufacturers, the belief that technology will improve outcomes, and demand from patients, surgeons, and health care systems.[17]

#### **Radical Prostatectomy**

Up to 85% of all radical prostatectomies performed in the U.S. are done using roboticassisted surgery. There are high initial upfront costs of one to two million dollars associated with purchasing a robot. There are also annual maintenance contracts which can cost \$150,000 or more per robot, and the cost of disposable instruments which results in much greater direct costs of robotic-assisted prostatectomy compared to open prostatectomy. In the U.S., most hospitals receive little or no additional payment from insurers for robotic-assisted surgery to offset these added costs. Many hospitals have marketed robotic-assisted surgery to patients, possibly as a way to recoup the increased costs of using robot surgical equipment.[26]

A meta-analysis of robotic-assisted versus open radical proctectomy reported that there were significantly less postoperative complications as well as a lower incidence of postoperative urinary incontinence at one year. There was no difference between the two techniques with respect to the amount of blood loss and finding cancer-free margins in the tissue removed. The authors stated that "in the narrow pelvic space, the flexible robotic arm makes the anatomical operation finer than the human hand, and it is easier to preserve the integrity of the nerve."\*[27] (\*cavernous nerve)

Another meta-analysis found that robotic-assisted radical prostatectomy was associated with less blood loss and need for blood transfusion, and a shorter length of hospitalization compared to standard surgery. There was no proof of the superiority of either surgical technique with respect to postoperative complications, cancer-free margins of tissue removed, cancer reoccurrence, urinary incontinence or sexual function. Robotic-assisted surgery was found to take more operative time and was more expensive than open surgery.[28]

## **Radical Cystectomy**

A study of robotic-assisted surgery versus open surgery for radical cystectomy (urinary bladder removal) in patients with bladder cancer reported that there were significantly less thromboembolic complications, wound complications, and days spent in the hospital within the first 90 days after surgery with robotic-assisted surgery compared to open surgery. At 18-month follow-up, there was no significant difference in the recurrence of cancer or mortality between the two groups.[29]

### Thyroidectomy

In 2011, the FDA withdrew approval of robotic-assisted thyroidectomy surgery and the manufacturer stopped supporting the procedure.[15] This was due to reports that low-volume medical centers with less than five cases per year were found to have a significantly higher complication rate than high-volume centers.[30] While robotic-assisted remote access thyroidectomy is still performed in other countries, it is rarely done in the U.S.[31]

# **Knee Arthroplasty**

A meta-analysis of robotic-assisted vs open total knee arthroplasty reported that there was more precise prosthesis positioning and less blood loss with robotic-assisted surgery. There were no statistically significant differences in the two groups in range of motion and complications after surgery. Several of the included studies found that the surgeons needed some experience with the equipment to perform the procedure optimally.[32]

# **Hip Arthroplasty**

The literature regarding robotic-assisted hip arthroplasty is mixed. A meta-analysis of robotic-assisted total hip arthroplasty compared to open surgery reported that robotic-assisted surgery improved component placement and reduced intraoperative complications. However, robotic-assisted surgery increased the risks of postoperative heterotopic ossification, dislocation, and the need for revision. Robotic-assisted surgery was found to increase surgical time by 20 minutes compared to standard surgery.[33] Another meta-analysis reported similar results.[34] However, a study of over 2,000 patients reported less postoperative dislocations with robotic-assisted surgery.[35] A different meta-analysis reported that robotic-assisted hip arthroplasty had significantly better component placement, less limb length discrepancies and no significant differences in the number of revision surgeries needed or long-term clinical outcomes

compared to standard surgery.[36] It is possible the different outcomes might be due to where the surgeons were on the learning curve or which manufacture's device was used. A systematic review reported that the surgeons' learning curve for robotic-assisted total hip arthroplasty was between 12 and 35 cases.[37]

#### **Mitral Valve Replacement**

Robotic-assisted mitral valve replacement was first performed in 1998 and received FDA approval in 2002. The 3-D imaging used in robotic-assisted surgery according to one author allows better visualization of the valve area and may obviate the need for a sternotomy.[38] In one study of 759 patients, robotic-assisted surgery took longer than open surgery, and the quality of mitral valve repair was judged to be equivalent for robotic-assisted surgery versus partial and complete sternotomy, and right mini-anterolateral thoracotomy. Neurologic, pulmonary, and renal complications were similar among groups. The robotic-assisted surgery arm had the lowest occurrences of atrial fibrillation, pleural effusion, and shorter hospital stays.[39]

#### **Coronary Revascularization Surgery**

A robotic-assisted CABG (coronary bypass graft) is where robotic arms and camera are placed in chest wall incisions and the left internal mammary artery is harvested using the robotic arms. This artery is then grafted onto the blocked coronary artery either through the incisions already in place or hand-sewn in place through a minithoracotomy. The procedures can be performed on both the beating heart (off-pump) and the arrested heart (on-pump).[38,40]

In one study of 326 patients receiving totally endoscopic coronary artery bypass graft surgery, 14% needed a larger incision. The need for a larger incision was found to be dependent on where the surgeon was on the learning curve with the equipment.[41]

#### **Pulmonary Lobectomy**

Robotic-assisted pulmonary lobectomy for cancer treatment is estimated to be used in about 20% of lobectomies in the U.S.[42] Additional surgical approaches include open lobectomy and video-assisted thoracoscopic surgery (VATS).

A meta-analysis of robotic-assisted lobectomy versus open lobectomy for cancer reported that robotic-assisted lobectomy had lower 30-day mortality rates than open surgery or video-assisted thoracoscopic surgery. Robotic-assisted lobectomy also had less complications and shorter durations of hospitalization than open surgery. In one study in the meta-analysis, blood transfusions requirements were lower with the robotic-assisted approach. Surgical times were found to be longer in the roboticassisted group.[43]

A systematic review reported that blood loss and length of hospital stay were similar between robotic-assisted lobectomy and video-assisted thoracoscopic surgery. Robotic-assisted lobectomy was superior to thoracotomy and equivalent to videoassisted thoracoscopic surgery for the incidence of persistent air leaks and hospital length-of-stay. There was no difference in survival between robotic-assisted lobectomy and video-assisted thoracoscopic surgery, however, robotic-assisted lobectomy was found to be more costly than video-assisted thoracoscopic surgery. The authors cautioned that large prospective studies were needed to confirm or refute those findings.[44]

### **Telerobotic Surgery**

Benefits of telerobotic-assisted surgery, where a surgeon operates on a patient from another site include providing healthcare to remote areas, allowing top specialists to participate in a patients care, [45] and its use in battlefield hospital units.

Issues include needing rapid data transmission to allow a safe procedure, mechanical failures, [45] and not having personnel at the bedside who can convert robotic-assisted surgery to open surgery which may prove to be problematic in some cases.

### Conclusions

Robotic-assisted surgery has created a revolutionary change in surgical procedures. In some areas, such as prostate surgery, there appear to be some significant advantages in using robotic-assisted surgery. However, a large systematic review of abdominopelvic surgery reported that many of the studies failed to find a significant difference in outcomes between robotic-assisted surgery and standard laparoscopic or open surgery.

Advantages of robotic-assisted surgery over open surgery include smaller incisions, in some cases less blood loss, and decreased hospitalization days. Some authors also felt that manipulation of surgical instruments in an anatomically small area might be better with robotic-assisted surgery.

Disadvantages of robotic-assisted surgery include longer operative times, the need for a significant learning curve to gain proficiency, and higher costs. There is also the possible need to change to an open technique, or the possibility of causing an injury during surgery due to mechanical or technical issues. There may be differences in outcomes of robotic-assisted surgery between academic centers and general hospitals.

In the U.S., the FDA revoked approval/clearance for robotic-assisted thyroid surgery. The approval was based on data from academic centers where many procedures were performed. However, when general hospitals doing a lower number of robotic-assisted thyroid procedures were allowed to perform the procedure, outcomes were much worse.

Another issue is that there is currently no consensus on agreed upon credentialling requirements for proficiency in robotic-assisted surgery, although hospitals can set up their own credentialling processes. Using the manufacturer as a necessary part of the credentialling process may potentially be a conflict of interest.

With the significant learning curve required to become proficient with these devices, it is possible not having those standardized guidelines may put some patients at risk for a complication or increased need to convert to an open procedure, especially if the surgeon is at the beginning of the learning curve.

There appears to be some selection bias inherent in the medical literature in studies of robotic-assisted surgery that may affect results. Patients with favorable anatomy, health, and pathology tend to be chosen by surgeons to undergo procedures robotically. Conditions that favor the choice of robotic surgery may also skew outcomes positively. By contrast, hazardous conditions will often require open surgery and may be more frequently associated with poorer outcomes.[46,47]

It is possible that in the future with the addition of artificial intelligence, improved technology, and surgeons who trained on these devices when they were residents that outcomes with robotic-assisted surgery will continue to improve over time.[17,48]

Finally, telerobotic-assisted surgery with the ability of having surgeons able to operate on patients in remote geographic areas or in battlefield hospital units, may improve care to some patients, although communications and mechanical failures, or not having personnel at the bedside who can convert robotic-assisted surgery to open surgery may prove to be problematic in some cases.

#### **Relevant Financial Relationships Statement**

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All other faculty, CME Planning Committee Members, and the CME Office Reviewers have disclosed that they have no relevant financial relationships with ineligible companies that could constitute a conflict of interest concerning this CME activity.

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\* Personal observation of Dr. Housman

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