The Cutting Edge

Robot-Assisted Surgery Is a Growing Field That Requires Standardization

"Come with me if you want to live." The robot played by Arnold Schwarzenegger in the film *Terminator 2* may have uttered those lifesaving words in a distant fictional future, but in our present day robots are already having quite a dramatic impact saving lives. In the United States and Europe, many surgeons now operate computer consoles that control robots that assist them in operations. The robot does not perform actions independently but serves as a direct extension of the surgeon's own hand.[1] From minimally invasive general surgery, pediatric surgery, gynecology, and urology, to cardiothoracic surgery, robotic surgical devices have become an increasingly familiar fixture in hospitals.

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Surgical robots are much more complex, both electrically and mechanically, than other devices typically used in an operating room (OR). They have a high degree of dexterity, which allows surgeons to operate in very tight spaces that would normally require open surgery. This external and internal contact with patients, distinguishes them from surgical equipment such as imaging devices and microscopes.[1]

As robotic devices continue to evolve and become less expensive, they will be used more frequently in ORs across the world. According to surgical robot company Intuitive Surgical, the number of US procedures done with the robots jumped to 367,000 in 2012, compared with 292,000 in 2011 and 228,000 in 2010.[2]

Advantages and Disadvantages

Proponents of robotic surgery point to its many advantages for surgeons. "Advantages over traditional laproscopic surgery include three-dimensional visualization with improved depth perception, improved dexterity, and instrument articulation. This improved dexterity and visualization offers some advantages in complex procedures, such as those for malignancies," says Suzanne B. Gavigan, MSN, CRNP, patient safety specialist, Office of Quality Monitoring at The Joint Commission.

Benefits to patients include shorter hospitalization, reduced pain and discomfort, faster recovery times, smaller incisions resulting in reduced risk of infection, reduced blood loss and transfusions, and minimal scarring.[3]

But the use of robots is not without detractors. As the popularity of robot surgery has grown, so have the number of injury reports. In 2009 the US Food and Drug Administration (FDA) logged 24 incidents. In 2012 that number nearly quintupled to 115, while deaths rose to 30 from 11.[4] However, these statistics don't necessarily mean robots caused deaths and injuries, only that they were involved in the surgeries.

Gavigan says a 2013 study looked at the one million cases of robotic surgery in the FDA adverse events database. From 2000 to 2012, only 245 events and 71 deaths were reported.[4] "The study author feels adverse events often go underreported with this new use of technology because it is difficult to separate surgeon error from device-related injuries, and there is currently little oversight in event reporting, and little incentive to improve reporting practices," she says.

Specific incidents related to robot surgeries in the last few years have also called attention to safety concerns. In one incident, a male patient's liver and spleen were allegedly punctured during a heart valve repair.[4] In 2012, researchers from Memorial-Sloan Kettering Cancer Center reported three cases of blood vessel burns caused by insulation failures with a robot.[4] Throughout the health care community there are many stories like these that shine a light on complications related to robots.

The Challenges of Robot-Assisted Surgery

Because robot-assisted surgery is still growing, many surgeons have not had extensive training in using the machines effectively. In the early stages of surgeons' learning how to work with robots, operations are commonly longer, which means greater fatigue for surgeons and nurse surgical staff, and greater potential for complications with anesthesia in the OR. To truly become adept at using robots, surgical teams must perform at least 150–250 procedures.6 Extended surgeries and long learning curves can also increase the risk for position-related patient complications.

Patient Positioning in Robotic Surgery—Patient positioning in extended robotic surgery is a major patient safety issue. Many operations involve the positioning of patients at angles that become more complicated when robots are involved. This is particularly true of Trendelenburg positioning techniques. In the Trendelenburg position, the body is laid flat on the back with the feet higher than the head by 15–30 degrees. The reverse Trendelenburg position has the body tilted in the opposite direction. In surgery, robot arms can partially obscure patients from view, and surgeons may become dissociated because they perform these operations sitting at a console away from the table.[2] Unlike surgeons, who can make location corrections after noticing a patient has slipped on the table, a robot is not programmed to compensate for changes in position. In some instances, a patient's small slide on the table will trigger the robot's arms to assume the primary role for restraining the patient.[7] Complications related to positioning can include patient neuropathy, blindness, necrosis, bruising, and potentially prolonged post-op pain.

Anesthesia in Robotic Surgery—Given the long duration of many robot-assisted surgeries, the management of anesthesia administered to a patient requires special attention. Access to patients is limited when the robot arms are in place due to the size and bulk of the robot, as well as to the draping over both the robot and patient. Patients in the Trendelenburg position for extended periods are at risk for an increase in the systemic release of catecholamine—hormones from the adrenal glands. That extra adrenaline could cause a patient to wake up in the middle of surgery. Other issues an OR staff must watch for include the

development of hypothermia, the hemodynamic and respiratory effects of the pneumoperitoneum, and blood loss. Administering anesthesia and evaluating and monitoring the patient are all important components of Joint Commission Provision of Care, Treatment, and Services (PC) Standards **PC.03.01.01** and **PC.03.01.05**. Element of Performance (EP) 2 of Standard PC.03.01.01 states that "a sufficient number of qualified staff are present to evaluate the patient, to provide the sedation and/or anesthesia, to help with the procedure, and to monitor and recover the patient." EP 1 of Standard PC.03.01.05 requires that "During operative or other high risk procedures, including those that require the administration of moderate or deep sedation or anesthesia, the patient's oxygenation, ventilation, and circulation are monitored continuously." (*See* "Related Requirements" on page 10.)

Costs Can Be High

Along with the risks associated with positioning, anesthesia, and the time needed to become proficient with robots, using these sophisticated machines can be very expensive. Robotic surgical systems have fixed costs of $1 million to $2.5 million for each unit,[5] plus the high costs of capital acquisition, limited use instruments, team-training expenses, equipment maintenance, equipment repair, and OR setup time.[1] In a consensus document on robotic surgery, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the Minimally Invasive Robotic Association (MIRA) estimate that the sum of maintenance costs each year is approximately 10% of the capital acquisition cost.[1]

Developing Standards for Safety in Robot-Assisted Surgery

All these potential problems and challenges associated with robot surgery can be difficult to address, particularly when the field is still new and developing. Right now there are no safety or training standards available for surgeons, registered nurses, or OR technicians. Universal protocols for positioning in robot surgery are also currently nonexistent.

Developing standards for robotic surgical procedures is becoming more important than ever. To reduce patient injury risks during robotic-assisted procedures, it is vital that the OR staff understand and practice the necessary safety steps. At the moment, the World Health Organization and other health care industry stakeholders are working to develop protocols for using and managing these new technologies. The SAGES-MIRA consensus recommends that uniform standards be developed and privileges to perform procedures with robots be requested. The consensus recommends that surgeons be adequately trained in the use of surgical robots prior to clinical use to maintain the highest levels of patient care. It states that surgical proficiency should be assessed for every surgeon, and credentialing granted only by the individual institutions where surgeons work. A system that monitors performance after a surgeon has been credentialed is required to maintain robot surgery privileges.[1]

Gavigan says the learning curve is variable: "Current guidelines would indicate that when a surgeon adopts a new technique they should be supervised or assisted by a more experienced colleague until satisfactory competency has been determined."

She adds that credentialing for robotic-assisted surgery within and across specialties should be based on training, experience, and documented current competency, per the American Congress of Obstetricians and Gynecologists Technology Assessment on Robot-Assisted Surgery (available at http://journals.lww.com/greenjournal/Citation/2009/11000/ACOG_Technology_Assessment_No__6__Robot_Assisted.36.aspx.)

Adding a Second Time-Out to Robotic Surgeries—In the attempt to standardize robot use, many experts are calling for new protocols during surgery. A recent study published in *Patient Safety in Surgery* has recommended a surgical checklist (*see* Figure 1, page 9), based on their studies, that is aimed at reducing perioperative complications and addressing obstacles presented by lengthy robotic surgeries.[2] The standardized checklist is designed to be used during a second "time-out," which takes place three to four hours after the start of surgery, and complies with The Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™, which requires preoperative verification, site marking and a time-out prior to incision (*see* "Related Requirements" on page 10 for the complete requirement).

Key elements of the checklist help to coordinate operative staff in verifying patient safety while addressing the unique concerns within each specialty.[1] According to the study, a second time-out gives the OR team an opportunity to identify and prevent problems related to robot-assisted surgery. It's essentially a double check to make sure the OR staff is performing the surgery successfully and the patient is properly protected for extended periods of time. It also offers nursing staff time to adjust equipment and verify surgical counts. Joint Commission Standards **PC.03.01.01** and **PC.03.01.05** both require that a patient be monitored during operative or other high-risk procedures. The additional time-out could help to ensure that requirement is met.

A second time-out also presents an opportunity for

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Related Requirements

UP.01.03.01
A time-out is performed before the procedure.

Elements of Performance for UP.01.03.01

1. Conduct a time-out immediately before starting the invasive procedure or making the incision.
2. The time-out has the following characteristics:
   - It is standardized, as defined by the organization.
   - It is initiated by a designated member of the team.
   - It involves the immediate members of the procedure team, including the individual performing the procedure, the anesthesia providers, the circulating nurse, the operating room technician, and other active participants who will be participating in the procedure from the beginning.
3. When two or more procedures are being performed on the same patient, and the person performing the procedure changes, perform a time-out before each procedure is initiated.
4. During the time-out, the team members agree, at a minimum, on the following:
   - Correct patient identity
   - The correct site
   - The procedure to be done
5. Document the completion of the time-out.
   Note: *The organization determines the amount and type of documentation.*

Standard PC.03.01.01 for Hospitals
The hospital plans operative or other high-risk procedures, including those that require the administration of moderate or deep sedation or anesthesia.
Note: *Equipment identified in the elements of performance is available to the operating room suites.*

Elements of Performance for PC.03.01.01

1. Individuals administering moderate or deep sedation and anesthesia are qualified and have credentials to manage and rescue patients at whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally. (*See also* MS.06.01.03, EP 6)
2. In addition to the individual performing the procedure, a sufficient number of qualified staff are present to evaluate the patient, to provide the sedation and/or anesthesia, to help with the procedure, and to monitor and recover the patient.
   Note: *Hospitals that provide obstetric emergency operative services can provide anesthesia services as required by law or regulation.*
5. A registered nurse supervises perioperative nursing care.
6. **For operative or other high-risk procedures, including those that require the administration of moderate or deep sedation or anesthesia:** The hospital has equipment available to monitor the patient's physiological status.
7. **For operative or other high-risk procedures, including those that require the administration of moderate or deep sedation or anesthesia:** The hospital has equipment available to administer intravenous fluids and medications, and blood and blood components.
8. **For operative or other high-risk procedures, including those that require the administration of moderate or deep sedation or anesthesia:** The hospital has resuscitation equipment available. (*See also* MM.03.01.03, EP 2)
10. **For hospitals that use Joint Commission accreditation for deemed status purposes:** In accordance with the hospital's policy and state scope-of-practice laws, anesthesia is administered only by the following individuals:
    - An anesthesiologist
    - A doctor of medicine or osteopathy other than an anesthesiologist
    - A doctor of dental surgery or dental medicine
    - A doctor of podiatric medicine
    - A certified registered nurse anesthetist (CRNA) supervised by the operating practitioner except as provided in 42 CFR 482.52(c) regarding the state exemption for this supervision
    - An anesthesiologist's assistant supervised by an anesthesiologist
    - A supervised trainee in an approved educational program

    Note 1: *In accordance with 42 CFR 413.85(e), an approved nursing and allied health education program is a planned program of study that is licensed by state law or, if licensing is not required, is accredited by a recognized national professional organization. Such national accrediting bodies include, but are not limited to, the Commission on Accreditation of Allied Health Education Programs and the National League of Nursing Accrediting Commission.*
    Note 2: *"Anesthesiologist assistant" is defined in 42 CFR 410.69(b).*

Standard PC.03.01.05 for Hospitals
The hospital monitors the patient during operative or other high-risk procedures and/or during the administration of moderate or deep sedation or anesthesia.

Element of Performance for PC.03.01.05

1. During operative or other high risk procedures, including those that require the administration of moderate or deep sedation or anesthesia, the patient's oxygenation, ventilation, and circulation are monitored continuously. (*See also* RC.02.01.03, EP 8)

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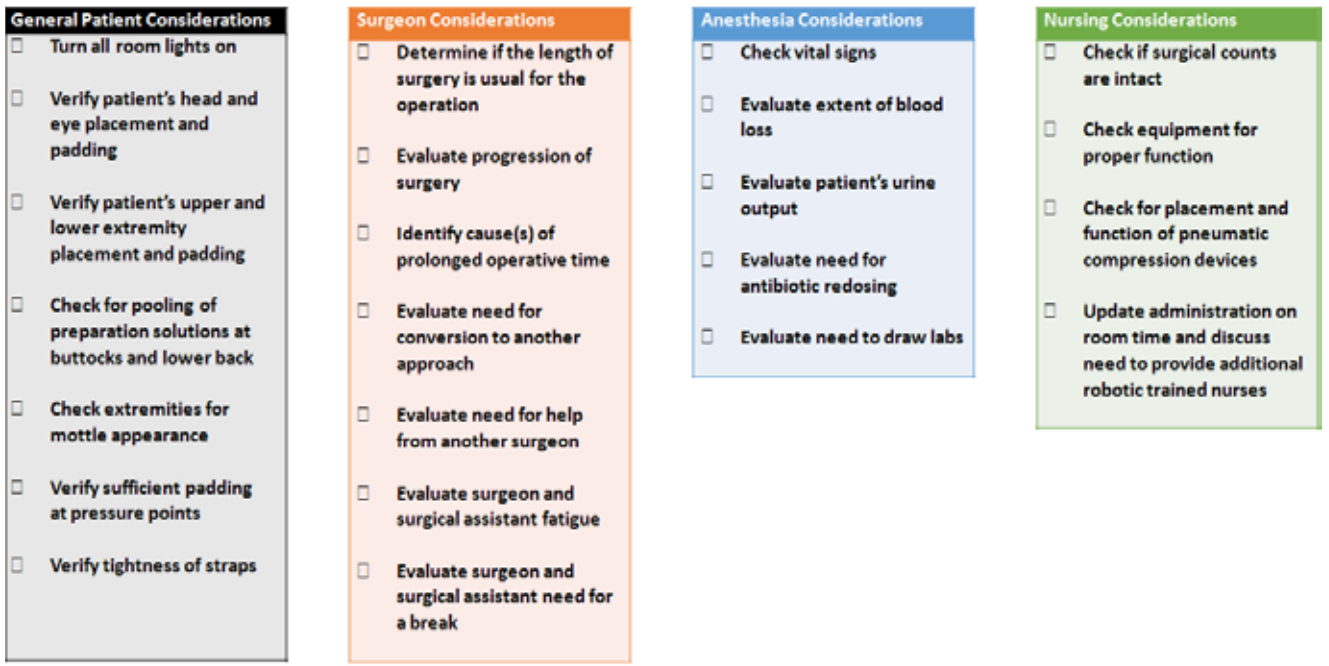
Figure 1. Checklist for a second time-out in extended robotic surgeries



Surgical time out checklist, customized for robotic surgeries. Used with permission.

surgeons to evaluate an operation's progress and better identify the challenges and limitations of the operation. A number of factors may delay the completion of the procedure. The length of robotic surgeries may cause surgeons to go out of sync with operative time. They are often sitting in these surgeries and may be less likely to experience muscle pain or fatigue. Although robotic surgeries can be less physically demanding than normal surgical procedures, the extended time period can still have an adverse mental effect on surgeons and their teams.[2]

Robots will undoubtedly play an increasingly larger role in the future of surgery. The advantages of improved precision, better visualization, and quicker recovery times for patients make robot-assisted surgery an important part of advancing medicine. Those advantages, however, also come with complications, such as longer operation times and greater learning curves that can significantly strain the OR staff. Gavigan says it's important that future researchers "evaluate long-term outcomes, cost-effectiveness, and patient satisfaction among all disciplines that utilize [robot] technology." Developing universal standards that address these issues and offer protocols for training, credentialing and performing robot-assisted surgery will also go a long way toward making sure the technology is used safely. TS

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