Rise of the Machines: Robotic Surgery, Patient Safety, and Liability

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The turn of the 21st century was witness to a significant technological milestone in American healthcare — the approval of the first robotic surgical system (RSS) by the U.S. Food and Drug Administration. Now, more than a decade later, robotic surgery is used for hundreds of thousands of procedures in the United States each year, and the number continues to grow.¹

Unlike in open surgery or traditional laparoscopy, in which the surgeon stands over the patient and uses his or her hands to operate the surgical instruments, robotic surgery uses a computer-assisted robot as an intermediary in the surgical process. The surgeon sits at a console and uses hand and foot controls to maneuver instruments and a small camera on thin robotic arms through small incisions in the patient. The surgeon is able to monitor progress using a three-dimensional viewer on the console.

During robotic surgery, the surgeon typically is in the operating room, but removed from the patient. However, the technology also offers the possibility of robotic telesurgery, in which the surgeon operates the robot from a remote location.²

Since its inception, robotic surgery has become a "symbol of medical progress," and has been featured prominently in popular print and electronic media.³ Both large and small healthcare organizations have invested in RSS technology, and the number and types of procedures done using robots have continued to expand over the years, reaching various specialties such as general surgery, urology, gynecology, cardiology, orthopaedics, and oral and maxillofacial surgery. With time, more applications for robotic surgery will most certainly emerge. For example, in dentistry, robots might be used to perform preventive, restorative, and curative procedures.⁴ Further, robots "could offer dentistry improved accuracy, predictability, safety, quality of care and speed of treatment."⁵

However, despite the growing interest in, and proven and purported benefits of, robotic surgery — such as greater precision and visualization, smaller scars, faster recovery, lower infection rates, and less pain — questions have arisen about patient safety and the appropriate use of this technology.
A 2012 article in *Trial*, a publication of the American Association for Justice, states that "RSS are so new that patients, doctors, hospitals, insurers, manufacturers, and the FDA are still trying to determine their efficacy and risks."6

This article examines some of the risk management concerns surrounding RSS — such as training, competency, credentialing, learning curves, proficiency, patient selection criteria, and informed consent — and offers strategies to help doctors minimize potential liabilities.

**Reconciling Business With Safety and Efficacy**

For many hospitals and healthcare organizations, the incentive to invest in RSS is significant. Robots have been marketed as a way to increase revenue and capture market share. The technology can offer a state-of-the-art advantage over competitors and provide an enticing recruitment tool for sought-after surgeons.

Further, direct marketing to patients has resulted in increasing pressure for hospitals to offer the cutting-edge robots as a treatment option. The authors of an article about anesthetic care in robotic surgery explain that, “In today’s information age, patients are more educated about their options and often have a strong desire to seek out the most advanced therapies, which makes the existence of a robotic program a marketing tool.”7

However, those who are cautious about RSS point to the limited research comparing robotic surgery outcomes with open surgery and traditional laparoscopic surgery. For example, in March 2013, the Massachusetts Board of Registration in Medicine issued a robot-assisted surgery advisory to its hospitals. Although the board acknowledged that RSS offer numerous technical advantages, they cautioned that large-scale, high-quality, prospective studies have not yet been done.8

A spike in RSS-related adverse events reported to the FDA’s Manufacturer and User Facility Device Experience (MAUDE) database also has raised concerns. Between 2012 and 2013, the number of adverse event reports linked to robotic surgery more than doubled9 — accompanied by a proliferation of national and regional media reports detailing deaths and injuries associated with RSS.

Additionally, and as a possible result of the media reports, a simple Internet search of robotic surgery lawsuits turns up numerous law firms seeking clients who have suffered complications or poor outcomes following surgery, such as burns, tearing of the intestines and arteries, organ and nerve damage, excessive blood loss, and bowel injuries.

Although the FDA notes that the increase in adverse event reports might be associated with greater use of robotic surgery and more public awareness,10 these reports still highlight the need for healthcare organizations and surgeons using RSS to evaluate
risks and take necessary precautions to maximize patient safety and minimize liability exposure.

**Evaluating Robotic Surgery From a Risk Management Perspective**

As the RSS market continues to surge and patient demand grows, more hospitals and healthcare organizations will likely invest in these systems. Further, because the robots carry a hefty price tag — costing between $1.5 and $2.3 million[^11] — it will be important for organizations to see a return on their investments, which may result in increased pressure on surgeons to use RSS.^[12]

Robotic surgery may potentially offer many benefits for both patients and doctors; however, like any new technology, it also faces challenges, and “questions remain about clinician learning curves, what the ideal training program is, how many procedures are needed to maintain proficiency, and what criteria hospitals should use to credential surgeons using these systems.”^[13] Additionally, issues related to patient selection, marketing, and informed consent and decision-making have surfaced as primary risk concerns.

**Training**

In the fall of 2013, the ECRI Institute released its list of top 10 health technology hazards for 2014. Number nine on the list was “Robotic Surgery Complications due to Insufficient Training,” which noted that RSS are being used with more frequency and for additional types of surgery without consideration of surgical teams’ training and proficiency.^[14]

ECRI’s list supports the notion that training has been, and continues to be, one of the top ongoing risk concerns for robotic surgery — in part because no universal consensus has been reached on the appropriate type and duration of training, and requirements vary widely between facilities.^[15]

Although product and technical training is offered through the device manufacturer, recent literature suggests that this training alone may not sufficiently prepare doctors to perform surgery with the robot.^[16] Ultimately, hospitals and healthcare organizations are responsible for determining their own standards for clinical training, proctoring and oversight, competency, and credentialing.

Guidance from professional associations and information from robotic surgery research studies and literature can help organizations establish appropriate criteria. Several recent research studies and systematic reviews focusing on robotic surgery call for training that (a) is based on competency rather than time or quantity, (b) uses graduated learning objectives, with assessment at each level, (c) involves simulation/virtual training, and (d) sets minimum criteria for demonstrating competency.^[17]
A consensus statement from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the Minimally Invasive Robotic Association (MIRA) describes a broad twofold approach to training that involves technical and capability training and training for specific procedures. The consensus statement further explains that surgeons must have a thorough knowledge base and practical experience, understand standard operating procedures and emergency protocols, and be able to anticipate risks and develop appropriate responses.\(^{18}\)

For example, surgeons must be prepared to convert to traditional laparoscopy or an open procedure in the event of technical problems or certain clinical complications. As the SAGES-MIRA statement explains, “The basic premise is that the surgeon(s) must have the judgment and training to safely complete the procedures as intended, as well as have the capability of immediately proceeding to an alternative therapy when circumstances so indicate.”\(^{19}\)

For doctors whose primary surgical experience is using RSS, conversion to open surgery may be problematic. In these cases, another surgeon who is experienced with open surgery should be available to assist if necessary.\(^{20}\) Surgeons also must be aware of the risks that may occur as the result of converting to traditional surgery — such as issues related to patient positioning and prolonged use of anesthesia — and have plans in place to manage those risks.\(^{21}\)

Running drills with the surgical team that simulate the appropriate steps to take during an emergency — such as disengaging the RSS, moving it away from the patient, and initiating a conversion to open surgery — can help prepare team members to handle various situations that might arise. Further, lessons learned from drills and actual surgeries can provide the foundation for the development of robotic surgery best practices and protocols.

**Learning Curve**

In addition to training considerations, surgeons should be aware of the learning curve associated with using RSS. In a recent FDA survey of a small sample of surgeons who are experienced with robotic surgery, all participants stated that they had to perform numerous surgeries using the robot before achieving proficiency. Although they did not think that the complexity of the device was a major barrier, many noted that it took
time to learn how to use the foot pedals, acquire needed hand–eye coordination, and operate the platform.22

Unfortunately, attaining proficiency with a surgical robot is not a cut and dry issue. The number of procedures required to demonstrate proficiency varies based on the type of procedure, and no firm standards have been set. Some estimates suggest that it may take hundreds of surgeries to attain high proficiency, while other estimates are lower.23 Further, a number of other factors also contribute to proficiency, such as basic skill, experience with technology, familiarity with the procedure, frequency of cases, and type of training.

Just as with other types of surgery, robotic surgery skills are honed over time. For less experienced surgeons, procedures may take longer and the risk of complications may be higher.24 Proctoring and mentoring opportunities, established as part of an organization’s credentialing guidelines, can help contribute to patient safety initiatives and address risks related to learning curve and proficiency.

Organizational policies also should establish criteria for maintaining proficiency over time, such as performance monitoring, continuing education, training, and recredentialing.

**Patient Selection Criteria**

One of the driving factors in the rise of robotic surgery is patient demand, but some patients who are eager for this new technology might not be ideal candidates due to comorbidities or other factors. For example, in the prostate surgery case mentioned previously, the patient was obese, diabetic, and had a history of heart surgery. These health conditions, combined with the surgeon’s limited RSS experience, may have ultimately contributed to the patient’s poor outcome.25

Thus, an important strategy for managing robotic surgery risk is careful consideration of patient selection criteria. All participants in the FDA’s 2013 survey of experienced robotic surgeons felt that appropriate selection criteria played a pivotal role in successful patient outcomes. Although they noted that criteria may vary across specialties, standards were primarily based on maintaining patient safety.26

The 2013 advisory from the Massachusetts Board of Registration in Medicine also emphasized the importance of establishing patient selection criteria, noting that
“Careful preoperative assessment of patient risk is critical for preventing perioperative complications. Both the patient’s comorbidities and the complexity of the robotic surgical case are important risk factors that should be considered.”

By developing greater awareness of potential risk factors and contraindications for robotic surgery, healthcare organizations and surgeons can create and implement patient selection guidelines and assessment protocols, as well as reinforce or improve quality measures. Further, documenting the assessment of patient risks in accordance with established selection criteria can help justify clinical decision-making.

Another crucial risk strategy is managing patients’ expectations related to robotic surgery, which may prove challenging for healthcare organizations and surgeons. Because robotic surgery is new and complex, direct claims about benefits and safety might be difficult to make. Also, aggressive marketing — such as promoting the robot at public events; billboard, radio, and television advertisements; and prominent placement on websites — may overestimate benefits, overpromise results, and/or fail to define specific risks, leading to inflated patient perceptions.

A 2011 study that examined robotic surgery information on 400 U.S. hospital websites concluded that hospital marketing of robots touted benefits, often ignored risks, and was strongly influenced by the manufacturer. Of the 41 percent of hospital websites that included robotic surgery information, 73 percent used manufacturer-provided stock images and text. Eighty-six percent made statements about the clinical superiority of robotic surgery, but few provided comparative data.

The study’s authors explained that “Because patients regard information on hospital websites as medical opinion of the physicians working at that hospital, hospital website information carries credibility that can influence patient choice.”

These same concerns prompted the American Congress of Obstetricians and Gynecologists (ACOG) to release a statement addressing robotic surgery for hysterectomies. In that statement, ACOG’s president stressed the necessity of providing patients with factual information and education about their treatment options. The 2013 Massachusetts advisory echoed this sentiment and encouraged hospitals to pay attention to whether their marketing efforts have influenced how they select patients.
A careful review of advertising and marketing efforts promoting robotic surgery may help healthcare organizations and medical staff pinpoint potentially misleading statements and identify opportunities for clarity. Ultimately, these strategies might assist patients in making more educated and informed decisions about their care.

**Informed Consent**

Concerns about aggressive marketing not only point to the need for accurate and objective verbal and written information, but they also highlight the essential role of informed consent in robotic surgery. Yet, because robotic surgery is fairly new, the “standard of disclosure of the risks and benefits that hospitals must provide each patient is fluid and evolving.”

However, even without firm standards, providers should carefully consider informed consent discussions for procedures involving robotic surgery. In addition to standard and required consent information, doctors may want to educate each patient about:

- The procedure he or she is having and how it is performed
- The potential risks of robotic surgery, particularly in relation to his or her specific condition
- The surgeon’s past experience with robotic surgery, particularly with the recommended robotic procedure
- Alternative options for treatment
- What will happen in the event of an emergency or complication (e.g., the surgeon will switch to open surgery or traditional laparoscopy), as well as any related risks

Taking the time to provide the patient with these details and answer any questions can help ensure that the patient has the appropriate information to make informed decisions about his or her care. As with clinical decision-making, the surgeon should document the informed consent process in the patient’s medical record and include copies of any related consent forms (with patient signature).

**Conclusion**

The concept of robot-assisted surgery likely seemed far-fetched in the not too distant past. Today, however, the concept is a reality, and the reality is growing by leaps and bounds. Many factors have contributed to the rise of this technology, including the pursuit of new minimally invasive treatment options, strategic healthcare decisions, savvy marketing, and patient demand.

Although the possibilities and potential that robotic surgery offer are exciting, they should not overshadow patient safety and risk concerns. Hospitals, healthcare organizations, and surgeons who utilize RSS should be aware of key risk areas related
to robotic surgery, such as training, credentialing, proficiency, patient selection, and informed consent.

Developing greater awareness of the risks and establishing training and credentialing guidelines, patient selection criteria, emergency protocols, detailed informed consent processes, and performance monitoring standards can help enhance safety initiatives and minimize liability exposure.

Questions to Consider

The healthcare community can anticipate that malpractice claims involving robotic surgery will grow as the number of robot-assisted surgeries increases each year. Although each case will be unique, some questions that might be considered as part of the discovery and litigation process include:

- What are the strengths and limitations of the surgical system used in the procedure?
- Did the patient have a preexisting condition that made him/her an undesirable candidate for robotic surgery?
- Did an informed consent process take place and was it documented?
- How many robotic surgeries has the surgeon performed?
- How often during the course of robotic surgery has the surgeon had to convert to a traditional laparoscopic procedure or open surgery?
- What are the surgeon’s and/or hospital’s morbidity/mortality rates for similar procedures?
- How many procedures similar to the patients are suggested for proficiency and competency?
- How much and what types of training has each member of the surgical team received? Has the training been documented?
- Did the lead surgeon oversee or approve the surgical setup?


Endnotes


16 Ibid; Peters, Robots holding the scalpel; ECRI Institute, Top 10 health technology hazards for 2014.


18 SAGES-MIRA, A consensus document on robotic surgery.

19 Ibid.


21 Peters, Robots holding the scalpel.


23 Peters, Robots holding the scalpel; Langreth, Intuitive robosurgery training seen lacking in lawsuits.


25 Ostrom, Failed robotic surgery focus of Kitsap trial.
26 FDA, Small sample survey.

27 Commonwealth of Massachusetts Board of Registration in Medicine, Advisory on robot-assisted surgery.


31 Ibid.


33 Commonwealth of Massachusetts Board of Registration in Medicine, Advisory on robot-assisted surgery.

34 Peters, Robots holding the scalpel.