Surgical Robotics for Patient Safety in the Perioperative Environment: Realizing the Promise

Fuji Lai, MS, and Deon Louw, MD

Surgery is facing an introspective junction of both promise and peril. Despite novel technologies and techniques, an unacceptable level of perioperative error exists in the modern operating room (OR). Surgical harm in the perioperative environment can be traced to various causes such as misjudgment, inexperience, communication breakdown, and fatigue. An increasingly old and frail population amplifies the consequences of these errors. ORs designed 50 years ago are cluttered with complex technologies that had not even been contemplated at the time. Surgeons, using new intraoperative tools such as MRI scanners, endoscopes, and microscopes have reached the limits of their dexterity and stamina: the spatial resolution of magnified images exceeds the spatial resolution of human digits, resulting in a ceiling on surgical performance. It is into this high-velocity and complex environment that we are ushering in a new era of robot-assisted surgery to extend the capabilities of the human surgeon.

These issues were the focus of the discussion of the Working Group on Surgical Robotics at the Integrated Research Team meeting on patient safety organized by the Telemedicine and Advanced Technologies Research Center. This white paper attempts to facilitate the road toward realizing that promise by outlining a research agenda. The paper will briefly review the current status of surgical robotics and summarize any conclusions that can be reached to date based on existing research. It will then lay out a roadmap for future research to determine how surgical robots should be optimally designed and integrated into the perioperative workflow and process. Successful movement down this path would involve focused efforts and multiagency collaboration to address the research priorities outlined, thereby realizing the full potential of surgical robotics to augment human capabilities, enhance task performance, extend the reach of surgical care, improve health care quality, and ultimately enhance patient safety.

Keywords: surgical robotics; patient safety; perioperative

From Millard Health, Edmonton, Alberta, Canada (DL).

Address correspondence to: Deon Louw, MD, Neurosurgical Consultant, Millard Health, 131 Airport Road, Edmonton, AB, T5G 0W6, Canada; e-mail: deon@suresurgery.com.
The Promise: Understanding What Robots Are Good At

The promise of robotic surgery is immense. The heart of these benefits lies in exploiting particular strengths of computers, such as tremor-filtered precision and repeatability, to enhance the capability of the average surgeon. Furthermore, surgical robots can import data from devices (especially imaging) into the OR for information augmentation. These capabilities enhance surgeon performance and quality of surgical care by enabling surgeons to push the envelope of innovative surgical care by allowing exploration of techniques not currently possible. They also simplify the performance of standardized procedures. In addition, there is the potential to reduce the occupational environment hazard by removing the surgeon from biohazards, for example, radiation exposure. Also, the computer assist can enable extension of surgical care into hostile or geographically remote areas as well, providing console-to-bedside care. For example, some of the advantages of robotic endoscopic surgery over traditional endoscopic methods include improved ergonomics, increased dexterity, better spatial mapping, enhanced visualization and stereoscopic depth perception, removed fulcrum effect, motion scaling, tremor reduction, faster patient recovery, and the ultimate removal of the barriers of time and space for remote telesurgery and telementoring when expertise is not local to the patient site. Ultimately, these benefits result in overall improvement in patient safety and hospital experience through reduction in invasiveness of surgical procedures, decreased pain, and shorter hospital stays.

Robots are also indefatigable and are good at holding scopes or retractors in place for prolonged periods. Another example would be that of neurosurgery, in which the neurosurgeon may need to maintain the same posture for hours on end. The use of a robot to preserve the tool position would allow the surgeon to engage in intervals of rest. A related advantage is that robots allow reindexing, whereby the hand controls can be readjusted to a more comfortable workspace.

Computer-enforced safety is a seductive benefit. One such feature is the virtual fixture or “no-fly zone.” The physical dissociation of the user (master) from the end effector (slave) in teleoperated systems has opened the possibility for creation of virtual barriers that can restrict tools to specified safe areas, keeping users from doing inadvertent damage to tissue. Because computer software converts user input to an action, protective algorithms can be inserted into the software to prohibit undesirable motion. Virtual fixtures could, for example, create safeguarding envelopes to allow surgeons to dissect arteries without inflicting damage to them, perform surgery close to a beating heart without accidentally contacting it, or conduct blunt dissection with a guiding track to limit the number of degrees of freedom. Another safety feature would be predetermined force limitation to prevent application of injurious forces. Computer-enforced safety can also exploit information connectivity between the various systems in the perioperative environment. This closed-loop control permits self-monitoring and regulation by alerting, limiting, or preventing certain actions from taking place.

Finally, the reclassification of some of these systems as computer-assist devices instead of robots has accelerated Food and Drug Administration (FDA) regulatory acceptance. Of paramount concern to the FDA are technical design, safety, and the risks of the device to the patient.

The Threats: Current Drawbacks and Needed Improvements

The introduction of a robotic system into the OR undoubtedly disrupts the existing perioperative workflow and process from the perspective of many stakeholders. In addition to the impact on efficiency, it could potentially also introduce new patient safety concerns. Many robotic systems have large footprints and are difficult to fit into already overcrowded ORs. These systems can limit access to the patient and be difficult to move and setup. Once the robot is in the room, it can become an obstacle that the surgical team must maneuver around. Taking a teleoperated endoscopic procedure as an example, we have the team usually consisting of at least 2 nurses, an anesthesiologist, the operating surgeon, and an assistant surgeon. Each surgical team member’s role needs to adapt to the introduction of a robotic system into the OR. For the surgeon, this involves an entirely new way of conducting surgery, including patient selection, port placement, increased perceptual demands particularly due to limited force or haptic feedback, and initially increased cognitive demands. In addition, the robotic configuration of these systems dictates that primary surgeons be removed from the patient’s side and the
sterile field as well as from the rest of the team. Surgeons lose the situational awareness of patient proximity, and they have limited visual information of the macroscopic surgical field through the scope image alone. This compels surgeons to be more dependent on the remaining team members for communicating the status of the patient as well as their prompt intervention in the event of a complication.

For the anesthesiologist, situational complexity and patient protection needs are increased. The robotic system imposes new methods of patient care. Anesthetic management may need to be temporarily modified by increased procedural duration during the initial robotic surgery learning curve. This is a significant point because increased time under anesthesia increases the risk for the patient. Patient protection responsibilities are also increased for both the anesthesiologist and the nurse. Furthermore, from the nurses' point of view, the robot increases the number and difficulty level of the tasks they must perform, including sterilization, setup, tool exchange, and access to the patient. The nurse's role as a protector of the patient is now also magnified by the presence of the robot near the patient. At the same time, they must spend energy and attention attending to the needs of the robotic system, which can divert their attention from the patient. A further implication of the initially increased procedure time is that a robotic case is more likely to run across personnel shifts. This is important to address as handoffs have been identified as critically vulnerable points in the perioperative process when information can be lost or misinformation introduced during the transition.5

Robotic surgery requires a radical culture shift from traditional methods. Training and the assessment of aptitudes, attitudes, and skills through appropriate metrics will be an important issue to ensure smooth transition to new modes of surgery without compromising patient safety. The initial steep curve when learning to conduct robotic procedures is seen as the most vulnerable period and presents the most significant risk to patients, and evidence shows that most injuries occur in the first few operations performed by trainee surgeons. While robotic surgery can extend the capability of minimally invasive procedures to surgeons who do not have extensive laparoscopic experience, it is important that this tool of a robotic surgical assist should not be misused by those who do not have fundamental surgical capabilities, and it is also important to prevent overreliance on such a tool. Regardless of whether a robot is used to assist a procedure, the same tenets of surgery apply in that the surgeon is still ultimately responsible for the patient. It is crucial that surgeons maintain their proficiency in open surgery methods as well as endoscopic methods to be able to respond and convert the surgery in the event of an unexpected situation.

Roadmap for Future Research: Priority Research Areas

The vision of the OR of the future is that of compatibility, interoperability, and modularity of surgical robotic systems with the ability to leverage digital data for computer-enhanced surgery.6 In addition to some of the human-system integration issues outlined in the previous section, there are further technical considerations that threaten the realization of the vision. Current robotic systems are limited in their applicability to different specialties and procedures. Systems tend to be very specialized and focused on specific procedures. Furthermore, most systems allow limited portability and mobility. For example, many systems do not make it easy to support procedures requiring a larger amount of translational area or to enable procedures requiring work in more than 1 anatomical area or “workspace envelope.” Limited availability of compatible instruments and equipment is also a challenge. There is still room for improvement in the range of instrument types available.

The current conceptions of robotic systems are also limiting. It is easy to fall back on traditional notions of robots that take over tasks currently done by humans. There are alternative robotic concepts that could be used such as robots that could perform interventions through natural orifices or microrobots that can be guided into the body to conduct minimally invasive interventions. The form factor of surgical robots has also tended to be traditional, for example, the use of master-slave configurations with surgeon consoles. There may be alternative approaches that could be explored that would essentially redefine the preconceived notion of the mode of use and form factors of surgical robots. Cyberhelmets with “looks that cure” and cybergloves manipulating virtual anatomy are some of these possible options.

It is also of note that the multidisciplinary and interdisciplinary collaboration between all civilian
and military stakeholders such as government agencies, standards organizations, research organizations, and developers will be essential to implement this integrated vision. Such collaboration could take the form of combining intellectual resources and identifying and fostering progress in the 5 pillars of priority research.

Task Characterization for Design of Collaborative Human-Robot Teams

Computer-assist systems that are well designed and effectively used have tremendous potential for improving the quality of health care and enhancing patient safety. As mentioned, the key to value in clinical use, however, lies not only in system functionality but also in the congruence of system design to actual clinical tasks, work practices, and context of use. An essential objective is to design robots according to detailed surgical requirements. It is necessary to characterize the work domain as well as task and user needs to design relevant robotic systems from the top down. Such a top-down approach would not only inform design efforts but also simplify validation efforts as the objectives, benefits, and value added by the robotic system will now be more clearly defined.

First, patient safety pull should drive development instead of a technology push. For robots to make significant inroads into the OR, robotic surgery cannot be a technology looking for an application. If we are taking the approach of redefining surgery from the conventional methods, it is important to understand the limitations of the latter and to start from a fundamental analysis of what the key issues are to design something that is useful and provides actual benefit for the surgeon and team. This would involve starting with a fundamental identification of the boundaries and task needs, for example, through their characterization and decomposition. An understanding of the basic skill, job, task, and subtask hierarchy in a surgical procedure and their reallocation or sharing between human and computer will be a critical matter. An understanding of human versus robotic roles is also vital for reconfiguring the surgical environment. There must be appropriate task sharing between the computer system and the human user to capitalize on the strengths of each. From the task analysis and decomposition, it is possible to identify the tasks that lend themselves to computer assistance. Interestingly, it may very well turn out that the largest opportunity may be robotic assist of tasks that are farther away from the patient, such as scrub nurse robots or, more distantly yet, supply chain management. The surgeon’s task is likely the most difficult to bring robotic assist to as it is at the most critical juncture with the patient and the most vulnerable sharp end of the system. Such definitions of robotic roles and tasks, standardization, and incorporation of surgical robotics into surgical ontology will be key for the seamless integration of robots into the perioperative process and workflow.

Definition of Safety Design Process, Protocols, and Computer-Enforced Safety Features

Safety expectations and guidelines need to be addressed. Robotics in nonmedical applications require constraining the robot to actions away from humans to minimize potential harm. However, that strategy does not work in the case of surgical robotics, where the robot in many instances must participate in a direct action on a human being. There needs to be consideration of safety throughout the design and testing process, and it should not be considered a “bolt on.” Potential hazards need to be identified and addressed. Safety for surgical robots requires consideration of all potential hazards including mechanical, electrical, software, and sterilization concerns. Mechanical safety, for example, includes adhering to principles of redundancy and reduced speed and power of actuators. Manipulators need reduced power and velocity within the working volume near the patient. General robotic safety features may include, for example, the “dead man’s switch.” To date, although various safety strategies have been identified, no standard safety guidelines have been developed for surgical robotics.

In addition to the safety issues related to technical design of the system, there are important safety considerations with regard to human factors. There is the issue of comfort level and trust of clinicians (not to mention patients) in the robotic system, and this is a barrier that must be overcome. The robot must not present as a “black box” but should be transparent to the surgeon. In particular, it is crucial to address the human factors of cognitive fit of the robot into the surgical process to align with FDA guidelines for safety. It is important for the surgeon to always have the capability to be in control of
the procedure and to override the system and regain direct control as needed. This emphasizes the need for established safety protocols in the event of unexpected complications. Furthermore, any computer-enforced safety features need to be designed to be congruent with user expectation and strike the appropriate level of user trust while preventing potentially dangerous overreliance on the computer assistance.

Information Integration

The OR of the future will be an increasingly information-rich environment. One of the indisputable benefits of surgical robotics is that the use of this technology makes data from other systems more readily available to the surgeon. Efforts to develop surgical robotic systems should focus on emphasizing the patient safety benefits afforded by data, computer, and multisensor integration. This fusion of the physical, biological, and informational will maximize efficacy and safety of the OR of the future, potentially permitting surgeons to transcend their human constraints.

This includes work that needs to be done to initially capture multimodal data for preoperative planning, intraoperative guidance, and as a platform for training and simulation as well as a method for identifying new surgical techniques. The challenge thus becomes how best to harness the power of information by mining the most salient data elements and presenting them in a meaningful way for preoperative and intraoperative information visualization and fusion, without resulting in information overload (described as “helmet fires” by fighter pilots).

Another fertile research area should be a dynamic integrated surgical safety project (ISSP), which evaluates the effect of robotics, virtual reality, and augmented reality on the situational awareness of the surgeon of tomorrow. These technologies will result in almost complete digitization of the surgeon’s surgical space, with its attendant benefits and risks. Critical analysis will lubricate the transition between the industrial age and information age models of health care delivery and have an integrated surgeon and integrated OR as objectives. The second author’s experience with the challenges of incorporating intraoperative imaging (magnetic resonance imaging [MRI]) into surgical work flow is just one motivator to minimize similar difficulties with robots. The ISSP would have a mandate to log an error bank, including near misses (or preferably, the term near hits), which would lead to the development of a surgical robotic manual of errata.

The Role of the OR as a Clinical and Technical Laboratory

A necessary step is to formally contrast randomized telerobotic, in situ robotic procedures and conventional surgery in the setting of randomized controlled trials (RCTs). Process data (reflecting operational efficiency) and outcomes data (particularly pertaining to complications) will be compared and, if there is any difference discerned, correlated with potential contributing factors such as latency and jitter. It will be difficult to justify routine use of telerobotic surgery in remote areas without this level of evidence. These trials should ideally be done relatively expeditiously, prior to so-called early adoption. Delaying trials results in the paradox of widespread adoption with subsequent de facto standard-of-care status but without the robustness of RCTs as a gold standard of validation. Attempts to recruit surgeons into trials at that stage will frequently result in ethical objections, a situation that has plagued the analysis of intraoperative MRI.

New robotic and associated imaging platforms will be sequentially tested with simulations, animals, cadavers, and finally in the OR or imaging suites. These technical innovations will drive diversity and safety and blur the distinction between imaging and intervention. Robots will initially be guided by extrinsic imaging modalities such as computed tomography, MRI, and endoscope or microscope cameras and then increasingly by the intrinsic imaging capabilities of their end effectors. An obvious example would be to couple miniature ultrasound devices such as intravascular ultrasound to surgical tools. Great attention should be paid to developing new classes of tools, designs of which are now liberated from conforming to the constraints of the human hand. Smaller, articulated and intelligent tools should offer unprecedented precision and safety. Tissue could be interrogated by sniffer tools that accurately differentiate tumor cells, marking them for pinpoint destruction by a laser. We should maximally exploit Moore’s law and its prediction that machine intelligence will eclipse human intelligence within a few decades by coupling this phenomenon to human factors research. These technical and tactical precepts will not only prevent but also treat patient harm.
Simulation, Training, and Certification

Robot workstations have the distinct advantage of doubling up as platforms for simulation. Recent research confirms the intuition that risk-free rehearsal of a procedure (probably at least 50 times) reduces surgical complication rates. However, most of us find that currently available simulators display modest fidelity, particularly for soft-tissue force-deformation modeling. A reasonable hypothesis is that superior simulation could accelerate safe training. Force metrics from surgical robots decorated with smart, strain-gauged tools could be coupled to tissue deformation data from a digitized video grid overlay. Apart from permitting superior calibration of conventional surgery, it should also increase the accuracy of viscoelastic finite element modeling and enhance the fidelity of simulation. This research program should occur within a context of parallel performance measurements of surgeons conducting conventional and robotic procedures. Measurements should include surgeon physiology (pulse, blood pressure, surface electromyography, electroencephalography, saliva cortisol), posture, efficiency, and impact metrics.

This performance quantification, of both real and simulated surgery, will provide a useful mechanism for the objective certification of surgeons and the evaluation of the efficacy of training techniques. Early consultation between a national committee of surgeons with relevant robotic experience and the American College of Surgeons would ensure the development of national objectives and guidelines.

Finally, lessons could be drawn from the space industry, which has long leveraged the seamless marriage of simulation and robotics for training astronauts to conduct complex dexterous manipulator tasks. For example, the Canadian Space Agency (CSA) has developed the primary robotic simulation training program for astronauts who use Canadarm2 on the International Space Station (ISS). The CSA instruction provides performance measurement and system validation, and is embedded in a mission-critical philosophy of error anticipation and avoidance. ISS robotic training techniques may offer a blueprint for generic surgical robotic training and warrant further review.

Concluding Remarks

Surgery is at a crossroads of complexity. However, there is a potential path toward patient safety. One of these paths that can be taken is to leverage computer and robotic assist techniques in the perioperative environment. Successful movement down this path would involve focused efforts and multiagency collaboration to address the research priorities outlined to realize the full potential of surgical robotics to augment human capabilities, enhance task performance, extend the reach of surgical care, improve health care quality, and ultimately enhance patient safety.

References