JUNE/JULY 2021

A PUBLICATION OF LAW BULLETIN MEDIA

CHICAGO LAWYER®

MED-MAL MATTERS

A TRUE HELPING HAND?

As robot-assisted surgeries grow so do questions

By THOMAS A. DEMETRIO and KENNETH T. LUMB

Since robotic assistance in surgery was first approved in 2000, its use has exploded. In 2014 alone, an estimated 570,000 procedures were performed using the da Vinci robotic surgical system.

According to Drs. Tara Kirkpatrick and Chad LaGrange, writing for Agency for Healthcare Research Quality Web M&M (Morbidity & Mortality Rounds on the Web), though robotic surgery proponents believe the systems improve surgical technique and improve patient outcomes, robot assistance creates a new set of risks and patient safety issues.

Robotic-assisted surgery (RAS) is a descendant of laparoscopic surgery. Both techniques utilize small incisions and carbon dioxide insufflation to expand and expose the operative space. Various instruments are inserted into the body through ports and manipulated by the surgeon using a camera also inserted through a port. In the laparoscopic technique, the surgeon directly manipulates the instruments through the ports.

In RAS, handpieces transmit the surgeons hand movements to the instruments, which then perform the movements, a kind of digital fly-by-wire system. The da Vinci robotic surgical system includes a built-in motion filter to minimize tremor, and foot pedals allowing for different types of energy and movement of the components inside the patient. The da Vinci system also sports two binocular lenses that create a magnified, three-dimensional image for the surgeon.

The purported benefits of RAS are mostly short-term, including smaller incisions, decreased blood loss, shorter convalescent time and a lower incidence of some surgical complications. Though there is still considerable debate over the magnitude of any long-term benefits of RAS over laparoscopic and open techniques, there is no doubt that RAS outcomes are affected by a relatively steep learning curve.

According to Dr. Kirkpatrick, RAS shares the same risks as open and laparoscopic surgery but adds risks specific to the RAS technology, including not only human error in operating or maintaining the equipment, but also mechanical failure of the equipment itself. Many different parts of the system can malfunction, including the robotic arms and instruments, the camera and the binocular lenses. Burns caused by arcing of the electric energy source is a particular problem.

By far the greatest risk of RAS arises from its learning curve. Studies clearly established that RAS outcomes directly correlate to operator experience. Though reports on the number of procedures necessary to provide enough experience to allow a surgeon to safely use the technology differ, some studies suggest as many as 250 procedures may be necessary.

Even as the surgical community works to master conventional RAS, researchers are adding artificial intelligence to the system in an attempt to allow it to perform procedures or parts of procedures autonomously. In 2016, Dr. Azad Shademan and colleagues published a report in Science Translational Medicine describing the complete and autonomous reconnection of a severed pig's intestines using a surgical robot with AI. Unlike standard RAS systems which translate a surgeon's movements in real-time, Dr. Shademan's system was controlled by AI algorithms receiving input from a variety of visual and tactile sensors.

Researchers are already working on systems to perform autonomous robotic procedures, or portions of procedures, in humans. The first step is to "teach" the surgical robot how to perform a specific procedure, which of course includes the recognition of patient-specific anatomy and the ability to adapt in real-time to achieve a predetermined surgical outcome.

Just as technological advances require changes in medical thinking, the use of robotic equipment has required lawyers handling cases stemming from its use to adapt. Discovery of the surgeon's training and experience with the device and the specific procedure involved has become much more important, along with the hospital's maintenance of the device. Where a patient suffers a "recognized complication," was she informed that the surgeon had only performed 95 similar procedures? Would she have consented to the use of RAS if fully informed of the particular correlation in RAS between experience and low complication rates?

Once AI enters the picture, potential areas of liability multiply. In addition to the operator's record, one must also determine how the robot was "trained." What databases were used? How many procedures did the system "view"? Were they real or virtual?

An even more fundamental question, though, is who is responsible for surgical error? The surgeon, the manufacturer or the hospital? The answer in most cases will likely be a combination of all three. CL

Thomas A. Demetrio is a founding partner of Corboy & Demetrio, representing victims of medical malpractice and personal injury.
TAD@CorboyDemetrio.com

Kenneth T. Lumb is a medical-malpractice attorney and managing partner at Corboy & Demetrio.
KTL@CorboyDemetrio.com