Medical Xpress

Remote-control surgery grows, despite inconclusive evidence

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Chubby, pink and anesthetized into unconsciousness and paralysis, 16-week-old Ian Lund was a small bump under blue drapes on an operating table at University of Chicago Medicine. Perched above him was a robot, with arms like a three-legged spider.

One long instrument, containing a camera, had been inserted through the baby's bellybutton. Two others had been slipped into small incisions in his left side, each with tiny operating tools. All three arms were controlled by a surgeon sitting in a boothlike console facing a wall several feet away.

Operating the surgical instruments with joystick-like controls and the camera with his foot, Dr. Mohan Gundeti carefully snipped away a blocked portion of Ian's left ureter, the tube that carries urine from his left kidney to his bladder, and sewed the healthy part back to his kidney.

The operation was a success; Ian would go home the next day. His mother, Denise Lund, burst into tears upon hearing the news.

"Can I tackle-hug you?" she asked, rising to embrace Gundeti.

The robot, known as the da Vinci Surgical System, was built by Intuitive Surgical Inc. The Sunnyvale, Calif., company has sold more than 1,500 robotic systems in the U.S.

Intuitive Surgical is a medical sensation, transforming surgery in some

fields, especially gynecology and urology, in about a decade. More than 250,000 hysterectomies and prostate removal surgeries were done with the da Vinci last year, according to the company. Surgeons are expanding use of the machines to other procedures, from gastric bypasses to thyroid cancer surgeries. Advocates of the devices say they make minimally invasive surgery possible for more patients, helping them recover more quickly and in less pain.

But patients wondering whether they should opt for robot-assisted surgery should be aware that the choice is sometimes more complex than the messages presented by hospitals and the company.

Despite a flood of scientific papers associated with the da Vinci, there is a dearth of randomized, controlled studies showing patients do best if procedures are performed with the da Vinci. Federal oversight of medical devices such as the da Vinci is light. There have been voluntary recalls - more than a dozen since 2005 - involving problems with software and surgical instruments. Lawsuits have helped raise concerns that some surgeons are using the devices before the doctors are adequately trained.

This month, a jury awarded a Chicago man's family $7.5 million after he died following a robot-assisted removal of his spleen in 2007 at the University of Illinois Hospital. Neither the hospital nor Intuitive was named as a defendant in the lawsuit. The family alleged that the man's small intestine was punctured twice during surgery, causing a fatal infection.

The man's surgeon testified it was the first time he had used the robot on a living person, according to court documents.

"The robot is the symbol of the current American health care marketplace - rapid widespread adoption with little to no evidence to

support it and increased costs," said Dr. Martin Makary, a surgeon at Johns Hopkins School of Medicine and author of a study of 400 hospital websites that found they were making unsupported claims about robot-assisted surgery.

The technology that eventually gave birth to the da Vinci robot was created in the 1950s by engineers who wanted to develop robotic arms that could be maneuvered from afar to handle hazardous materials or go places people cannot easily go, such as in space or at the bottom of an ocean.

Eventually people wondered whether the technology, which had been expanded and refined, could be used to improve surgery.

Before the da Vinci, minimally invasive surgery was accomplished with hand-held long instruments and a camera introduced through guiding tubes inserted through small incisions. Known as laparoscopic surgery, that approach spared patients a long scar while potentially reducing complications, pain and recovery time.

But laparoscopic surgery proved hard for many surgeons to learn. The instruments had limited movement compared with the human wrist, and the technique was difficult to adapt to more complex procedures.

The engineers behind the da Vinci aimed to solve those problems, said company CEO Gary Guthart, an engineer who has been with the company since 1996. The da Vinci system would let the surgeon sit and move tools designed to mimic the natural motion of the wrist. The tools would move intuitively. Minimally invasive surgery would be easier to learn. A special video camera would offer a three-dimensional image.

Makary said he remembers when he saw a da Vinci system for the first time, at a surgery conference. Surgeons crowded the exhibit booth, vying

for a chance to try the robot.

"It was the hottest thing," he said.

By 2009, U.S. News and World Report had put the da Vinci robot on the cover of its best-hospitals issue.

"The public perception was if you don't have a robot, you aren't one of the best hospitals," said gynecologic oncologist Dr. John Chan, a surgeon at the University of California, San Francisco.

According to Intuitive, about two-thirds of top-tier U.S. hospitals - including 15 in Chicago - have at least one da Vinci surgical system, which cost $1.1 million to slightly more than $2 million, plus a yearly maintenance contract that can cost up to $180,000.

Despite the enthusiasm, there is not conclusive evidence on whether robot-assisted surgery is worse, better or the same than other approaches.

A 2011 review of studies involving robot-assisted partial nephrectomy, a surgery to remove part of the kidney, found no randomized, controlled clinical trials comparing approaches, but also no indication the procedure was less safe or led to worse outcomes. Last month, researchers reported that they found no randomized, controlled clinical trials, pro or con, on robot-assisted surgery for gynecological cancers.

Doctors are divided over the benefits.

"The marketing largely has sort of suggested that (with robot-assisted surgery) everything is better: better potency, better continence," said Dr. William Catalona, director of the clinical prostate cancer program at the Robert H. Lurie Comprehensive Cancer Center of Northwestern University at Northwestern Memorial Hospital. "Actually, that turns out

to be untrue."

Even the data on one of the most popular robot-assisted surgeries, the radical prostatectomy, are mixed. The surgery is a difficult one, requiring the surgeon to remove the cancerous prostate without damaging nerves that control a man's continence and sexual function. Give the nerves too wide a berth, and cancer may be left behind. Get too aggressive, and the nerves may be damaged, risking impotence or incontinence.

One 2010 review of studies comparing approaches to the prostatectomy questioned whether valid conclusions could be drawn about one technique over another at all due to the lack of strong studies.

"I believe that robotic prostatectomy is not only not better than open prostatectomy, it is not as good," wrote Catalona, who has performed more than 6,000 open prostatectomies and is a vocal critic of the push for robot-assisted surgery, in an email.

Dr. Gregory Zagaja, a surgeon who helped develop the robot-assisted surgery program at University of Chicago Medicine, said robot-assisted prostatectomies are as good as open.

"If you look at (the scientific literature), cancer control and sexual function and urinary control, they are pretty much equal," said Zagaja, who has performed about 1,800 robot-assisted procedures. "The perceived benefit is that they will be able to get back to full-functional capacity faster."

Intuitive CEO Guthart said there are 4,600 peer-reviewed clinical papers involving the da Vinci system, including more than 500 comparative studies.

"The literature is incredibly deep," he said.

He said there are not many blinded, randomized, controlled clinical trials because it is hard to do such trials in surgery in general. Patients don't want to leave decisions about surgery up to what amounts to a coin toss, experts say.

Those studies will never happen, said urological surgeon Dr. Arieh Shalhav, who founded the robot-assisted surgery program at University of Chicago Medicine. "That shift to robot-assisted surgery was so fast."

Guthart said he disagrees that the jury is still out on robot-assisted surgery and cited a number of studies showing benefits, including a 2011 analysis of studies done by the Canadian Agency for Drugs and Technologies in Health that found statistically significant differences favoring the robot over open surgery and laparoscopic surgery in some areas. But that study warned that the evidence wasn't as strong as it could be, and that it was unclear how meaningful those differences were.

Shalhav said the popularity of the robot-assisted surgery is evidence itself.

"We should not ignore the 'wisdom of the crowd,'" he wrote in an email.

For patients unsure of whether they want to join the crowd, one key variable is the experience of the surgeon.

Studies have shown that surgeons learning to operate using the da Vinci face a steep learning curve. Accustomed to being guided by the feel of tissue, surgeons must learn to be guided by their eyes, as the robot offers no sense of touch. They must develop hand-eye coordination without seeing their hands.

Some of that can be learned using Intuitive's surgical simulator, on cadavers or animals, and in being mentored by more experienced surgeons. But eventually, a surgeon has to hone his or her skills on living people.

Researchers have tried to determine how long it takes surgeons to master the technique, delivering the same results a patient would have gotten with a traditional surgical approach. Intuitive estimates the number is about 20 cases. Other studies have put the number higher, at dozens of cases to well more than 1,000.

"There is no doubt experience matters," said Shalhav, who has done more than 1,500 robot-assisted surgeries. "At about 500 cases, something clicked."

At that point, he felt he could handle the most complex cases, he said: "Until then, everything was with learning."

Juan Fernandez was Dr. George Salti's first robot case, in January 2007. Salti's attorney, David Hall, said the surgeon had been fully trained on Intuitive's simulator program and had observed a dozen procedures on human patients. He also brought in a surgeon with lots of robot experience to co-manage the operation.

Hall said Salti and the other surgeons in the operating room said the procedure was uneventful. But Fernandez became desperately ill soon after the operation. Two small holes were discovered in his small intestine.

Hall said there was no evidence the surgeons caused the holes, but the jury disagreed, awarding the family $7.5 million.

In a way, baby Ian is a living comparison of open versus robot-assisted

surgeries. Weeks before Ian's da Vinci procedure, Gundeti, who has performed about 112 robot-assisted cases, operated on the child's other ureter. It was blocked to such an extent that his kidney was being seriously damaged, and the baby was not large enough to have the operation done with the robot yet.

So Gundeti did it the old-fashioned way. He made a 2-inch incision in Ian's right side and did the work directly with his hands, holding tiny tools.

Ian went home about three days after the operation, his parents said.

"It was definitely more sore when he was cut versus the robotic," said his mother, Denise Lund. "It was completely different."

Denise Lund is a veteran of the open surgery too, having had the same problem as a child.

Talking about it, she reaches to her side. "I still have a scar," she said. "But they fixed me."

WHAT TO ASK YOUR SURGEON

Here are some questions patients should ask their surgeon when considering a robot-assisted procedure:

When did you do your first robot-assisted procedure? How were you trained? How many robot-assisted cases have you done? How often do you do them? How many robot-assisted cases have you done of my procedure?

Are you more comfortable doing this type of procedure laparoscopically, robot-assisted or the traditional open approach? What are the pros and cons of each?

What happens if the robot malfunctions during surgery or you have to convert to open surgery? How many open cases of my procedure have you performed? How often do you do them?

What kind of training on the da Vinci do the nurses and other surgeons in the operating room get? How experienced are they? How experienced are they in converting to an open procedure mid-surgery?

Will you be mentoring another surgeon during my procedure? Will he or she be doing any of it? If so, how many cases has he or she performed?