

Robots in the OR

With Guidance of Surgeons, Four-Armed Devices Make Tricky Incisions in Operations

By **BERNARD WYSOCKI JR.**

A FOUR-ARMED surgical robot costing \$1.2 million is becoming a fixture in a growing number of hospital operating rooms. But is it the next wave in minimally invasive surgery, or technological overkill at an exorbitant price?

The da Vinci surgical system has been on the market since 2000, but its sales have taken off only in the past year or so. Regulators have cleared the device for a lengthening list of surgical operations, and the robot has won a following among several prominent surgeons. Among them are urologists who use it for prostate removal in cancer patients, and cardio-thoracic surgeons who deploy the robot to assist in heart-valve repair.

Made and marketed by **Intuitive Surgical Inc.**, of Sunnyvale, Calif., the company has installed just over 200 of these robots world-wide, with 61 sold last year, about 70% of them in the U.S. The company has also installed systems in Canada, Europe, Japan and Australia.

In operating the device, a surgeon sits at a console a few feet from the patient, peering into a high-powered camera while guiding the robotic arms, inserted into the patient's chest, to perform cutting and stitching deep inside the body.

"This is the most expensive pair of scissors you could ever buy," says W. Randolph Chitwood, chairman, department of surgery, at East Carolina University in Greenville, N.C. He has performed about 130 mitral-valve repairs on patients using the da Vinci robot and is a strong advocate of the device, saying it provides unmatched precision for delicate operations.

"For the patient, there's less pain, less blood loss and faster recovery time," he says. Conventional open-heart surgery requires much larger openings in the chest cavity.

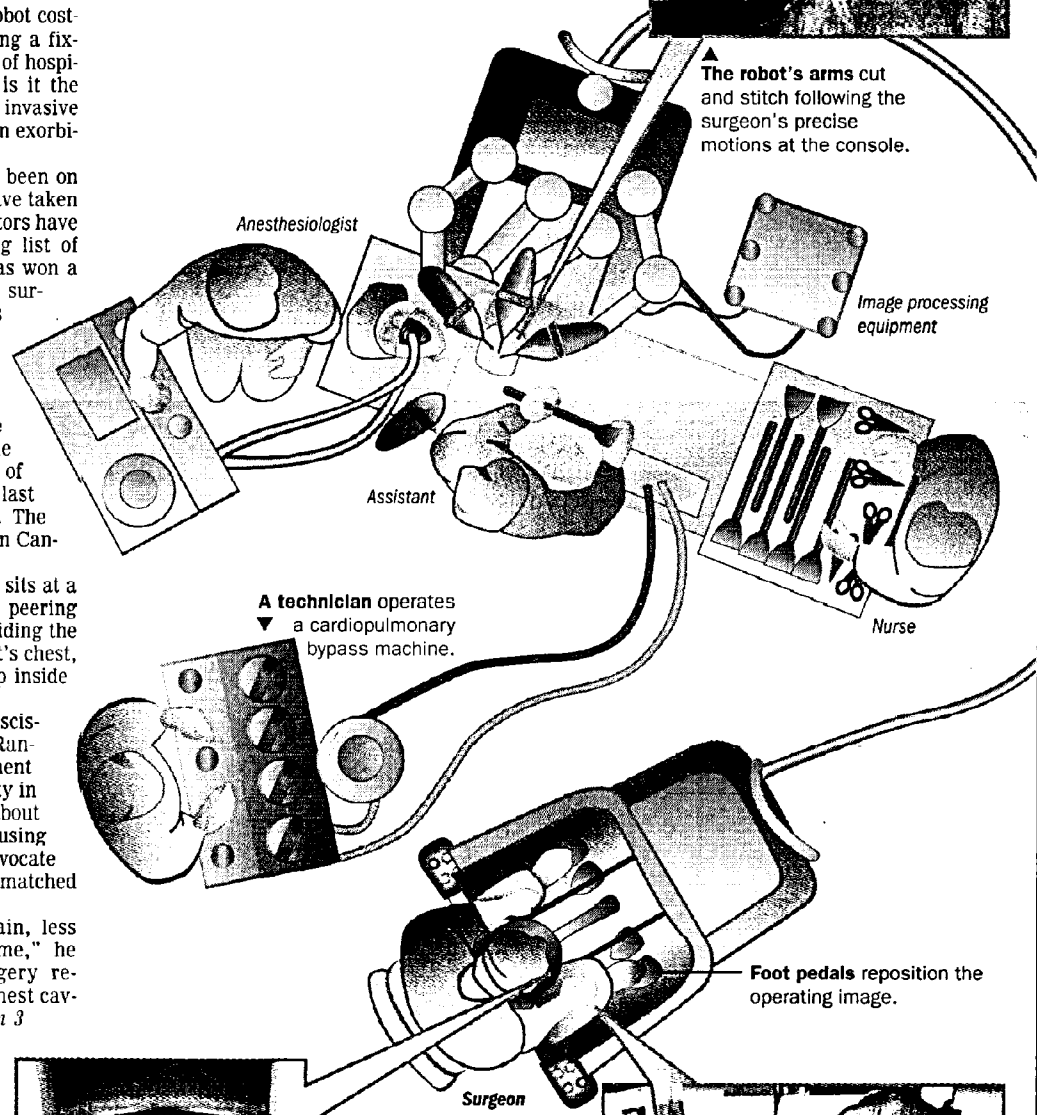
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Hands-Off Heart Surgery

The \$1.2 million da Vinci surgical robot can cut and stitch deep inside the body, making surgery less invasive and speeding recovery time. A look at how the operating floor is set up using the robot during open-heart surgery;



▲ The robot's arms cut and stitch following the surgeon's precise motions at the console.



▼ A technician operates a cardiopulmonary bypass machine.

Foot pedals reposition the operating image.

▶ The surgeon looks into a high-powered camera, called InSite Vision, to see 3-D images of the operative field.



▶ The surgeon manipulates tools, called console masters, which move the EndoWrist robot. The robot replicates the surgeon's movements on the operating table.



Rachel Pak/The Wall Street Journal

Source: Intuitive Surgical

ity, longer hospital stays and a greater chance of needing blood transfusions.

Even proponents, however, worry about the steep price tag. "The cost has to come down or it could become like the Concorde" supersonic transport, which stopped flying in November, says Mani Menon, chairman of urology at Henry Ford Hospital in Detroit, where he and his colleagues used the da Vinci robot in more than 400 prostate removals last year. But the price won't be brought down by intense competition anytime soon; Intuitive Surgical bought its chief rival in the robotic-surgery marketplace last year.

Despite the high cost, hospitals may feel compelled to buy a da Vinci system because some patients are starting to demand it. "If you can't offer this, you are going to lose your patient base," says Edward Janosko, chief of urology at East Carolina University, part of the North Carolina state system.

Although it is less invasive than traditional forms of surgery, the robot-assisted procedure are still complicated and delicate. In a mitral-valve repair, the patient's heart is stopped for about two hours, with bypass machinery in the operating room taking over the heart's function. A pair of robotic arms are inserted through the chest wall. The operation also requires a 2-inch incision opening up the heart, enough room for a second surgeon to do hands-on collaboration and for an endoscopic camera.

Earlier this month, one patient told Dr. Chitwood the day before the procedure, "I was surprised to hear that they would have to stop my heart." Dr. Chitwood told the patient that he couldn't guarantee 100% success, but that of more than 125 previous cases, none had died from the procedure. (Two patients died months later from other complications.) In this case, the patient had a successful operation but had an allergic reaction to medication after surgery and died a few days later.

Most of the time, however, the mitral-valve repair goes like clockwork, as it did last Monday when 65-year-old William Ogden, a Wilmington, N.C., retiree was wheeled into the operating room. At the console, the "remote" surgeon sees the heart and his robotic instruments in three dimensions, magnified 10 times. The surgeon uses thumb, forefinger and normal wrist movement to manipulate the robotic arms, which have tiny knives or forceps at the tips. The surgeon manipulates the camera from a foot pedal. A fourth robotic arm is available, but unused by Dr. Chitwood in these operations. In a typical case last week, the operation took a bit over two hours, about a third of that time spent cutting and rebuilding the damaged heart valve.

Advocates say that in complex surgery, the robotic assist is more precise and more practical than "keyhole" surgery, which uses small incisions to insert long lighted, laparoscopic instruments. Moreover, both of these techniques—long instruments or robotic arms—are far less invasive than traditional open-heart surgery, still used for some operations.

But the device poses risks—potentially fatal—in the hands of inexperienced surgeons. In December, the family of a Tampa, Fla., man filed suit against St. Joseph's Hospital in the 13th Judicial Circuit Court, Hillsborough County, Fla.,

charging the hospital was negligent in allowing two doctors lacking experience and training to use the robot in a 2002 procedure. The patient, a 53-year-old high-school teacher, died in the aftermath of an aborted robotic kidney removal.

At the time of the incident, St. Joseph's issued a statement calling it a "tragic isolated accident that does not jeopardize future care" but required all of its surgeons wishing to use the robotic system to take additional training courses. The hospital has since filed a motion to dismiss the case, which is pending. No charges were brought against the doctors, nor were charges brought against Intuitive, the maker of the robot.

The big costs of da Vinci go beyond those of the hardware itself and include the extra training of doctors and staff. Procedures often take longer than traditional "open" surgery, especially at first. And typically, the robotic-assisted procedure requires more medical personnel in the operating room, raising costs to doctors and hospitals at a time when nursing staff is in short supply and insurance reimbursements are usually fixed, and don't always cover costs. The company says, however, that some postoperative hospital costs are lower after robot-assisted surgery, such as nursing time, since patients generally recover faster.

At East Carolina, surgeons say that the hospital gets paid a fixed fee of about \$25,000 for the total costs of each heart-valve repair regardless of whether robotics are used. That figure includes the hospital stay and other costs and is enough for East Carolina to make a small profit. The procedure, with or without robots, is covered by Medicare and private insurers.

At present, only a tiny fraction of surgeries involve robotic assistance. About 3.4% of radical prostate surgeries in 2003 were performed using robotics, says Eric Miller, senior vice president at Intuitive Surgical, although the rate is rising fast. Using the da Vinci system for such surgeries will be a hot topic at the American Urology Association meeting in May, says Dr. Janosko. And while the number is rising, and clinical results are impressive, there's still debate among surgeons over whether it's really more precise. The stakes are high: In such a delicate operation, a surgical mistake can leave the patient impotent or incontinent for life.