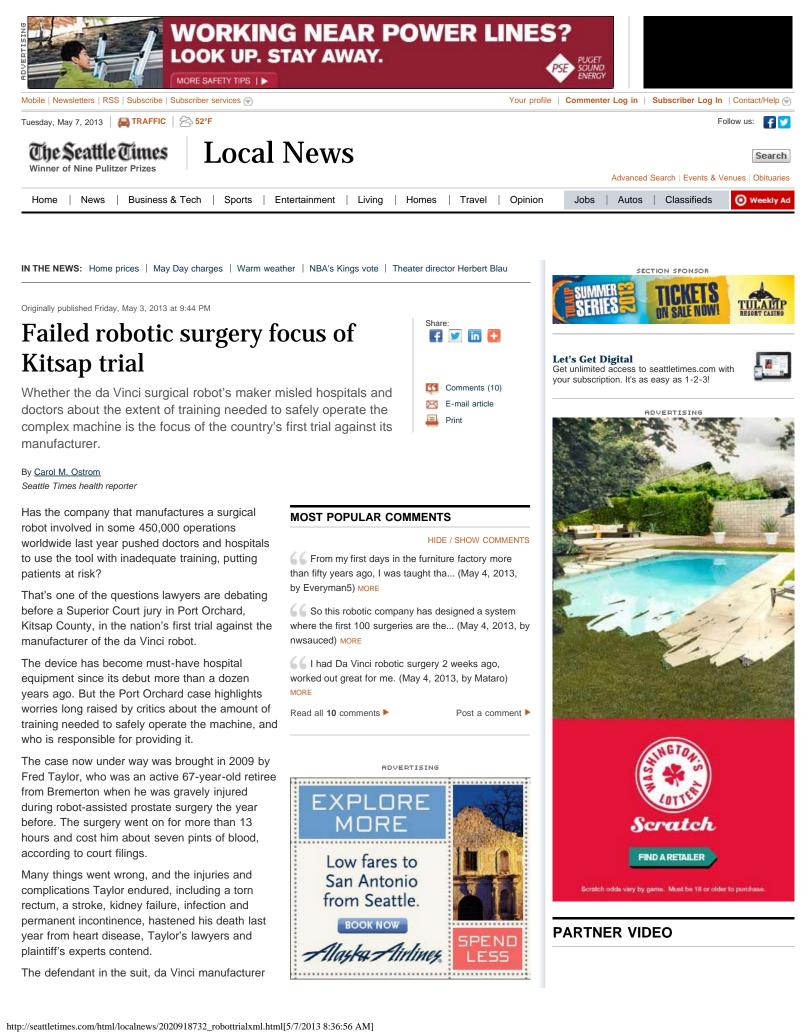
Failed robotic surgery focus of Kitsap trial | Local News | The Seattle Times



Intuitive Surgical, says the robot worked as designed and the company isn't responsible for surgical mistakes.

Taylor's was the first unsupervised robotic-surgery case for the surgeon, Dr. Scott Bildsten, who had previously done only two prostate surgeries with the robot. Bildsten, 57, had done over 100 prostate surgeries in the traditional open manner, using large incisions, with no complications, according to information filed in the case.

The robot allows doctors to make much smaller incisions.

Bildsten, in court papers, said Intuitive, based in Sunnyvale, Calif., led him to believe he could safely perform surgery with only a company training course and the two supervised surgeries.

If he had known the truth about the steep learning curve and time needed to master the robot, he said in court papers, he likely would never have agreed to be trained on it.

Intuitive, for its part, said it warned Bildsten and other doctors to pick simple cases with nonobese patients for their first few robotic procedures.

Taylor, a 280-pound diabetic who had undergone previous heart surgery, was not a good candidate for a first unsupervised robot-assisted surgery, the company said.

The company has said robot-assisted surgeries, overall, are safer than open surgeries, and patients recover faster. In part, that's because the operation is done through small keyhole openings, rather than large incisions.

The robot's tiny, multidirectional arms, controlled by the surgeon from a remote console that provides a 3-D view, can reach into tight spaces, and the robot's software eliminates the shaking of a surgeon's hands. The company and many surgeons also say that being able to sit during long surgeries reduces fatigue.

In Taylor's case, Intuitive has argued that the rectal tear actually happened after the robot was removed, nearly nine hours into the surgery, and Bildsten converted to an open procedure.

Exactly how much training is necessary for surgeons to safely use the da Vinci, and the quality of the company-provided training, has been debated since the complex and expensive surgical robot first made its appearance some 13 years ago.

Taylor's lawyers have offered testimony from company-sales people detailing the pressure to sign up doctors and hospitals to use the device.

Last year, Washington state's Health Technology Assessment Program looked at robotic surgeries, and assessments by doctors varied greatly. Some said the robot, with its magnified field of vision and small, powerful tools, can enable average surgeons to tackle more difficult surgeries and give expert surgeons even more abilities.

Others, however, cautioned that the robot technology can add considerable time to surgeries, as well as risks such as unintentional tissue lacerations or burns, particularly if doctors aren't experienced in its use.

There is no national standard for training, although some robotic-surgery experts are working to develop certification courses similar to other specialties.

Hospitals vary widely in requirements to use the machine — which can cost \$1.8 million or more with some medical centers mandating time on a simulator.

Originally, Taylor and his wife, Josette, sued Bildsten, a member of Kitsap Urology Associates, which is now part of the Franciscan Health System, and Harrison Medical Center, where the surgery was performed.

Harrison Medical Center and Bildsten have both settled in the case, which now focuses on whether Intuitive deliberately dumbed down its training in order to sell more robots, and whether it improperly implies to doctors and hospitals that surgeons can safely operate the machine after minimal training.

Harrison's attorney, Rando Wick, said Taylor's is the hospital's only robotic-surgery case that has had complications other than those likely with any type of surgery, such as minor bleeding or infections.

But Harrison will look carefully at Intuitive's training program in the future for any doctors who need to learn to use the robot, Wick said. "You really have to rely on the manufacturers and people setting out new equipment to adequately train your staff."

Dr. William Scott Helton, director of Virginia Mason Medical Center's Liver, Pancreas and Biliary Surgical Center of Excellence, said in court papers that the company's scaled-back training program Bildsten attended was "inadequate and unreasonable to ensure patient safety."

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A responsible company, said Helton, would have told Harrison and Bildsten that there is a "variable and unknown learning curve" for prostate surgeries for any given urologist.

Bildsten, for his part, said in court filings that Intuitive never told him what he now believes to be true: that he wouldn't be getting results equal to his open procedures until he'd done 100 or more robotic surgeries.

If he had been told that, "I would not have performed da Vinci surgery on Fred Taylor," he testified in court.

Intuitive has more than two dozen lawsuits filed or pending against it by patients, as well as a recent case filed in federal court in California by shareholders seeking class-action status. The shareholders' suit alleges the company made false and misleading statements about the safety and effectiveness of procedures using the robot.

The Taylor case, filed in Kitsap Superior Court in 2009, includes actions based on wrongful death and the Washington Products Liability Act, which establishes that product manufacturers have duties related to marketing and to warn and instruct on the use of their products.

The trial, which began in mid-April, is expected to last several more weeks.

The story includes material from Bloomberg News. Carol M. Ostrom: costrom@seattletimes.com or 206-464-2249. On Twitter @costrom.



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