The Technology that Could Save Robotic Surgery Millions

Software diagnostic research debugs robotic surgical systems

By Henry Lenard

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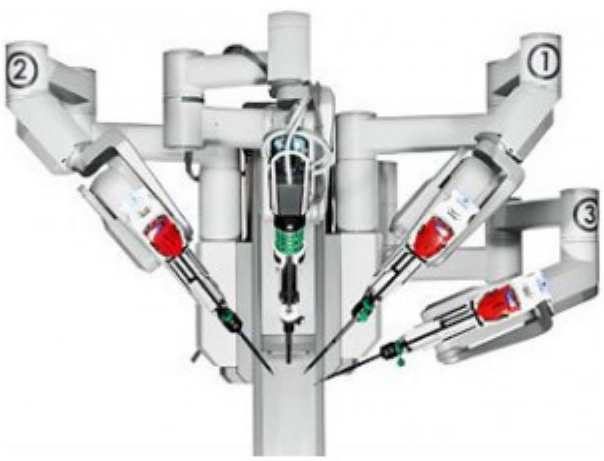
An increase in the number of malfunctions and complications in surgeries involving Intuitive Surgical's da Vinci robot has prompted new scrutiny by the U.S. Food and Drug Administration.

Growing safety concerns

Since early last year, the FDA has 500 reported incidents of problems with robotic surgeries, with at least five deaths. The agency does not distinguish between surgeon error and problems with the device itself, but Intuitive Surgical is facing a growing number of lawsuits.



In a press release, Intuitive Surgical said the rise in incidents "does not reflect product performance but rather a change in MDR (Medical Device Reports) reporting practices." Adding that of the increase in device malfunction reports, "the vast majority were related to instruments and not to systems. None of these device malfunction MDRs involved reportable injuries or deaths."

According to the FDA, the number of robotic-assisted surgeries has increased in the U.S. from 25,000 in 2005 to nearly 450,000 last year. The bulk of those involve the multi-armed da Vinci, which carries a price tag of $1.45 million plus an annual service agreement of $100,000 or more. The robot can now be found in 1,400 hospitals – or one-in-four – across America. Da Vinci is the only robotic system cleared for soft-tissue surgery by the FDA, although other robotic devices are approved for such procedures as neurosurgery and orthopedics.

A new approach to design flaw detection

This dramatic increase in robotic surgeries and growing concern about their safety gives new importance to the National Science Foundation-funded research by Carnegie Mellon University and the Johns Hopkins University's Applied Physics Laboratory reported recently by Robotics Business Review that hopes to reliably detect software bugs and verify the software safety of surgical robots.

"Our focus was on skull-based surgery," said Andre Platzer, assistant professor of computer science at Carnegie Mellon, who led the research study with Yanni Kouskoulas of Johns Hopkins' APL. "The standard past practice has been to try out hundreds and thousands of situations, but that is miniscule to the actual amount that can come up. Our robotic verification algorithm allows us to consider virtually every possible orientation of the robot simultaneously," he said.

Surgical robots are an example of a hybrid, cyber-physical system. These complex, computer-controlled devices are growing in usage and finding a way to prove they are free of design errors is the challenge confronting computer scientists. Hybrid systems have infinite variations of the physical world that must be accounted for, unlike traditional systems which may be complex but have a finite number of variations.

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Andre Platzer, assistant professor of computer science at Carnegie Mellon

According to Mr. Platzer, the new theorem-proving technique would be most helpful if used during the design of the robotic system instead of after the fact.

"Each control decision has a time lag because of the sensor update. Time delays are very complicated in dense areas like a skull, where you are making life-and-death decisions in a space of a millimeter or a sub-millimeter," Mr. Platzer said. "The algorithm needs to be done before the surgical procedure as the surgeon doesn't see all of the intricate geometry of the patient such as the aorta and central nervous system. The surgeon must make sure he never goes into a dangerous area."

Good news for the FDA

This formal verification technique could also change the way regulators evaluate new devices, said Mr. Platzer, providing more assurance of safety than now possible.

"The really difficult question for certification authorities like the FDA is how to assure the surgical robot is actually safe for use on a patient. Is there enough confidence in the system," Mr. Platzer said. "Our approach can help verification techniques by looking at them all at once to provide much higher assurance. We want to have surgical robotic systems verified and certified to a higher level."

"I talked to a medical doctor a while ago who had a good analogy on the difficultly of skull-based surgical procedures," Mr. Platzer said. "Suppose you had two balloons of almost the same size and you inflate one inside the other. Now imagine having to do surgery in between the two balloons without ever touching one of the boundaries because that would make the balloons explode. That is what the surgeon faces."

Mr. Platzer said that while his research focuses on skull-based surgery, it is principally designed to give feedback to surgeons and would be helpful to other types of robotic surgery as well.

Next stage development

While the research shows great promise, Mr. Platzer said it remains years away from implementation. "We have to really scrutinize everything. We need to make sure the surgical robot technology is mature enough to be helping, not hurting, the surgeon or patient. It must be scalable and robust," he said.

The next step, Mr. Platzer said, is to develop more complete geometrical configurations to assist the way surgeons handle the delicate boundaries beyond which healthy and vital tissue can be harmed without slowing them down unnecessarily.

He noted that the da Vinci system was in development for 10 years and expects a similar time frame for the new verification approach.

"This is an example of the general phenomenon of how computation technology is helping our society make really better and informed decisions," Mr. Platzer said. "Computers alone can't help. Physics alone can't help. It is the combination of computation and physical control that can solve problems that earlier generations could only dream of. Mathematically, it is very challenging."

About the author

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Henry Lenard is the former editor-in-chief of the Pittsburgh Business Times and also was editor-in-chief of the former Industry.Net, a national network of regional publications covering manufacturing and computer technology.