



## Risk Prevention in Laparoscopic Surgeries

Laparoscopic robotic surgeries allow surgeons to make much smaller incisions than those used in traditional surgeries. When surgeons insert special instruments through small cuts in a patient's body, they can use a video monitor and laparoscope (a tiny video camera) to view what's happening inside the body and perform the operation. Using these instruments, the surgeon doesn't have to manually reach into the patient, leading to a minimally invasive experience. Surgeons can make several small cuts instead of one large cut, each typically no more than a half-inch long [Ref. 1].

Yet laparoscopic surgeries are not without risk. Even highly used surgical robots, such as the da Vinci robot, have had their share of issues. Complications can occur due to the patient's condition and the type of surgery being performed. These complications include [Ref. 2]:

- Loss of a large amount of blood, resulting in the need for a blood transfusion
- Inadvertent cuts, tears, punctures, burns or other injury to organs, structures or tissues
- Loss of a needle, instrument fragment or any other object used during surgery within the patient's body
- Anesthesia risks, which can include heart attack, stroke, blood clotting deep in the body, blocked lung arteries, pneumonia (serious lung infection), dental injury, injury to the vocal cords and other complications that can lead to death
- Patient-positioning injuries, which can include hemodynamic, intraocular pressure, neurologic and soft tissue injuries

### Best Strategy for Preventing Risks

Even though the risks of laparoscopic surgery are low, they are life threatening when they occur. Therefore, we need risk avoidance strategies. Our long experience in safety tells us the best strategy is for the team to brainstorm ideas as to what can go wrong. To do thor-

ough work, the team can become familiar with proven risk analyses tools such as Preliminary Hazard Analysis (PHA), Fault Tree Analysis (FTA) and Failure Mode and Effects Analysis (FMEA) [Ref. 3].

For each hazardous scenario, use one of these options in the following priority order:

1. Prevent hazards (prevent causes of risks so the risk cannot happen)
2. Use fault tolerance design so there are at least two ways to verify the right output before a harm is done
3. Design-in ways to fail safely to avoid harm
4. Use prognostic monitoring processes to give early warnings of harm

### Prevent Hazards

According to a recent consensus statement, robotic telesurgery, in which the surgeon may be located at some distance from the patient, poses unique risks [Ref. 4]. For example, precise control of the robot depends on the quality of the data connection between the surgeon's console and the operating room robot. Issues pertaining to the quality and maintenance of such data connections may be beyond the control of the surgical team, but they still represent a risk management challenge of which the organization must be mindful. A team should be assigned to assure that data is reliable and secure.

### Use Fault Tolerance Design

If there is no way to assure the data is reliable and secure, the next best alternative is to have at least two redundant ways to verify that the desired output is the same. For example, the flight control software in the Boeing 777 contains three independently developed redundant codes to verify that the safe output is identical.<sup>1</sup>

<sup>1</sup> The author of this article, Dev Raheja, was a consultant to Boeing.



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### Design to Fail Safely

If there is still no safe strategy, the robot should be designed to monitor every safety-related measurement and shut down in the event of error before any harm is done. An architecture of a fail-safe control for robotic surgery has been developed, which uses two independent processing units to calculate the position values and compares the results before passing them to the drives [Ref. 5]. This system also includes several other safety functions, such as a redundant measuring system using a tripod within the hexapod kinematics, monitoring functions or watchdogs. The safety requirements for the system are derived from the regulations of the

medical device directive (MDD) and from a risk analysis of the control system.

### Give an Early Prognostics Warning of Harm

The University of Maryland's Mechanical Engineering Department has developed a Prognostics Health Monitoring (PHM) system that monitors every output that can result in a failure of the system [Ref. 6]. It covers tools and techniques of health monitoring in terms of novel methods for in-situ monitoring, approaches for resource-efficient data collection, algorithms for data reduction and parameter extraction identifying precursors based on failure mechanisms, and techniques for failure prediction. ●

### References

1. “What Is Laparoscopic Surgery?” WebMD, accessed on May 29, 2020, <https://www.webmd.com/digestive-disorders/laparoscopic-surgery>.
2. “Safety Information — Surgical risks: Patient facing,” Intuitive Web site, accessed May 29, 2020, <https://www.intuitive.com/en-us/about-us/company/legal/safety-information>.
3. Raheja, Dev. *Preventing Medical Device Recalls*, CRC Press, Boca Raton, FL, 2016.
4. “Potential Risks of Robotic Surgery,” The Joint Commission, June 2014, accessed on May 29, 2020, [https://www.jointcommission.org/-/media/depcreated-unorganized/imported-assets/tjc/system-folders/joint-commission-online/quick\\_safety\\_issue\\_three\\_june\\_2014pdf.pdf](https://www.jointcommission.org/-/media/depcreated-unorganized/imported-assets/tjc/system-folders/joint-commission-online/quick_safety_issue_three_june_2014pdf.pdf)
5. Laible, Ulrich, Thomas Bürger and Günter Pritschow. “A fail-safe dual channel robot control for surgery applications,” *Safety Science*, Vol. 42, No. 5, p. 423-436, June 2004, <https://www.sciencedirect.com/science/article/pii/S0925753503000808#!>.
6. Pecht, Michael. Course: Prognostics and Health Management, University of Maryland, College Park, Maryland, <https://web.calce.umd.edu/general/education/phm.html>.