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Perspective

Robotics: The Latest On The da Vinci Surgical System

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A Winning Formula: Procedure, Performance and Marketing

Success with robotics in the orthopedic space is predicated on selecting the right procedure, delivering clinical results and placing a Company's marketing horsepower behind the robotic technology. Only by demonstrating meaningful value from a clinical and economic standpoint, can orthopedic companies like Stryker (following its recent acquisition of MAKO), Blue Belt, and Mazor effectively transform a targeted procedure (knee or spine) into a "significantly better one" in a manner similar to Intuitive Surgical's success with robotic prostate removal.

The Issue

According to a draft analysis reported to the FDA by Rush University Medical Center (Rush), the University of Illinois (UI) and Massachusetts Institute of Technology (MIT), the da Vinci robotic-surgery device (made by Intuitive Surgical/California) has been linked to “an overall increasing trend in the rate of injury and death reports”.
Recently made available to the Wall Street Journal, the draft analysis focuses on all adverse-event reports made to the FDA from 2000 to 2012 and is consistent with observations made in a recent published study from Johns Hopkins University (JHU).

The Detail Behind The Issue

A Rush cardiac surgeon and the co-authors of the draft analysis (from UI and MIT) confirmed the following during the 12-year period studied:

- Almost 4,800 adverse events were reported in the US, including 85 deaths
- There were about 415 patient injuries
- Approximately 3,400 device malfunctions occurred

Although the overall rate of adverse events – including malfunctions – declined over the period studied, there was an increase in the injury and death rate to about 50 reports per 100,000 US procedures in 2012, from slightly over 13 reports per 100,000 procedures in 2004.

The Rush cardiac surgeon "found that the rate of injury and death adverse events has actually gone up. That's the most striking thing". He added that "many hospitals that bought the robotic-surgery device did small numbers of hysterectomies, prostatectomies and other operations, and that as a consequence some surgeons haven't become proficient enough".

The authors plan to present their analysis at a medical meeting in early 2014.

A Recently Published Study on da Vinci: John Hopkins University

In a recent study published in the *Journal for Healthcare Quality*, researchers at JHU – who studied the FDA's databases – found that:

- Many adverse events go unreported or are incorrectly reported,
- These factors were likely contributing to a less-than-accurate portrayal of the dangers associated with the da Vinci Surgical System,
- Several of the cases weren't reported to the FDA until after they had made national headlines, as reported by MassDevice.com, and
- Eight of JHU's adverse events were either improperly reported or never reported at all.

The researchers also discovered that poorly done gynecological procedures accounted for 22 of the deaths reported in the FDA's databases. Hysterectomies had the highest reported complications, representing 43% of the injuries – primarily episodes of excessive bleeding – according to MassDevice.com.

According to the researchers:

- "The number reported is very low for any complex technology used over a million times….and most likely masks the real risks of robotic surgery"
- "Doctors and patients can't properly evaluate safety when we have a haphazard system of collecting data that is not independent and not transparent. There may be some complications specific to the use of this device, but we can only learn about them if we accurately track outcomes."
- "There is no justification for the skyrocketing increase in robotic surgery… attributed to aggressive advertising by the manufacturer and hospitals seeking more patients. 4 in 10 U.S. hospitals promoted robotic surgery on their websites, often using wording provided by the manufacturer. Some of the claims exaggerated the benefits or had misleading, unproven claims".
- "The rapid adoption of robotic surgery... has been done by and large without the proper evaluation"

The FDA's Response(s):

The Agency said it wasn't aware of the draft analysis – and added that:

- They were uncertain whether the numbers represented a true increase in clinical problems or simply an increase in the rate of reporting as the device gained more attention, and
- Officials admitted that they have not checked medical databases from insurance companies or the VA to determine the reason

However, the FDA's interest in Intuitive Surgical's adverse events apparently began in the 2011-2012 timeframe.

In January of 2013, the FDA asked surgeons whose hospitals belong to the agency's Medical Product Safety Network to participate in a 10-question telephone survey about the da Vinci System. Surgeons were asked about user training, common equipment repairs, patient selection, the complications they saw and how they compared with those seen in conventional surgeries, and what procedures are the best and least suited for the da Vinci device. An FDA spokesperson said the survey was conducted "after we observed an increase in the number of reports we received about the da Vinci Surgical System." The FDA official seemed to offer some cover for Intuitive by stating the following: "An upward trend in adverse events does not necessarily mean that a medical device is faulty. Sometimes, upswings occur because more clinicians are using the device".

- "Increased publicity sparked by lawsuits or product recalls also can boost the number of adverse events, but this does not necessarily indicate a true rise in event occurrence".
- "The reports may contain false, incomplete, or duplicative information. Accordingly, they cannot be construed to establish or compare rates of event occurrence".
- "Since it is difficult to know why the reports have increased, FDA has elected to talk with surgeons. Such a survey is a routine part of [medical device] surveillance."

That said, the FDA conducted an on-site inspection of Intuitive Surgical in 2013 – and followed the visit by sending a warning letter to the Company. Interestingly, the FDA warning letter stated "the Company had made safety changes in the recommended handling of the device because of adverse-event reports but hadn't reported the changes to the FDA prior to the agencies inspection in 2013".

Intuitive Surgical's Response(s) To Draft Analysis And FDA

The Company disagreed with the draft analysis and confirmed that "our analysis shows the rate of death is essentially flat, and that the rate of injury varies over time, but that there isn't any statistically significant trend". Intuitive Surgical also stated in a recent SEC filing that "it is correcting any violations that the FDA detected".

Intuitive Surgical disputes there's been a true increase in problems and says the rise reflects a change it made last year in the way it reports problems. For example, in September 2012, the company said it began reporting certain device malfunctions — such as cable breaks — that had not been submitted before.

A Company spokesperson suggested that the da Vinci System "has an excellent safety record with over 1.5 million surgeries performed globally, and total adverse event rates have remained low and in line with historical trends".

However, Intuitive Surgical did claim in a recent SEC filing that "as of September 30, 2013, it was defending about 50 product liability lawsuits over alleged injuries or deaths from robotic surgery".

In addition, the Company warned consumers in November of 2013 that instruments used in its surgical robots "can momentarily stall during procedures". The FDA classified the problem as a Class I recall – the agency believes the product could cause "temporary or medically reversible health problems" or the "remote possibility of serious health problems". Although the instruments aren't being recalled from the market, Intuitive "informed surgeons and other hospital staff about the possible problem and to schedule inspections of the instruments for possible repair or replacement".

Other Issues

In the September issue of the *European Journal of Obstetrics & Gynecology and Reproductive Biology*, a report raised another issue with robotic surgery – cost. The authors claimed "when considering overall medical care, the use of robotic-assisted surgery was found to be 1.6 times more expensive than conventional surgery".

Commercial Success Of The da Vinci Surgical System

The da Vinci is Intuitive's only product – and the only robotic system cleared for soft-tissue surgery by the FDA.

The da Vinci is used for operations that include removing prostates, gallbladders and wombs, repairing heart valves, shrinking stomachs and transplanting organs. Its use has increased worldwide, but the system is most popular in the United States. The most common robotic operations include prostate removal — about 85 percent of these operations in the U.S. are done with the robot.

Almost 1,400 U.S. hospitals have at least one da Vinci system. Each costs about $1.4 million, plus $100,000 or more a year in service agreements.

The number of da Vinci worldwide robotic surgery procedures has increased significantly – approximately 25% in 2012 versus 2011 alone (to 450,000 from 360,000) – and almost quadrupled since 2008 when 114,000 da Vinci procedures were performed.

What Can Orthopedic Robotic Companies Learn From Intuitive?

Select the right procedure(s), deliver clinical results and put your marketing horsepower behind the robotic technology.

Although robotics companies likely hold a 15% (or greater) market share of the partial knee business in the US, they will need to continue to demonstrate meaningful value – from a clinical and economic standpoint – in order to "transform" unicompartmental knee surgery into a significantly better procedure – and in a manner similar to robotic prostate removal.

Expansion by orthopedic robotic companies into total hips, total knees, total shoulders, total ankles, and the patella-femoral joint will gain traction only if those orthopedic companies deliver a value proposition that includes improved patient satisfaction and outcomes, improved hospital efficiencies, reduced error rates, risk and cost and/or an enhanced experience for the surgeon and hospital – for each procedure.

There is clearly recognition of the benefits of robotic systems as a strong marketing tool to enhance brand awareness and bring new patients through a hospital's doors. And young, new surgeons are clearly drawn to the precision of robotic-assisted surgery. However, selecting the right procedure and transforming that procedure into a "better one" by delivering clinical performance will be the winning formula going forward in the orthopedic space.

Don Urbanowicz is Principal of Urbanowicz Consulting, an advisory firm with a musculoskeletal focus seeking to enable clients to achieve strategic and transaction-related goals by capitalizing on market opportunities. UC offers a unique perspective on how large global companies approach strategy, valuation, negotiations, due diligence and integration, and a thorough understanding of achieving success throughout all phases of the transaction process.

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