In February 2013 the Food and Drug Administration, spurred by what looked like a dangerous spike in reported problems, initiated a survey among surgeons who used the da Vinci robotic system (from Intuit Medical, Inc.). Since 2009, 71 deaths apparently connected with this system had been reported. Overall, reports of injuries more than doubled during the first eight months of 2013, compared with the same period in 2012.

This was something new. The advantages of robotically controlled surgery had been widely touted, on health system websites, YouTube, and even billboards, since its introduction in 2000. Marketing departments at hospitals, eager to carve out a competitive niche, noted the benefits of this approach, including less pain, diminished bleeding, and shorter hospital stays. The medical literature featured a steady stream of papers reporting novel applications of robotic surgery.

Robotic surgery, then, had been for more than a decade the cutting-edge technology with the “wow” factor, purportedly able to improve just about everything people don’t like about surgery. And surgeons could enjoy greater precision, a clear and unobstructed 3-D view of the anatomical area being operated on, and, not to be overlooked, a chance to sit down at a remote console while performing lengthy procedures.

But now, as scientific articles tally up more and more specific numbers for adverse events, for an ever-lengthening list of procedures, linked with robotic surgery, the plaintiff’s bar has spread a wide net, in search of possible victims of robotic surgery. Here, we outline the weak links in what is known about the specific risks vs. benefits of robotic surgery, and how the plaintiff’s bar exploits these. To illustrate how this works, we cite two examples of what are still “gray areas” in regard to robotic surgery: training and certification/credentialing, and informed consent.

First, though, the naysayers on robotic surgery, the plaintiff’s bar among them, had to find some precise numbers on the adverse outcomes with this procedure.
Incidence: in search of hard numbers

Johns Hopkins Professor of Surgery Martin Makary, MD, MPH, has been something of a contrarian on the topic of robotic surgery for several years. In June 2011, he reported his review of 400 randomly selected websites showed that “hospitals have outsourced patient education content to the device manufacturer, allowing industry to make claims that are unsubstantiated by the literature” (Johns Hopkins Medicine press release).

He concluded, “It’s dishonest and it’s misleading.” Makary noted that none of the websites mentioned risks. Similarly, the July 2013 issue of Journal of Obstetrics and Gynecology reported that fewer than 5% of hospitals include information on the complications (or costs) of robot-assisted gynecologic procedures.

Against the benefits that hospitals commonly note, Makary ticked off the disadvantages of the robotic technique: surgeries usually take more time and thus keep patients under anesthesia longer, and they are more costly. The websites Makary looked at also failed to note the specific surgical technique that was being compared with the results with robots—the standard of care in many instances, laparoscopic surgery, or “open” surgery?

In mid-2013, Makary published a paper that did nail down some hard numbers. Between January 2000 and August 1, 2012, there were, he said, 245 events reported to the FDA. These included 71 deaths and 174 nonfatal injuries. His conclusion was captured in the article’s title: “Underreporting of Robotic Surgery Complications” (Journal of Healthcare Quality, August 27, 2013).

Training and credentialing

In late December 2012, a widely quoted report by stock-research firm Citron Research cited inadequate training as one factor in adverse outcomes. So, how much training and practice are in fact crucial, to ensure that a surgeon is adequately prepared to work with a da Vinci?

It depends, in the case of robotic surgery, on a dizzying array of variables. These include the anatomic site of the surgery and the specific procedure under consideration. This is one important weakness in articles in both the professional and popular press. They lump all of the possible procedures within the single term, “robotic surgery,” failing to make distinctions about the key factors such as anatomic site of the procedure, patient selection, other available options for surgery, and how long the procedure has been done successfully via robotic techniques.

The medical literature on certification and credentialing for robotic surgery, in many instances, offers exhortations rather than answers. “Surgical training in robotics should involve a structured, competency based curriculum that allows the trainee to progress in a graduated fashion” (J.Y. Lee and colleagues, Department of Urology, University of California-Irvine (Journal of Urology, April 2011). The aim here, they say, is “an expert-determined, standardized educational process, including a minimum of proficiency.”

But many of the published articles provide, as guidance, only a specific number of cases that surgeons must complete before they can serve as the primary surgeon with the robot. In a May 4, 2010, Wall Street Journal article, quoted medical professionals said it would take at least 200, and as many as 700, procedures before a surgeon could be considered proficient.

The American College of Obstetricians and Gynecologists, in a May 2013 “Statement on Robotic Surgery,” by ACOG president James T. Breeden, cautioned that, “Studies show there is a learning curve with new surgical technologies, during which there is an increased compli-
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Informed consent

Again, there is no clear consensus on what is sufficient to ensure informed consent for robotic surgery. Because the robot is still relatively new, the standard of disclosure of risks and benefits hospitals must provide is fluid and evolving. Some contend that in situations where a procedure is novel or a practitioner is unfamiliar with it, the duty is to disclose all relevant information.

Char Lee and colleagues, of the University of California, San Francisco, Department of Surgery, surveyed 85 surgeons and 383 postoperative patients to find out what they considered essential information for three surgical techniques: standard open, laparoscopic, and robotic. Compared with the surgeons, patients placed more importance on nearly every type of information, but especially on volumes and outcomes. In regard to robotic surgery, the authors say, “a clear majority of both patients and surgeons agreed that it was essential to disclose the novel nature of the procedure, potentially unknown risks and benefits, and whether it would be the surgeon’s first time performing the procedure” (Surgery, April 2013).

They add, “When accurate volumes and outcomes data are available, surgeons should discuss these as well.”

The process of obtaining informed consent for robotic surgery is, clearly, still a work in progress. But the plaintiff’s bar is already making what they deem inadequate informed consent a focus of MPL suits. Here is what plaintiff’s attorney J. Douglas Peters recommends (Medical Negligence, May 2012):

During discovery, it is imperative to request production of all informed consents. Ask whether the surgeon advised the patient that robotic surgeries are relatively new procedures and discussed the surgery’s risks and limitations and the operating surgeon’s experience. Use interrogatories to find out how many RSS procedures the surgeon had performed as lead surgeon before your client’s surgery, especially those involving the same RSS used in your case. Ask how often the surgeon’s practice has had to switch to an open or laparoscopic procedure during surgeries similar to your client’s—which usually happens only when something goes wrong and adds time and risk to the operation—and what the morbidity and mortality rates are for both the surgeon and hospital for similar robotic surgeries. Did the surgeon present this information to your client when obtaining consent?

 Plaintiff’s case: creating the story

Paul Levy is the former CEO of Boston’s Beth Israel Hospital. Now, he devotes part of his time to a blog, “Not Running a Hospital.” In an April 14, 2013 post, he plays devil’s advocate, and outlines what he thinks would work as a narrative structure for MPL cases against surgeons who use the robotic approach. It is pinned to a series of purportedly dubious decisions by the hospital and the surgeon.

1. The hospital purchased the robotic system, despite the absence of peer-reviewed evidence of its efficacy, vs. other forms of laparoscopic and open surgery.
2. The hospital spent a significant sum on marketing the availability of its new device. Note (if possible) that the marketing campaign has succeeded: the market share of the hospital for the procedures advertised increased.
3. The doctors in the hospital have poor documentation on why they opted to use robotic surgery on particular patients.
4. Even if there is a record of training, the evaluation of his performance in that training session was not done by an objective observer. The form and duration of training have not been decisively proven effective. At the hospital-governance level, the medical executives have failed to address the issue of granting privileges for use of the robot when the concerns about the rigor of training and the documentation of it haven’t been addressed.
5. Similarly, if the doctor used the robot in novel procedures, beyond what is done by the preponderance of physicians, the medical executive committee has not systematically addressed the issue of granting privileges for use of the robot that sufficiently consider this issue.

In his blog post, Levy notes that “Each of these opportunities to enhance the plaintiff’s case can be offset by an appropriate risk management approach.” But he wonders how many MPL companies are aware of this new vulnerability—and taken steps on behalf of their insured to minimize the risk.

“Ut tu severes, tu metes”

Or, “As you sow, so shall you reap.” In spite of all the concerns about potential injuries, and possible MPL actions, enthusiasm for the da Vinci is unabated. JPMorgan Chase reported on October 3, 2013 that half of all general surgeons plan to add robotic systems within two years, in response to general demand.

What might be termed the “hyper-marketing” of robotic surgery, coupled with a dearth of information about its potential risks, including post-surgical complications, was actually something of a setup: as soon as the bad news did start coming in, the plaintiff’s bar was going to have a field day with it.

Should you find yourself with a few minutes to spare, Google “robotic surgery” and “complications.” The collection of sites with domain names like “www.thedavincilawsuit.com” will tell you more than enough about the imminent future for MPL and robotic surgery. MPL companies should advise their insureds who use robotic surgery to bolster their practices with thorough documentation on the areas proved vulnerable to claims, especially the complex area of what constitutes sufficient training and experience with this supremely high-tech device.

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