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Medicolegal Review of Liability Risks for Gynecologists Stemming from Lack of Training in Robot-Assisted Surgery

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ABSTRACT The advances in robot-assisted surgery in gynecology evolved after most practicing gynecologists had already completed residency training. Postgraduate training in new technology for gynecologists in practice is limited. Therefore, gynecologists with insufficient training who perform robot-assisted surgery may potentially be at risk for liability. In addition to the traditional medical negligence claims, plaintiff attorneys are seeking causes of actions for lack of informed consent and negligent credentialing. Thus, it is essential that gynecologists be aware of these potential liability claims that arise in a robot-assisted malpractice suit. This commentary provides an overview of the current medicolegal liability risks originating from lack of training in robotic surgery and seeks to raise awareness of the implications involved in these claims. A better understanding of the doctrine of informed consent and seeking assistance of proctors or experienced co-surgeons early in robotics training are likely to reduce the liability risks for gynecologic surgeons. Journal of Minimally Invasive Gynecology (2011) 18, 512–515

Keywords: Informed consent; Insufficient training; Lawsuit; Negligent credentialing; Robotic surgery

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In 2005, the US Food and Drug Administration approved use of the da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA) in gynecology. The *New England Journal of Medicine* reported that from 2007 to 2009, the number of da Vinci systems installed tripled in the United States and doubled worldwide [1]. It is estimated that the da Vinci system is in use in nearly 1400 hospitals worldwide (Fig. 1) [2]. Among the fastest growing populations of users are gynecologists.

Most gynecologists using robot-assisted technology completed their residency training before the integration of robotics in the academic curriculum. The minimum US Food and Drug Administration certification standard is completion of a 1- to 2-day training practicum in the use of the da Vinci surgical platform. Typically, this training involves practice in using the surgical apparatus on fresh pig or human tissue [3]. Credentialing and surgical privilege standards are determined by hospitals. A universal standard in regulating credentialing for gynecologic surgeons using robotics has yet to be set [4]. With prevalent discrepancies in regulating standards for gynecologic surgeons using robotic surgical devices, plaintiff attorneys are using insufficient training and credentialing to seek negligent litigation claims. The claim of negligent credentialing is recognized in at least 32 states [5].

Furthermore, plaintiff attorneys are trying to prove breach of standard care following known inherent surgical maloccurrences and complications. Typically, these known complications or maloccurrences of surgery are more difficult to litigate on the grounds that they are not legal for medical malpractice (unless, for example, there was a delay in diagnosis). Discussing the known inherent risks of a procedure are a vital component of the doctrine of informed consent.

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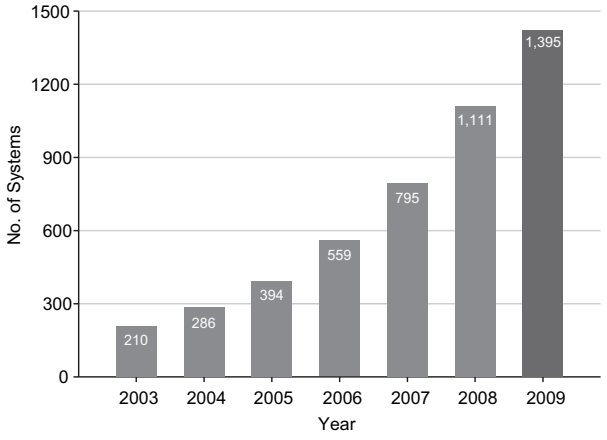
Fig. 1

Increasing trend of the da Vinci Surgical System installed base. Source: Intuitive Surgical SEC filings. Adapted from Bregel E. Investment in robotic surgical systems. Youngester. http://robotics.youngester.com/2010/03/investment-in-robotic-surgical-systems.html. Accessed October 19, 2010.



However, owing to the changing dynamics of robotic litigation lawsuits, gynecologists who perform robotic surgery could be held accountable for these intrinsic surgical complications. Cause of action would be for negligence in obtaining proper informed consent despite disclosing inherent surgical risks because the gynecologist's robotic training was not disclosed to the patient.

Overview of Robotics Malpractice Controversy

In May 2010, a medical malpractice lawsuit against 2 gynecologists and a community hospital was filed. In this case, the plaintiff had agreed to undergo a robot-assisted hysterectomy with her gynecologic surgeon, who was to be supervised by another gynecologist. During the robot-assisted procedure, the plaintiff patient sustained bilateral ureteral injuries. After the surgery, this known inherent maloccurrence was recognized, and subsequently the plaintiff patient underwent surgical repair of both ureters [6].

Complications and maloccurrences are possible in the course of any surgical procedure. These inherent adverse events can occur and compromise patient outcome. Nevertheless, such complications are deemed inherent to the procedure because they can occur even when the operation is performed expertly by the best of surgeons. It is a physician's duty to inform patients of these inherent known risks. However, even when such inherent risks are discussed, gynecologists who perform robotic surgery may still be faced with litigation claims. The plaintiff's attorney alleged improper informed consent, not because the patient was unaware of the known intrinsic complications that arose but because previous knowledge of the gynecologist's insufficient training and experience with robotics might have affected the patient's decision to undergo the robotic-assisted hysterectomy [7].

For a plaintiff attorney to claim medical malpractice, 4 components must be demonstrated. First, it must be established that the physician had a duty of care to patient. Second, there must be evidence that this duty was breached, and third, an alleged injury must be present. Fourth, a causal connection must be demonstrated that this breach in duty led to the proximate alleged injury. A plaintiff attorney potentially can have cause of action against gynecologists who perform robotic surgery for failure to obtain informed consent, and against hospitals for negligent credentialing.

Improper Informed Consent, a Cause of Action

According to the established doctrine of informed consent of the American College of Obstetricians and Gynecologists, consent is based on disclosure of information and sharing of interpretations of its meaning by a medical professional. The accuracy of disclosure, insofar as possible, is governed by the ethical requirement of truth-telling. The adequacy of disclosure has been judged by various criteria, which may include the following: the common practice of the profession, the reasonable needs and expectations of the ordinary individual who might be making a particular decision, and the unique needs of an individual patient faced with a given choice [8].

Two legal standards exist for failure to obtain informed consent: the prudent physician standard and the reasonable patient standard. The most common standard applied in most states is the prudent physician standard [9], which establishes what a reasonably prudent physician would typically disclose to patients in similar situations as determined by expert physician testimony. The reasonable patient standard requires physicians to disclose risks that a reasonable patient would need to know to make decisions with informed consent [10]. Important categories of disclosure exist to help clarify the important concepts a physician should communicate with the patient. Among them are discussing the diagnosis and the nature of the patient's condition, the purpose and nature of the proposed treatment, the associated risks and benefits, the probability of success, the collateral effects and material risks of adverse outcomes, and alternative treatments [8].

In light of recent lawsuits involving robotic surgery, gynecologists are now faced with ongoing clarification needed in the scope of informed consent disclosures. A case in Maryland highlights one aspect of this controversy. In December 2002, a complaint was filed against defendant physician for medical negligence in failure to obtain informed consent. The plaintiff patient had undergone a revisionary mastoidectomy in the left middle ear because of a cholesteatoma, and alleged that he sustained injuries during the procedure [11]. In addition, the plaintiff alleged that the defendant had not informed him that because of a previous medical problem, the procedure was more complex and that the defendant surgeon, who had performed only 1 revisionary mastoidectomy in the last 3 years, was not so