The advent of midurethral mesh slings has revolutionized treatment for stress urinary incontinence (SUI), and transvaginal mesh procedures seek to do the same for pelvic organ prolapse (POP). With an increasing number of women undergoing surgery for SUI and POP annually, the number of complications reported to the US Food and Drug Administration (FDA) can be expected to increase as well. The FDA has recently issued a public health notification regarding these complications associated with surgical correction of POP and SUI with transvaginal mesh. This warning stated that “the most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence” and later suggested that physicians “report adverse events related to surgical mesh that do not meet the requirements for mandatory reporting.” Many gynecologists may be hesitant to continue offering vaginal mesh procedures secondary to recent FDA warnings and the many advertisements from plaintiff attorneys seeking patients with complications related to use of mesh. In light of a recent decision by the US Supreme Court and strategies by manufacturers of medical devices to escape liability, it is imperative that gynecologic surgeons using transvaginal mesh document proper informed consent in the medical records. The purpose of this commentary is not to deter gynecologic surgeons from using transvaginal mesh when appropriate, but to provide an overview of current medical-legal controversies and stress the importance of documenting informed consent.

**Key words:** informed consent, lawsuit, mesh, pelvic organ prolapse, stress urinary incontinence

Cite this article as: Mucowski SJ, Jurnalov C, Phelps JY, et al. Use of vaginal mesh in the face of recent FDA warnings and litigation. Am J Obstet Gynecol 2010;202:x.ex-x.ex.

### Complications of transvaginal mesh and overview of available data

Since 2005, the FDA has received >1000 reports from 9 surgical mesh manufacturers of serious complications associated with mesh use in repair of POP and SUI. A review of the last 301 Manufacturer and User Facility Device Experience Database complications shows that 119 have resulted from using vaginal mesh placement procedures and 64 from midurethral slings. This is a 3:1 ratio for vaginal mesh compared to slings. The potential complications of using transvaginal mesh are wide ranging, from mild to life threatening. The most common complications, as reported in the FDA Public Health Notification, include mesh erosion through the vagina, infection, pain, urinary problems, recurrence of prolapse or incontinence, dyspareunia, and perforation of the bowel, bladder, vessels, or nerves during insertion.

As with any surgery, complications are a known risk, and it is the physician’s duty to inform the patient of all potential adverse outcomes at the time of consent. The use of transvaginal mesh for repair of POP has increased tremendously in the past few years. Only recently have systematic reviews and clinical practice guidelines been available to guide the physician in the science of vaginal mesh implantation. Although the research is in its early stages, it is possible that there may be a subgroup of patients who could benefit from these new techniques. Similarly, the vaginal compartments where these meshes should be placed will be better delineated, as will the most efficient methods of their placement. Presently, there is limited evidence from randomized controlled trials to guide decisions as to when and how to use graft materials. However, the United Kingdom has published several guidelines on the use of vaginal meshes by their National Institute for Health and Clinical Excellence (NICE). Although helpful, it is important for physicians in the United States to realize that the NICE guidelines may not meet the legal standards applied to show a breach in the US standard of care. Therefore, it remains difficult for providers to find consistent data that can be used when counseling patients about the long-term follow-up and complications regarding the use of mesh.
Learned intermediary doctrine and preemption

The concept of learned intermediary doctrine should be understood by gynecologists using products that are the subject of ongoing litigation, such as transvaginal mesh. The learned intermediary doctrine shifts the liability of harm caused by a medication or medical device away from the manufacturer and onto the physician prescribing or using the product. Overall, under learned intermediary doctrine, if a manufacturer adequately warns a physician of a product’s potential complications and risks, then they do not possess the legal duty to warn patients of possible dangers associated with their product. Instead, the duty to warn falls on the physician prescribing the product.

This legal doctrine is frequently used by manufacturers as a legal shield to shift liability for warning patients away from manufacturers and onto physicians. For example, in Linsley v C.R. Bard Inc, the manufacturer of Marlex mesh used the learned intermediary doctrine to shift liability of the duty to warn patients of potential complications onto physicians. This suit stated that mesh “was and is a prescription medical device, which requires that it be used only upon order of a qualified physician, thus the warning required is not to the general public or to the patient, but to the prescribing physician.” Therefore, C.R. Bard Inc. (Murray Hill, NJ), as the manufacturer of the mesh, only has a legal duty to warn physicians, not patients, of the risks associated with the use of their product. As a result, physicians are left with the responsibility of warning patients of potential complications of a product used in surgery.

Johnson & Johnson (New Brunswick, NJ), the parent company of Ethicon (Somerville, NJ), a manufacturer of mesh used in tension-free midurethral tape procedures, has used the learned intermediary doctrine to shift liability away from itself in suits involving its pharmaceutical product, the Ortho Evra Patch. Whether Johnson & Johnson will choose to use the learned intermediary doctrine to shift liability onto physicians that use their transvaginal tape remains unclear in the early stages of litigation. Manufacturers that use the learned intermediary doctrine to shift responsibility onto physicians risk alienating them and losing the trust of the physicians who prescribe or use their products in surgical procedures. If physicians become aware of a manufacturer’s legal tactic to shift responsibility to the physicians, they may decide to no longer prescribe or use that product. In the long run, this may be more financially detrimental to a manufacturer than defending itself in a lawsuit. However, this would depend on physicians’ understanding of the learned intermediary doctrine and becoming aware of a manufacturer’s use of the learned intermediary doctrine in court. Physicians in busy clinical practices are unlikely to be familiar with this tactic or to be aware of which manufacturers are using the learned intermediary doctrine to shift responsibility onto physicians. This may explain why manufacturers frequently choose to use the learned intermediary doctrine when confronted with litigation pertaining to their products prescribed or used by physicians.

If the learned intermediary doctrine is used by a company in suits involving transvaginal mesh, gynecologists can attempt to redirect responsibility to the manufacturer by showing that they did not receive adequate warning of risks associated with the use of their product. However, with the recent FDA warnings, it will be difficult for gynecologists to successfully argue they were not aware of the potential complications involving the use of mesh in vaginal reconstructive surgery. Alternatively, a better choice for gynecologists defending themselves from liability is to assure there is documentation in the medical record that the patient was properly informed of the potential complications that may be encountered with mesh use in vaginal reconstructive surgery.

Another recent development that significantly impacts existing and deters future lawsuits against manufacturers of medical devices is the 2008 US Supreme Court case Riegel v Medtronic Inc. In this case, the US Supreme Court held that the preemption clause enacted in the Medical Device Amendments, 21 USC §360k (1976), bars claims challenging the safety and effectiveness of a medical device given premarket approval by the FDA. As a result, patients injured by a medical device previously approved by the FDA have little recourse other than to sue their physicians. This recent US Supreme Court decision makes it imperative that physicians document proper informed consent in the medical records to protect themselves from lawsuits stemming from their use of a medical device such as transvaginal mesh.

The concept of informed consent has been applied in court against physicians since 1972, when Canterbury v Spence determined that the average patient must be assumed to have little or no understanding of medicine as an art, so all risks must be disclosed to patients when obtaining their consent for procedures. When there is documentation in the medical record of obtaining consent, the presumption is in the physician’s favor that proper informed consent was given to the patient. However, this is a rebuttable presumption that the injured patient may have an opportunity to refute. Nevertheless, the legal presumption is in the physician’s favor, and it would be difficult for the patient to prevail in a claim for lack of informed consent when such documentation is in the medical record. For instance in 2006, Polcari v Dottino, the plaintiff’s lack of informed consent claim against her gynecologist was dismissed on the grounds that there was documentation illustrating that the physician “fully explained the benefits, risks and possible complications, as well as the possible alternatives to the proposed treatment,” in addition to the patient’s signature on the consent form, further demonstrating that informed consent was obtained from the patient prior to the procedure. As a result, it cannot be stressed enough that documenting informed consent is critical before attempting any gynecologic procedure. Gynecologists should be particularly mindful of informed consent when offering a procedure with a known multitude of potential complications as reported in an FDA Public Health
Notification, such as placement of transvaginal meshes.2

Fiduciary responsibility

The relationship between the physician and the patient is one of fiduciary responsibility, meaning that the patient seeks out a physician, trusting that the physician possesses a level of knowledge necessary to inform the patient.12 This is essential when providing informed consent of surgical procedures. To protect patients, the gynecologist should have sufficient data to justify the performance of a procedure, and if these data are not available, or are of short term, it is the physician’s duty to properly inform the patient of this fact. In practicality, the gynecologist may justify the use of a new product if they believe its use improves the quality of care offered to their patients without creating undue harm.

This understanding of a fiduciary relationship is crucial in regard to the development and improvement of mesh technologies. Currently, the FDA approval for new devices does not appear to be as stringent as it is for new medications. For a new or improved device to be legally marketed and distributed in the United States, it only has to go through the FDA’s Premarket Notification 510(k) process, where the main prerequisite is to demonstrate “equivalency” to existing devices.9,12-15 Many new medical devices enter the market through this process. For instance, in 2005 the FDA authorized the marketing of 3148 devices under 510(k) and granted premarket approval to just 32 devices.9 As a result, many products, including transvaginal meshes, may reach the market and the hands of gynecologists without ever being used in human beings or without any safety, efficacy, or adverse outcome data.

Using such devices without adequate data puts the burden on the physician to properly counsel the patient in all aspects of the procedure, including all benefits and possible risks. The physician must disclose the purpose, benefits, and risks of such new treatments, including those risks that have not been quantified but are plausible. Without an adequate evidence base, there may not be sufficient knowledge of risks or benefits of new treatments, leaving the patient unable to provide informed consent.16 The gynecologist may decide to use transvaginal mesh in practice as long as the gynecologist is familiar with the anatomy, skilled in the performance of the surgical procedure, and able to manage possible complications.

Potential causes of action against physicians

Overall, there are 2 major potential instances where physicians may find themselves liable in a lawsuit surrounding the use of transvaginal mesh. The first is basic medical negligence in using mesh that is knowingly harmful to the patient, and the second is failure to obtain adequate informed consent for the procedure. To have cause of action for medical negligence in using mesh, the patient as a plaintiff would need to prove in court that the physician breached the standard of care by using mesh and that this breach in standard of care caused the patient harm. Proving medical negligence would be a very difficult undertaking in court when the gynecologist uses transvaginal mesh for its intended use in surgical correction of POP or SUI.

Because it is unlikely plaintiff attorneys will be successful in arguing the use of FDA-approved mesh by itself was a breach in the standard of care, a claim for failure to provide proper informed consent is a more common avenue for plaintiff attorneys to pursue a cause of action against gynecologists. In regard to obtaining proper informed consent, there are 2 standards, that of the prudent physician and that of the reasonable patient. Which standard is used varies on the state where suit is being litigated. Most states use the prudent physician standard, which examines whether the physician named in the suit behaved in a manner that a reasonably prudent physician would in similar circumstances. To use the prudent physician standard, an expert witness is needed to determine what exactly the prudent physician would usually disclose to a patient when obtaining consents. On the other hand, a minority of states hold physicians to the reasonable patient standard, where the physician should disclose the risks, benefits, indications, and alternatives that a reasonable patient would want to know. This standard does not require expert testimony in court.17

The best way for gynecologists to avoid potential action against themselves is to obtain and document adequate informed consent, regardless of which standard is used in their state. It is important to document the discussion of the known risks of using transvaginal mesh, including the known, unique risk associated with the use of graft material, namely exposure, erosion, or rejection. This risk does not exist with native tissue repairs. In addition, the relative lack of long-term data on the durability of using vaginal mesh for surgical correction of POP and adverse events associated with vaginal graft use should be mentioned. These can be outcomes such as delayed graft exposure/erosion, rejection, fistula formation, chronic pain, dyspareunia, infection, failure to correct prolapse, persistent or worsening urinary incontinence, and the possible need for additional surgery to correct graft-related adverse events.5 Also, it is prudent for the gynecologist to document that the patient was offered the opportunity to ask any questions and that all questions were answered prior to the signing of consents.

Comment

For physicians to best protect themselves from potential lawsuits involving transvaginal mesh repairs, documentation of proper informed consent is crucial. With an erosion rate from 2-11%13,18 and the resulting potential for lawsuits brought against gynecologists, it is important to discuss in detail with the patient the risks of using mesh and the alternatives when obtaining consent. It may be sensible to have a separate consent form for POP and SUI procedures using mesh in addition to the standard hospital forms when obtaining patient consent for these surgeries. As a result, the gynecologist establishes a documented customary way that proper informed consent is obtained from patients undergoing procedures involving the placement of transvaginal meshes. In doing so, the gynecologist makes it very difficult for plaintiff attor-
ney to successfully argue that the physician failed to provide proper informed consent before the time of surgery.

It is also the gynecologist’s responsibility to be aware of substantial risk factors that could exclude a patient from being a candidate for mesh placement. In directly inquiring as to whether the patient has any such risk factors, the gynecologist may avoid being accused of negligently using transvaginal mesh. In addition, the practicing gynecologist should address the points brought up in the FDA notification at the time of consent, namely informing patients of the permanence of mesh, along with the possibility of additional procedures in the event that discussed complications occur. Furthermore, the gynecologist should address the need for close follow-up to identify any complications in an early state. Overall, the impact of the procedure on the patient’s quality of life should be stressed, both in the event of success and complications. Also, as mentioned in the FDA Public Health Notification, it is prudent of the physician to provide the patient with a written copy of the manufacturer’s patient labeling information. It may also prove to be useful to refer patients to the NICE guidelines, as their leaflets are designed to help patients who have been offered mesh treatments determine if mesh use is right for them.

Conclusion

The authors of this commentary believe that the use of transvaginal mesh in repair of POP and SUI continues to be an excellent option for many patients and a relatively safe form of treatment that should continue to be provided despite the current FDA warning and litigation surrounding its use. It is important for gynecologists to recognize the rapidly changing mesh products available and the likelihood of their obtaining FDA approval through the Premarket Notification 510(k) process. In addition, the physician must be aware of the lack of long-term data surrounding the use of transvaginal mesh in repair of POP and SUI.

In light of the recent US Supreme Court decision in Riegel v Medtronic Inc, and in conjunction with manufacturers’ use of the learned intermediary doctrine to shift liability to physicians, it is now much harder for injured patients to sue manufacturers of medical devices. Patients injured from the use of a medical device now have little recourse other than to sue their physicians, claiming lack of proper informed consent. However, this current legal environment involving transvaginal mesh repair for POP and SUI should not deter gynecologists from offering this service to those patients who, using their clinical judgment, may best benefit from the procedure. As long as physicians maintain the fiduciary relationship and properly obtain and document informed consent, they should be more comfortable in offering and performing transvaginal mesh repairs despite current litigation.

REFERENCES