Pelvic Mesh and Malpractice: Current and Future Concerns

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The recent FDA (Food and Drug Administration) proposal of May 1, 2014 to reclassify surgical mesh for transvaginal pelvic organ prolapse repair from a class II to a class III device and urogynecological surgical instrumentation from a class I to a class II device continues to highlight the importance of the potential medicolegal risk implications of using these products. Avoiding litigation and taking care of patients are at the forefront of all surgeons' daily thoughts and actions.

Every surgery can involve potentially unforeseen risks despite skillful execution of treatment, while standard of care is not equivalent to perfection in practice or a guarantee of recovery. However, surgeries that involve transvaginal mesh with FDA bulletins and clinical practice guidelines (CPGs) offer a number of pitfalls that urologists must consider during surgical planning, the informed consent process, and the management of expectations and complications.

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Statements by the AUA, AUGS (American Urogynecologic Society) and SUFU (Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction) support the judicious use of mesh on a case by case basis. Mesh does increase anatomical success in the anterior compartment and can be considered first line treatment for recurrent prolapse. Physician discretion and patient characteristics must have a role in deciding where mesh may be most appropriate.

However, many questions arise when considering this issue. Should mesh be favored for those presenting at a younger age as their connective tissue is demonstrably weaker, or should it be avoided if they are more sexually active? Should mesh be favored in those with chronic constipation or cough who may be at higher risk for failure? Should mesh be favored in the elderly to mitigate the risks of failure and potential repeat anesthesia, and/or if no longer sexually active? The potential level of forethought may seem beyond what would be desirable for the reasonable urologist.

For a brief legal primer in the classic definition of malpractice, negligence involves 4 tests that must be met for a successful claim, namely 1) duty, 2) breach of duty, often interpreted as standard of care, 3) damages or harm sustained, and 4) causation, damages as a direct result of harm sustained.[1] Breach of duty constitutes the 3 areas of 1) lack of informed consent of risks and alternatives (to mesh) and the option to change one's mind once risks are known, 2) unnecessary surgery (mesh) and 3) inadequate technique.

In addition, lack of documentation of the informed consent process conversation, not just a consent form, is often overlooked due to busy office schedules and high patient loads, but

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constitutes a common weakness that can be exploited by plaintiff counsel.

In terms of mesh, the most common potential causes of action would be medical negligence (knowingly using mesh that is harmful) and failure to obtain adequate informed consent. All mesh currently on the market, whether for pelvic organ prolapse or stress urinary incontinence, is legally approved by the FDA, but this does not absolve the surgeon of liability.

Major questions arise simply with the question of mesh. What is important to disclose about mesh? Are some meshes better than others? How much mesh is enough or too much? Does the device class need to be disclosed? Should the physician discuss all FDA bulletins about mesh with the patient? Is there less risk and liability if only using a class II device vs a class III mesh product? Will there be more liability if and when certain mesh products become reclassified to class III such as mesh kits or mini-slings? Will standard of care change if and when device classification changes? Does experience with mesh and case volume mitigate the liability for using class III devices? Should urologists be obligated to disclose their experience with mesh, their qualifications, overall case numbers, successes and complications, research and financial conflicts of interest?

There are even more questions about mesh, and yet the singular answer is likely yes to all these questions raised to blunt liability and ensure more thorough disclosure. Is this feasible and/or practical? Furthermore, will the patient recall all the information the physician provides? And what responsibility do training programs have in regard to mesh surgery?

Malpractice in terms of negligence refers to a level of competent care, while informed consent refers more to patient self-determination.[2] To address competence means to follow the explicit recommendation of the AUA and AUGS that surgeons who use mesh must undergo rigorous training in pelvic anatomy and surgery, must be properly trained on specific mesh techniques, and must be able to recognize and manage complications.

The "prudent physician" and the "reasonable patient" must realize that high volume mesh operators should be preferred and deferred to for mesh cases in light of the impending reclassification of many pelvic mesh kits and mini-slings. Risk avoidance behavior by referring cases to a high volume operator is potentially beneficial for all parties concerned. That is the current reality of our specialty. The patient trusts the physician who has a fiduciary responsibility to provide sufficient data to justify mesh use, whether personal or published, and review the unknown but plausible risks. Disclosing personal experience helps mollify the threat of deception, and speaks to the good intent and good action of the physician.

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Malpractice is not medical error and a competent physician is not liable for an undesirable result. Proper informed consent must convey educating the patient more than just signing a waiver of responsibility. A therapeutic alliance must be developed,[3] avoiding the temptation to describe surgery as minor or to say nothing can go wrong. Uncertainty must be acknowledged by physician and patient and documented. The patient should be reassured that if complications arise the physician will be there every step of the way. The office chart must reflect the depth of the discussion of the informed consent process, not merely that it occurred.

Should litigation arise, surgeon notes that describe why a surgical choice was made will act as a strong defense of proper preoperative planning. Patients should be asked to explicitly acknowledge understanding, and this must be documented, including alternatives such as doing nothing and that reconstruction is never 100% successful. Poor communication and inadequate informed consent are at the core of most claims. It is always better to say too much than to say too little.[4]

Clinical practice guidelines may be used to lend credence to an expert witness, to impeach an expert witness, to defend a physician for following the document as the standard of care or to suggest physician deviance from the standard of care.[5] CPGs are best practice recommendations based on evidence and sometimes expert opinion to ensure consistency of care (but may not necessarily always equate with quality).[6]

If urologists do not follow guidelines, does that imply a breach of the standard of care? What if conformity to the guidelines leads to injury by not tailoring treatment when indicated? Trial attorneys are aggressively and more commonly relying on CPGs as "powerful weapons for attorneys because they are consensus recommendations founded on medical evidence that the medical community has formally adopted."[7] They can be used as a sword to blunt the defense claim of the well-intentioned physician's judgment or discretion, and can be used to blunt the defense's expert witness whose opinion may be well substantiated but not in line with guidelines.

If urologists are not familiar with practice guidelines they can be accused of not being current with medical knowledge and, thus, violating the standard of care. Plaintiff counsel may not reveal in pretrial deposition their strategy of using CPGs in order to surprise the defense later on. Defense arguments that CPGs are "cookbook medicine" may only be partially successful unless the physician defendant or their expert can explain why the CPGs were not followed. Moreover, as hospital systems, large physician groups and insurance companies grapple with Obamacare and the attention to cost sensitive medical service, CPGs may be used to compel homogenized patient care and force cost reductions by threatening physicians with liability when not in compliance. Where does that leave clinical experience and reasonable judgment?

Those with fellowship training and/or years of experience must

- maintain and hone skills
- stay informed
- attend meetings and courses
- have a thorough informed consent process about mesh and alternatives, and thorough documentation of such
- use a separate mesh consent form
- address the FDA bulletins and device
- class of a product
- sharpen proper communication skills
- manage expectations
- identify high risk patients in whom to avoid mesh or those who may benefit from its use
- give out device information
- follow patients treated with mesh
- postoperatively for at least 1 year

The sage advice of Alvin Toffler is apropos, as "the illiterate of the 21st century will not be those who cannot read and write, but those who cannot learn, unlearn, and relearn." ◆

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