

Informed consent cannot be obtained for use of vaginal mesh

TO THE EDITORS: I was interested to read the Clinical Opinion “Use of vaginal mesh in the face of recent FDA warnings and litigation.”¹ The authors stress the importance of documenting informed consent, although they state that “it remains difficult for providers to find consistent data to use when counseling patients about long-term follow-up and complications after the use of mesh.”

I respectfully disagree. It is not merely “difficult”—it is impossible. Sufficient data do not yet exist regarding the use of vaginal mesh in procedures for pelvic organ prolapse. In the absence of these data, obtaining truly informed consent itself is impossible. Therefore, the use of vaginal mesh for prolapse should be treated as experimental, and patients should provide consent on that basis. The American Society for Reproductive Medicine provides a useful definition of the term “experimental”: “Procedures (including tests, treatments, or other interventions) for the diagnosis or treatment of infertility will be considered experimental or investigational until the published medical evidence regarding their risks, benefits, and overall safety and efficacy is sufficient to regard them as established medical practice.”²

Surgeons, and even some savvy patients, may be familiar with the general risks of mesh placement. However, what remains unknown is the true magnitude and consequences of these and other complications. Therefore, patients have no way

of balancing the unknown magnitude of these risks against the potential benefits. Even worse, it is impossible to adequately inform patients of the potential benefits of vaginal mesh-based procedures for prolapse.

In conclusion, obtaining informed consent from patients for vaginal mesh placement during prolapse surgery cannot be achieved in light of the current dearth of data regarding risks and benefits. Women choosing to undergo such procedures should understand their experimental nature. Documentation in the medical record that patients accept the absence of such data and choose to proceed anyway may be a better choice for surgeons who continue to offer vaginal mesh-based procedures for prolapse in their clinical practice. ■

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