



Joint Recommendations Issued on Use of Vaginal Mesh for POP

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Washington, DC-- Due to concerns about the safety and efficacy of synthetic mesh placed vaginally for the treatment of pelvic organ prolapse (POP), its use should be reserved for high-risk women for whom the benefit may justify the risk, according to The American College of Obstetricians and Gynecologists (The College) and the American Urogynecologic Society (AUGS). In a joint Committee Opinion issued today, the groups also say there is an urgent need for the development of a national registry to track outcomes for all current and future patients who receive vaginal mesh implants.

The uterus, bladder, urethra, small intestine, rectum, and top of the vagina are held in place by the pelvic floor muscles and connective tissues. "When these muscles become torn or stretched, pelvic organs can drop down and bulge into the vagina causing pelvic organ prolapse," said Cheryl B. Iglesia, MD, former chair of The College's Committee on Gynecologic Practice. Childbirth is a major cause of POP, but menopause, aging, intense physical activity, being overweight or obese, prior pelvic surgery, straining to have bowel movements, chronic coughing, and genetic factors are also to blame. Some women with POP have no bothersome symptoms; others have pelvic pressure, lower back pain, urinary incontinence, sexual difficulties, or problems having a bowel movement.

"The incidence of POP continues to grow," said AUGS President Matthew D. Barber, MD. "More than 350,000 women undergo surgery for this condition in the US each year."

In 2001, the US Food and Drug Administration (FDA) reviewed and cleared the first surgical mesh for the repair of POP. The FDA based its clearance on the surgical mesh's "substantial equivalence" to surgical mesh used for hernia repair. Clearance does not require clinical data supporting either efficacy or safety of synthetic mesh for POP. An estimated 100 mesh devices or kits for POP surgery have subsequently been cleared by the FDA, although not all are currently marketed.

In July 2011, the FDA issued a Safety Communication, "Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse," identifying the use of vaginal mesh as an issue of "continuing serious concern." "Some women who have complications resulting from vaginal mesh will require additional surgery to try and correct the problem," said Dr. Iglesia. "Unfortunately, some women will continue having pain even after corrective surgery because complete removal of the mesh may not be possible. For this reason, it's important to understand that, in many cases, POP can be successfully treated without mesh and women and their doctors really need to weigh the risks and benefits before deciding on a course of action." Dr. Iglesia added that in her expert opinion as an urogynecologist familiar with mesh implants, "if a woman has had mesh implanted but is not experiencing any symptoms, no treatment is necessary, but her doctor should monitor her for potential complications."

Although POP repair is performed surgically through incisions in the abdomen or through the vagina, **today's Committee Opinion [and the FDA Safety Communication of July 2011] addresses only the vaginal placement of mesh for POP.** "Although many patients have no complications from surgical mesh placed vaginally, a small but significant group experience permanent and life-altering problems, including pelvic pain and painful sexual intercourse because the mesh erodes through the vaginal wall," said Dr. Iglesia.

The recommendations of The College and AUGS include the following:

- Continued audit and review of outcomes as well as the development of a surveillance registry for all current and future vaginal mesh implants;
- Outcome reporting for prolapse surgical techniques clearly defining success, complications, and total reoperation rates;
- Surgeon training for vaginal mesh placement specific to each device, including surgical experience with reconstructive surgery and thorough understanding of pelvic anatomy;
- Rigorous comparative effectiveness trials of synthetic mesh and native tissue repair and long-term follow-up;
- Patient counseling that there are alternative native tissue repairs and that synthetic mesh is permanent, as well as discussion of the risks, benefits, and alternatives to the procedure;
- Limiting use of POP vaginal mesh repair to high-risk women for whom the benefit may justify the risk;
- Adoption of new mesh products and devices only with clinical long-term data demonstrating equal or improved safety and efficacy compared with existing products and devices.

"It's important that both physicians and patients dialogue about POP surgery so they can review treatment options and make informed decisions about care," said Dr. Barber. "We recommend that patients also visit www.voicesforpfd.org, an online patient community for women with pelvic floor disorders for additional information."

Committee Opinion #513 "Vaginal Placement of Synthetic Mesh for Pelvic Organ Placement" is published in the December 2011 issue of *Obstetrics & Gynecology*.
<http://www.augs.org/d/do/289>

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