American Urogynecologic Society

Advancing Female Pelvic Medicine and Reconstructive Surgery

Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders

In July 2011, the U.S. Food and Drug Administration (FDA) released a white paper [1] and safety communication [2]on the safety and effectiveness of transvaginal placement of surgical mesh for pelvic organ prolapse. Since then, some state medical organizations, healthcare systems, and insurance companies have considered, or adopted, complete restrictions on the use of transvaginal mesh for pelvic organ prolapse or stress urinary incontinence.

The American Urogynecologic Society (AUGS) is a non-profit organization of over 1500 physician and allied health members. AUGS represents the largest professional society representing Female Pelvic Medicine and Reconstructive Surgery specialists. We specialize in treating pelvic floor disorders, especially pelvic organ prolapse and urinary incontinence. We are actively involved and engaged in this matter of transvaginal mesh and are working with all stakeholders including the FDA and the National Institutes of Health (NIH).

The American Urogynecologic Society strongly opposes any restrictions by state or local medical organizations, healthcare systems, or insurance companies which ban currently available surgical options performed by qualified and credentialed surgeons on appropriately informed patients with pelvic floor disorders.

Our justification for this position statement is described below.

1. **A complete restriction on the use of surgical mesh was not the stated intent of the FDA safety communication.**

Restrictions that prohibit the use of synthetic mesh in the treatment of prolapse or incontinence do not represent the findings of the FDA investigation [1]. Neither the FDA Advisory Panel, the NIH, the American College of Ob/Gyn (ACOG), nor AUGS has recommended removing any mesh products from the market or withholding them from surgeon use.

2. **The decision on surgical alternatives should be made by the patient and her surgeon.**

Decisions regarding the treatment of women with pelvic floor disorders, including the use of surgical mesh, should be made between surgeons and their patients after careful evaluation and discussion of the risks, benefits, and alternatives to surgery. AUGS strongly supports the FDA recommendations that surgeons thoroughly inform patients seeking treatment for pelvic organ prolapse about the risks and benefits of all potential treatment options including non-surgical options, non-mesh surgery (i.e. native tissue vaginal repairs), surgical mesh placed abdominally, as well as transvaginal mesh placement. Non-mesh surgical treatment options also carry risks of surgical complications. No one approach has proven to be superior in all cases and it is particularly essential that specialists who regularly treat advanced and/or recurrent prolapse are able to maintain a complete set of treatment options in order to provide

the most effective and individualized care. A ban on alternative surgical treatment interferes with the patient-physician relationship and withholds FDA acceptable options that the patient and her physician may decide is the best treatment option for her particular clinical situation. A ban on the use of synthetic mesh materials would potentially prohibit many women from accessing the full range of treatment options available. With restrictions of patient options, certain patients would be denied this alternative and need to seek care elsewhere or have another procedure to treat their pelvic organ prolapse that may not be the most appropriate choice after careful discussions between the patient and her physician and with full, informed consent. These restrictions, which could become law, significantly interfere with the doctor- patient relationship. As noted in a recent editorial in the New England Journal of Medicine, "Laws that specifically dictate or limit what physicians discuss during health care encounters also undermine the patient–physician relationship. Physicians must have the ability and freedom to speak to their patients freely and confidentially, to provide patients with factual information relevant to their health, to fully answer their patients' questions, and to advise them on the course of best care without the fear of penalty."[3]

3. A ban on surgical mesh would prohibit the surgical studies mandated by the FDA and recommended by the NIH, ACOG, and AUGS.

The ACOG and AUGS joint committee opinion concluded that rigorous comparative effectiveness randomized trials of synthetic mesh and native tissue repair and long-term follow-up are ideal. [4] In the July 2011 safety communication, the FDA did **not** recall transvaginal mesh or remove transvaginal mesh for pelvic organ prolapse from the market; however some companies have decided to cease manufacturing of certain vaginal mesh for prolapse products. The FDA is mandating, through the 522 study mechanism, that manufacturers (of currently approved devices) enroll patients into prospective, carefully monitored post-market research studies to help determine the efficacy and safety of these procedures. The FDA issued over one hundred 522 orders in January, 2012. AUGS has partnered with the FDA, NIH, ACOG and industry to build a national registry for Pelvic Floor Disorders, the PFD Registry. This has been an enormous and collaborative effort with several stakeholders actively participating to define the correct data elements, timing of assessments and determination of statistical analysis plans. The PFD registry, which will include nested 522 studies from at least four major companies, is scheduled to launch in the second half of 2013.

The Pelvic Floor Disorders Network, a clinical trials network funded by the National Institutes of Health (NIH), is about to launch a randomized trial of transvaginal mesh versus non-mesh, native tissue repair for uterine prolapse. The fact that this group of experts has spent the last year reviewing the literature, developing a protocol that has been reviewed and approved by the PFDN Steering Committee, its Data Safety and Monitoring Board, its External Advisory Committee, the FDA, and the IRBs at all clinical sites, and is about to implement such a study should provide proof that national experts in the field of Urogynecology are not opposed to the placement of transvaginal mesh given appropriate clinical indications, informed consent and sufficient surgical training – even in a randomized setting. With a ban on transvaginal mesh for pelvic organ prolapse surgery, the studies and surgical audits recommended by the FDA, ACOG, and AUGS cannot be performed. These restrictions would have a chilling effect on the advancement of science and evidence on these vaginal mesh procedures by discouraging much needed comparative effectiveness research.

4. In some circumstances transvaginal mesh for pelvic organ prolapse may be the most appropriate surgical option.

ACOG and AUGS in a joint committee opinion published in December 2011 concluded that "Based on available data, transvaginally placed mesh may improve the anatomic support of the anterior compartment compared with native tissue repairs" but given the increased risk of complications recommended that "pelvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse (particularly of the anterior compartment) or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures" and that such procedures be performed by appropriately trained surgeons.[4] The 2012 Cochrane Review: Surgical Management of Pelvic Organ Prolapse concluded that "The use of mesh or graft inlays at the time of anterior vaginal repair reduces the risk of recurrent anterior wall prolapse on examination. Anterior vaginal polypropylene mesh also reduces awareness of prolapse however these benefits must be weighed against the increased operating time, blood loss, posterior or apical prolapse and reoperation rates for mesh exposures associated with the use of polypropylene mesh".[5] A review of more current studies from 2011 and 2012 suggest that transvaginal mesh placed by experienced mesh surgeons may have mesh erosion rates comparable to abdominally placed mesh. [6]

There are certain clinical situations where many would agree the use of transvaginal mesh is not only acceptable, but preferred. Examples of these clinical situations include: patients with recurrent prolapse after a non-mesh, native tissue repair; or patients where an abdominal approach may pose additional and potentially more significant surgical risks like patients with pulmonary co-morbidities or patients with known significant intra-abdominal adhesions. It is our strong opinion, that there are subsets of women with prolapse, and in some cases those with the most advanced disease, in whom the benefits of transvaginal mesh outweigh the risks and a blanket ban on the use of these products compromises patient care.

5. Any restriction of mesh slings for the treatment of stress urinary incontinence is clearly not supported by any professional organization or the FDA.

A common misunderstanding is that mesh slings for the surgical management of stress urinary incontinence (SUI) were included in the 2011 FDA warning; however, the warning was about transvaginal mesh for prolapse and was titled, "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of *Vaginal Placement* ***for Pelvic Organ Prolapse***."[1] In this document, it was explicitly stated: "The FDA continues to evaluate the effects of using surgical mesh for the treatment of SUI and will report about that usage at a later date." In early 2012, the FDA sent 522 letters to industry mandating post marketing approval study for vaginal mesh products used to treat pelvic organ prolapse and single-incision mini-slings for SUI. However, it is particularly important to note that full-length midurethral slings were excluded from the mandated post marketing studies. In a recent study involving 53 expert urologists and urogynecologists (of whom >90% were fellowship trained) and who could select among many surgical options, the full-length synthetic midurethral sling was the preferred option in 93% for the surgical treatment of primary stress incontinence.[7] Full-length midurethral slings, both retropubic and transobturator, have been extensively studied, are safe and effective relative to other treatment options and remain the leading treatment option and current gold standard of care for stress incontinence surgery.

6. **Any restriction of mesh placed abdominally for the treatment of prolapse is clearly not supported by any professional organization or the FDA.**

To clarify, the 2011 FDA warning only reviewed the topic of **transvaginal** placement of mesh for pelvic organ prolapse. There is no justification for any restriction for mesh placed abdominally (i.e. mesh sacrocolpopexy, including laparoscopic and robotic approaches) for the treatment of prolapse.

7. **Instead of a ban on mesh we recommend the implementation of credentialing guidelines so that mesh procedures are performed by qualified surgeons.**

It is imperative that local hospitals and health systems establish and strictly enforce robust processes to both credential and audit surgeons with specific expertise, experience, training and skill to perform these procedures. AUGS has developed, and **published credentialing guidelines** for transvaginal mesh surgery for pelvic organ prolapse[8] and sacrocolpopexy for the treatment of pelvic organ prolapse[9]. It is critical for a surgeon performing these complex procedures to be adequately trained with a proctor present for each type of transvaginal mesh procedure they are seeking to receive credentials. Proctoring should also be required of surgeons requesting new privileges for sacrocolpopexy. These guidelines are also available on the AUGS website at http://www.augs.org/p/cm/ld/fid=202.

While credentialing and audits are generally addressed locally we strongly oppose any ban on mesh due to the reasons outlined above, and propose the following strategies as the most appropriate and effective means to align the policies of each hospital and healthcare system with quality and surveillance strategies that have been broadly accepted by key stakeholders involved in this important issue.:

a. Adopt the published AUGS credentialing guideline for transvaginal mesh and the guideline for sacrocolpopexy at local hospitals.
b. Establish a broad group of trained pelvic floor reconstructive experts to review cases and complications of both mesh and non-mesh prolapse repair.
c. Ensure that there are appropriate resources and patient management systems in place to identify and manage mesh and non-mesh related complications.
d. Track both surgeons and specific products being implanted as these may each influence efficacy and complications. As with any complex surgical procedure, surgeon performance should be assessed and addressed on an individualized rather than collective basis.
e. Mandate a thorough, standardized informed consent process for mesh placement. AUGS provides surgeons with an Informed Consent Toolkit as a means to help standardize the quality of the mesh-related consent process. This is available publically on our website at http://www.augs.org/p/cm/ld/fid=174.

References

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