

An update on transvaginal mesh for CUA Members

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On April 16 2019, the United States Food and Drug Administration (FDA) published an update to its previous statements on transvaginal mesh.¹ The FDA ordered all manufacturers of surgical mesh systems for transvaginal repair of anterior compartment prolapse to stop selling and distributing these products immediately. The FDA also advised those who have received a prior transvaginal prolapse repair with mesh that “there is no need to take additional action if you are satisfied with your surgery and are not having any complications or symptoms.” At this time there has not been any additional guidance from Health Canada on transvaginal mesh since 2014.²

The updated FDA statement is in keeping with the 2017 CUA statement on transvaginal mesh, which states that the routine use of transvaginal mesh for prolapse repair does not appear to be supported by the current evidence, and its use should be restricted to specialized pelvic floor surgeons and specific clinical situations.³ The concern regarding the use of mesh for pelvic organ prolapse (POP) stems from the increased complications and minimal difference in functional and anatomic outcomes compared to traditional native tissue repairs.³ There has been a significant decrease in the utilisation of transvaginal mesh for prolapse since the initial FDA warnings^{4,5}, and the number of companies manufacturing prolapse mesh systems has also decreased significant. With the new FDA statement, it is likely that the availability of transvaginal mesh systems for prolapse will be limited in the future.

Unfortunately, despite the clear differences in the indication, complications, and intensity of clinical study, midurethral slings (MUS) for stress urinary incontinence (SUI) are often inappropriately drawn into the dialogue about transvaginal mesh for prolapse. The situation is similar this time, with recent media reports inappropriately stating for example: “FDA Pulls All Vaginal Mesh Products Off the Market”.⁶ It should be emphasised that the FDA’s most recent statement does not apply to sacrocolpopexy mesh, or midurethral slings.

The CUA is committed to promoting excellence in surgical care for women with SUI. Midurethral slings continue to be a well-studied, and appropriate option for many women with stress incontinence. Surgeons offering midurethral slings should counsel patients on the various treatment options for SUI, and their expected outcomes. If MUS is an appropriate option, then the surgeon should review the potential complications of this procedure and be prepared to diagnose and manage them. In cases were a patient does not wish to have a midurethral sling, the patient should be offered alternative non-mesh-based procedures.

References

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