SUFU
Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction

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Monday, April 22, 2019

Jeffrey E. Shuren, MD
Director, Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue WO66-5429
Silver Spring, MD 20993

Dear Dr. Shuren,

SUFU, the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction, is the leading medical society that represents Urologists and other medical professionals dedicated to treating women with pelvic floor disorders including stress urinary incontinence (SUI) and pelvic organ prolapse (POP).

The purpose of this letter is to reaffirm SUFU's support of polypropylene vaginal mesh for the surgical treatment of female SUI. The synthetic polypropylene mesh midurethral sling (MUS) is the most commonly performed surgery for SUI and is recognized in clinical practice guidelines as a standard of care for this condition. Extensive data exist to support the use of the MUS for the treatment of female SUI, with minimal morbidity compared with the alternative surgical options. Advantages of the MUS, compared to other surgical options such as autologous fascial slings and colposuspension, include shorter operative and anesthetic time, reduced postoperative pain, and less voiding dysfunction with a surgery that is routinely done in the outpatient setting. In addition, the MUS has a proven track record with the longest follow-up of surgery for SUI in the literature. Mesh-related complications can occur following polypropylene sling placement, but the rate of these complications is acceptably low. Furthermore, it is important to recognize that many sling-related complications are not unique to mesh surgeries and are known to occur with non-mesh sling procedures as well.

We are concerned that the publicity related to the withdrawal of mesh products for the treatment of pelvic organ prolapse (POP) will result in unsubstantiated concerns about polypropylene slings. We have observed that many of the complaints related to polypropylene slings

(e.g., urinary retention, voiding dysfunction, bladder/urethral injury) are not specific to mesh, but rather are intrinsic risks of sling surgery regardless of the material from which the sling is constructed. In many cases, some risks are actually greater for the non-mesh slings than they are for mesh slings. Accordingly, **any restriction of the use of synthetic polypropylene mesh slings for the treatment of SUI would be a disservice to women who choose surgical correction of SUI and could potentially result in an increased number of complications and/or suboptimal outcomes** in women undergoing surgery for SUI.

We strongly feel that physicians must counsel their patients through a shared decision making process regarding the treatment options for SUI and counsel them regarding the specific risks, benefits, and alternatives of mesh prior to proceeding with treatment of SUI. We also agree that surgeons who wish to perform synthetic sling surgery should undergo rigorous training in the principles of pelvic anatomy and surgery, be properly trained in specific sling techniques and be able to recognize and manage complications associated with synthetic mesh sling placement.

In the coverage of the most recent FDA decision ordering manufacturers to stop selling and distributing transvaginal products for POP, the lay press and media have made no attempt to differentiate mesh slings for SUI from mesh kits for POP. We hope that this distinction is clear to the FDA, and **we would encourage the FDA to release a statement which distinguishes mesh midurethral sling procedures from mesh POP procedures**.

With regard to the transvaginal mesh product statement issued last week, SUFU was surprised to read about the decision, particularly as the three year data (requested by the FDA) are not yet available. Part of the challenge is that though the majority of women do well with the MUS, they are, for the most part, silent. We hope that as future decisions are made about the use of mesh slings for the treatment of SUI, the panels evaluating this are able to focus on the volume of data available in the literature.

Finally, **we would respectfully request that future FDA discussions related to synthetic mesh slings for the treatment of female SUI include representation from organized Urology** (SUFU as well as the American Urological Association). Urologists are leaders in the operative management of SUI in women and have significant expertise and experience that would be of value when making decisions about such treatments.

Regards,

Heather Swanson

Heather Swanson, Executive Director

on behalf of the SUFU Board of Directors