Guest Editorial

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Synthetic full-length midurethral slings remain the standard of care for SUI surgery

Misperceptions of mesh safety persist—among both patients and providers

The current surgical options for managing stress urinary incontinence (SUI) include:

- midurethral slings (MUS)
- open or laparoscopic retropubic suspensions
- pubovaginal slings
- urethral bulking injections.

These options—specifically MUS, which are the predominant SUI surgical procedure and the clear standard of care—remain in the surgeon's armamentarium after the July 2011, FDA safety warning.[1]

Confusion persists

A common misunderstanding is that full-length MUS were included in the 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, when the FDA sent letters to industry for postmarketing approval study requests,[2] full-length MUS (but not single-incision mini-slings), were excluded from further study.

On page 24 of this issue, the technique for a pubovaginal sling is very well described by Drs. Karram and Zoorob in their article, "When and how to place an autologous rectus fascia pubovaginal sling." There may be a place for this pubovaginal sling procedure for women with previous urethral surgery or radiation, but studies are needed to determine if repeat MUS or pubovaginal slings are the best procedure for recurrent incontinence. You should not get the impression that the current mesh controversy justifies abandoning the full-length MUS for a pubovaginal sling.

Unfortunately, television ads by law firms trawling for potential clients with any mesh in their vagina have created confusion among patients that synthetic MUS for incontinence is the same as transvaginal mesh for prolapse. In most clinical scenarios, rather than validating the patients' concerns about the safety of synthetic mesh and performing a pubovaginal sling procedure, **the most appropriate course of action is detailed, evidence-based patient education** about MUS safety and efficacy to counter the patient's misperceptions of safety concerns.

A bit of history on MUS

The first retropubic MUS was the tension-free vaginal tape (TVT) procedure published by Ulmsten in 1996.[3] This minimally invasive outpatient procedure using a 1-cm wide strip of polypropylene mesh has revolutionized the management of SUI and has been the most studied

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Instant Poll

How do you educate your patients on the use of surgical mesh?

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surgical procedure in all of gynecology. A PubMed search of "tension-free vaginal tape" reveals more than 2,000 publications.

MUS vs pubovaginal slings. In a recent updated systematic review of 39 randomized controlled trials comparing different SUI procedures, midurethral slings and pubovaginal slings had similar cure rates. Pubovaginal slings, however, had more postoperative lower urinary tract symptoms and a higher reoperation rate.[4]

Pubovaginal slings require an 8-cm lower-abdominal incision, general or regional anesthesia, and hospitalization (usually). They also have higher risks of intraoperative bleeding and wound complications (including incisional hernias) than MUS. By contrast, MUS require 3 small 1-cm incisions and can be performed on an outpatient basis with local anesthesia and sedation. Postoperative recovery is significantly easier and shorter with MUS than with pubovaginal slings. Pubovaginal slings performed with human cadaveric material and porcine material have inferior outcomes to autologous material.[5]

Modifications to MUS included transobturator approaches, which have comparable efficacy to the retropubic approach.[6] In this century, the full-length MUS procedures are the predominant SUI surgical procedure and the clear standard of care.

In a recent study involving 53 urologists and urogynecologists (of whom >90% were fellowship-trained), use of full-length MUS was the preferred procedure in 93% of primary stress incontinence surgical procedures.[7] In fact, full-length MUS have been so successful and safe that extrapolation of a small ribbon of mesh under the midurethra to larger sheets of mesh for the entire vagina is what produced our current transvaginal mesh controversy. The vaginal erosion rates of 10% that have been seen with much larger pieces of transvaginal mesh are only 1% with MUS.[8] Studies have not demonstrated common or significant vaginal pain or pain with intercourse after MUS.

How do you respond when your patient asks about mesh use in her surgical procedure?

The July 2011 FDA safety warning urged patients to ask their surgeons about the benefits and risks of mesh use before going forward with surgery involving synthetic mesh. The American Urogynecologic Society developed the *AUGS Transvaginal Mesh Informed Consent Toolkit* to aid surgeons in answering patients' questions. This toolkit is available online (www.augs.org/informedconsent). Among other resources, you will find guidance on answering the following questions:

- Why do you think I am a good candidate for mesh?
- Why are you choosing surgical mesh for my repair?
- How likely is it that my repair could be successfully performed without using surgical mesh?
- What results have other patients had with this product?
- Which specific side effects should I report to you after surgery?

Let's educate our patients

In my clinical practice, I have found that educating patients about the safety and efficacy of synthetic MUS is extremely successful. I urge you to not replace on a widespread basis the most studied, safe, and successful treatment for SUI with a procedure that is considerably more invasive and complicated and can be more painful and require a longer recovery. We all must do our best to clear up the confusion created by misleading television advertisements by law firms. **Full-length synthetic midurethral slings remain the current standard of care for stress incontinence surgery.**

References

1. Center for Devices and Radiological Health, Food and Drug Administration. Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Vaginal Placement for Pelvic Organ Prolapse. Silver Spring, MD: Food and Drug Administration; July 2011. www.fda.gov/downloads/medcaldevices/safety/.../UCM262760.pdf. Accessed October 15, 2012.
2. Urogynecologic Surgical Mesh Implants. FDA Web site. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm. Updated January 4, 2012. Accessed October 15, 2012.
3. Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 1996;7(2):81–55.
4. Novara G, Artibani W, Barber MD, et al. Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol. 2010;58(2):218–238.
5. Simsiman AJ, Powell CR, Stratford RR, Menefee SA. Suburethral sling materials: best outcome with autologous tissue. Am J Obstet Gynecol. 2005;193(6):2112–2116.
6. Richter HE, Albo ME, Zyczynski HM, et al; Urinary Incontinence Treatment Network. Retropubic versus transobturator midurethral slings for stress incontinence. N Engl J Med. 2010;362(22):2066–2076.
7. Nager CW, Brubaker L, Litman HJ, et al; Urinary Incontinence Treatment Network A randomized trial of urodynamic testing before stress-incontinence surgery. N Engl J Med. 2012;366(21):1987–1997.
8. Novara G, Galfano A, Boscolo-Berto R, et al. Complication rates of tension- free midurethral slings in the treatement of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices. European Urology. 2008;53(2):288–308.