

Frequently Asked Questions for Health Care Providers *Midurethral Slings for Stress Urinary Incontinence*

Midurethral slings (MUS) were first performed in Europe in the early 1990s. The U.S. Food and Drug Administration (FDA) approved the first MUS for use in the United States in 1998. By 2013, 3.6 million MUS had been placed worldwide.¹ Full-length MUS are considered safe and effective by the FDA.²

In 2008, the FDA issued a public health notification on complications associated with transvaginal mesh. The FDA updated the notification in 2011 and 2013. Importantly, they issued a MUS specific update in 2019 that affirmed prior conclusions that “the safety and effectiveness of multi-incision slings is well established in clinical trials that followed patients for up to 1 year.” They also noted that there are studies with longer term data, although fewer in number.

The media attention and complexity of the ongoing litigation has created confusion regarding the medical community's position on the safety and effectiveness of MUS. The purpose of this document is to provide information for health care providers who care for women considering surgical management of stress urinary incontinence (SUI).

Does the evidence indicate that midurethral slings are effective for the treatment of stress urinary incontinence?

Robust evidence, including high quality scientific papers in national and international medical journals, supports the use of MUS as a treatment for SUI.³ There are more than 2,000 publications in the scientific literature describing MUS in the treatment of SUI. These studies include the highest level of scientific evidence in the peer-reviewed scientific literature.³ The MUS has been studied in virtually all types of patients, with and without comorbidities, and all types of SUI. Numerous randomized, controlled trials comparing types of MUS, as well as comparing MUS to other established SUI procedures, have consistently demonstrated its clinical effectiveness,³⁻⁶ safety, and patient satisfaction.⁶ Among historical SUI procedures, the MUS has been studied as long in follow-up as any other procedure and has demonstrated superior safety and efficacy. This includes a recent 17-year follow-up study.⁷

Large government funded studies have evaluated the safety and efficacy of the MUS, finding the procedure to have a low complication rate and a high success rate. One study examined more than 95,000 women undergoing a mesh MUS for the first time and found that fewer than 5% required repeat surgery for SUI after 9 years.⁸ No other surgical treatment for SUI has been subject to such extensive investigation.

Does the evidence indicate that midurethral slings are safe in the treatment of stress urinary incontinence?

The MUS is the most studied anti-incontinence procedure in medical history. Furthermore, it is likely that more individuals have undergone this surgical procedure for the treatment of SUI than any other. MUS have a 2% risk of mesh erosion through the vagina, meaning a small portion of the mesh may be visible or able to be felt in the vagina. This can often be fixed by removing that small piece. Other risks include making a small hole in the bladder, during the procedure (which typically does not have any long-term consequences), urinary tract infection (which can be treated with antibiotics), some difficulty urinating after the procedure (which usually resolves on its own but occasionally requires adjusting the sling). Many of these complications occur in other urinary incontinence procedures and are not unique to MUS.

What is the material used for midurethral slings and have studies shown the material to be safe?

Currently available MUS are composed of macroporous, monofilament polypropylene, sometimes known as Amid Type I mesh. As a suture material, polypropylene is widely used, durable, and employed in a broad range of sizes and applications. Polypropylene material has been used in most surgical specialties

(including general surgery, cardiovascular surgery, transplant surgery, ophthalmology, otolaryngology, gynecology, and urology) for over 5 decades, in millions of patients in the United States and the world. As an implant for the surgical treatment of SUI, macroporous, monofilament polypropylene has demonstrated long-term durability, safety, and efficacy for up to 17 years.⁷

Are all midurethral slings currently available in the United States made of the same type of material?

Yes. Although the manufacturing, packaging, size, and specific implantation techniques vary between procedures and are proprietary, all MUS available in the United States are made of polypropylene knitted into a macroporous mesh.

Does the polypropylene mesh degrade over time?

Polypropylene is a stable and well-accepted biomaterial with over 5 decades of use. In recent years, concerns regarding the degradation of the implanted polypropylene have been raised as a result of very high-magnification images that show portions of some explanted synthetic meshes with “cracked” surfaces.⁹ These surface changes were further hypothesized to lead to adverse clinical outcomes, though this is not supported by the extensive peer-reviewed literature. These changes were later demonstrated to be a complex of protein and formaldehyde deposits on the mesh.¹⁰ Furthermore, prospective studies have followed patients with implanted MUS for 17 years and show excellent durability and safety of the procedure.⁷ Analysis of 1,000 explanted mesh grafts used in hernia repair demonstrated preserved structure and distance between woven fibers, further arguing against degradation.¹¹

Is there scientific evidence that the mesh used in polypropylene midurethral slings causes cancer in humans?

Tumors related to the implantation of surgical grade polypropylene for MUS in humans have not been reported. There is no compelling evidence supporting human malignant transformation related to polypropylene despite the millions of individuals implanted with various forms of this material spanning well over a half century worldwide. Two published studies with more than 10,000 patients found no increase in cancer in patients who underwent MUS.^{12,13} It is known that tumor formation related to biomaterials in animals is largely dependent on the physical rather than the chemical configuration of the implant, with smooth large surface areas (discs and thin sheets) being potentially carcinogenic, and irregular disrupted surfaces (eg, those that contain pores as in meshes) lacking carcinogenicity.^{14,15}

Has there been an FDA recall of midurethral slings or the mesh material?

The 2019 FDA update confirmed that “complications associated with the use of surgical mesh slings currently on the market for SUI repair are not linked to a single brand of mesh” and there are no product recalls. The FDA did not suggest that the material or implantation of MUS were dangerous or should be stopped. They reported that the safety and effectiveness of multi-incision MUS are well-established in clinical trials for up to 1 year and that longer follow-up is available but there are fewer long-term studies. They noted that the most common mesh specific complication is exposure of mesh through the vaginal wall with an average rate of mesh exposure at 1 year of approximately 2%.

Are single-incision slings different than full-length midurethral slings?

Single-incision slings are placed through a single vaginal incision with no suprapubic or groin incision. The strip of mesh used in this sling is shorter than in a full-length midurethral sling, so they are also referred to as mini slings. Studies comparing single-incision slings to transobturator full-length MUS show similar efficacy^{16,17}, though these studies have shorter length of follow-up outcomes and fewer patients than the studies of full-length MUS.¹⁸

References

1. Medicines and Healthcare Products Regulatory Agency. *A summary of the evidence on the benefits and risks of vaginal mesh implants*. London, UK: Medicines and Healthcare Products Regulatory Agency (MHRA). Available at www.gov.uk/government/publications/vaginal-mesh-implants-summary-of-benefits-and-risks. Accessed Nov 5, 2020.
2. U.S. Food & Drug Administration. *Considerations about surgical mesh for SUI*. Available at: <https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/considerations-about-surgical-mesh-sui> . Accessed October 28, 2020.

3. Ford AA, Rogerson L, Cody JD, et al. *Mid-urethral sling operations for stress urinary incontinence in women*. Cochrane Database of Systematic Reviews 2017, Issue 7. Art. No.: CD006375. DOI: 10.1002/14651858.CD006375.pub4.
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):218-38.
5. Ward, K. and P. Hilton, *Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence*. BMJ. 2002;325(7355):67.
6. Richter HE, Albo ME, Zyczynski HM, et al. *Retropubic versus transobturator midurethral slings for stress incontinence*. N Engl J Med, 2010;362(22):2066-76.
7. Nilsson CG, Palva K, Aarnio R, et al. *Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence*. Int Urogynecol J. 2013;24(8):1265-9.
8. Gurol-Urganci I, Geary RS, Mamza JB, et al. *Long-term Rate of Mesh Sling Removal Following Midurethral Mesh Sling Insertion Among Women With Stress Urinary Incontinence*. JAMA. 2018;320(16):1659-1669.
9. Clave A, Yahi H, Hammou JC, et al. *Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants*. Int Urogynecol J. 2010;21(3):261-70.
10. Thames SF, White JB, Ong KL. *The myth: in vivo degradation of polypropylene-based meshes*. Int Urogynecol J. 2017;28(2):285-97.
11. Klinge U, Klosterhalfen B. *Modified classification of surgical meshes for hernia repair based on the analyses of 1,000 explanted meshes*. Hernia. 2012;16(3):251-8.
12. King AB, Zampini A, Vasavada S, et al. *Is there an association between polypropylene midurethral slings and malignancy?* Urology. 2014;84(4):789-92.
13. Chughtai B, Sedrakyan A, Mao J, et al. *Challenging the myth: transvaginal mesh is not associated with carcinogenesis*. J Urol. 2017;198(4):884-9.
14. Ratner BD, Hoffman AS, Schoen FJ, et al. eds. *Biomaterials Science: An Introduction to Materials in Medicine - 3rd Edition*. 2013, Academic Press: Waltham, MA.
15. Oppenheimer BS, Oppenheimer ET, Stout AP, et al. *The latent period in carcinogenesis by plastics in rats and its relation to the presarcomatous stage*. Cancer. 1958;11(1):204-13
16. Nambiar A, Cody JD, Jeffery ST, et al. *Single-incision sling operations for urinary incontinence in women*. Cochrane Database of Syst Rev. 2017 Jul 25;7(7): CD008709. DOI: 10.1002/14651858.CD008709.pub3.
17. White AB, Kahn BS, Gonzalez RR, et al. *Prospective study of a single-incision sling versus a transobturator sling in women with stress urinary incontinence: 3-year results*. Am J Obstet Gynecol. 2020;223(4): 545.e1-545.e11.
18. Kobashi KC, Albo ME, Dmochowski RR, et al. *Surgical treatment of female stress urinary incontinence: AUA/SUFU guideline*. J Urol. 2017;198(4):875-83.

Our Organizations

The American Urogynecologic Society (AUGS), founded in 1979, is a non-profit organization representing more than 2,300 members including practicing physicians, nurse practitioners, physical therapists, nurses, and health care professionals, as well as researchers from many disciplines, all dedicated to treating female pelvic floor disorders (pelvic organ prolapse and urinary incontinence). AUGS promotes the highest quality patient care through excellence in education, research, and advocacy.

The Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU), is the premier non-profit organization dedicated to improving the art and science of Urology through basic and applied clinical research in urodynamics and neurourology, voiding function and dysfunction, female urology, pelvic floor dysfunction and reconstruction, and to disseminate and teach these concepts. It is the oldest professional organization dedicated to this field consisting of interested physicians, basic scientists, and other health care professionals, and has grown to over 700 members.

This document reflects clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Its content is not intended to be a substitute for professional medical judgment, diagnosis, or treatment. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient.

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