

Frequently Asked Questions for Patients ***Midurethral Slings for Stress Urinary Incontinence***

What is a midurethral sling?

A midurethral sling is a small mesh strip used in surgery to treat stress urinary incontinence, a type of urine leakage that occurs during activities such as laughing, coughing, or exercise. The midurethral sling works to prevent or significantly reduce the loss of urine during these activities.

What is “mesh”?

Mesh in this document refers to a woven fabric made of a material called polypropylene that has been used in the human body for over 50 years.

How is the surgery done?

The surgery is performed through a small incision in the vagina below the urethra (the tube through which urine passes from the bladder). Through this incision a half-inch wide strip of polypropylene mesh is placed between the urethra and the vagina. The ends of the sling are passed out of small incisions in the groin or above the pubic bone, allowing a hammock of mesh support under the urethra. Using suture that eventually will dissolve, the vaginal incision is closed. The incisions on the groin or pubic area skin are closed with either surgical glue or dissolvable suture.

What is the difference between a midurethral sling and vaginal prolapse mesh?

A midurethral sling is used to treat stress urinary incontinence. A vaginal prolapse mesh is placed through a vaginal incision to correct a vaginal bulge or pelvic organ prolapse (eg, prolapse of the front wall of the vagina or “cystocele,” prolapse of the back wall of the vagina or “rectocele,” or prolapse of the top of the vagina which may include the uterus). Vaginal prolapse mesh is made out of the same material but is larger and often placed in a different location than the midurethral sling mesh.

Are midurethral slings safe?

The midurethral sling is considered safe and effective by the U.S. Food and Drug Administration (FDA). Complications can occur but they are typically minor and usually can be repaired. These most commonly include mesh exposed through the lining of the vagina. However, as with any surgery, more serious complications can occur, like the mesh pushing into the urethra or bladder. Our societies believe that for most patients the benefits of the MUS outweigh the risks.

Has the midurethral sling been recalled by the FDA?

No. The current knitted polypropylene midurethral sling has not been recalled by the FDA. The full-length knitted polypropylene midurethral sling has been reviewed by the FDA and found to be safe and effective. The mesh products intended to repair pelvic organ prolapse are different than those used to repair stress urinary incontinence.

Is a midurethral sling different than a single-incision sling?

Single-incision slings are placed through a vaginal incision without incisions in the groin or pubic area. The strip of mesh used in this sling is shorter than in a full-length sling, so they are also referred to as mini slings. Studies comparing single-incision slings to other full-length midurethral slings show similar efficacy,¹ though these studies have shorter length of follow-up outcomes and fewer patients than the studies of full-length midurethral slings.²

What sort of evidence supports the effectiveness safety of the midurethral sling?

The midurethral sling procedure is the most studied surgery to treat stress urinary incontinence and there have been more than 2,000 articles published about it. Results of these studies have appeared in prestigious medical journals such as the *New England Journal of Medicine*. Two large government funded studies have evaluated the midurethral sling's safety and effectiveness – both found the procedure to have a low complication rate and a high success rate.

How long have midurethral slings been used?

The midurethral sling was first performed in Europe in the early 1990s. The FDA approved the first midurethral sling for use in the United States in 1998. Since that time, more than 3.6 million midurethral sling procedures have been performed worldwide.³

Scientific articles report a high satisfaction rate with few serious long-term complications related to the midurethral sling (10-17 years after the sling was placed).^{4,5}

What are the complications of midurethral slings?

Midurethral slings have a 1-2% risk of mesh exposure in the vagina, meaning a small portion of the mesh may be visible or able to be felt in the vagina. This can often times be fixed by trimming it. 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), and/or some difficulty urinating after the procedure (which usually resolves on its own but occasionally requires cutting or revising the sling). Many of these complications occur in other urinary incontinence procedures and are not unique to midurethral sling procedures. One large study, of 17,000 patients, noted that after 5 years, 1.1% of patients needed reoperation for a problem with the sling (difficulty urinating, vaginal mesh exposure, pain, bleeding, or infection).⁶ The slings also do not always work as expected to correct the stress incontinence.

Are there other options to treat stress urinary incontinence?

There are non-surgical treatments for stress urinary incontinence, including behavioral techniques, vaginal inserts, and pelvic floor muscle exercises. Multiple scientific studies have found the midurethral sling to have a higher cure rate for stress urinary incontinence than pelvic floor physical therapy.⁷

Other procedures for the treatment of stress urinary incontinence include the injection of a bulking substance into the urethra to treat stress urinary incontinence. Although not as effective nor as durable as the surgical stress urinary incontinence treatments, urethral bulking injections are important non-mesh alternatives and can sometimes be done in the office.

Historically, more than 130 procedures for stress urinary incontinence have been described. Examples of these procedures include fascial slings made from tissue taken from the patient's own body or Burch suspensions done with sutures through an abdominal incision. These procedures may be considered by your doctor as a treatment for stress urinary incontinence. In general, however, the midurethral sling has been found to be as effective as any of these procedures and is as durable (the surgery maintains its favorable effects just as long or longer). In addition, in many cases the pain related to the procedure, the time required to recover from the surgery, and time to return to normal activities (including work) is less for the midurethral sling than for many of these surgical procedures.

What about the advertisements about vaginal mesh and slings?

Initially, in 2008, the FDA issued a public health notification on complications associated with transvaginal mesh. In 2011, the FDA updated its statement and noted that complications associated with transvaginal mesh used to repair prolapse are not rare and that it was continuing to evaluate mesh use for the midurethral sling. In 2013, the FDA updated its position, noting that "the safety and effectiveness of multi-incision slings is well established in clinical trials that followed patients up to 1 year." Transvaginal mesh used for prolapse repair is a different use of mesh and has since been ordered off the market by the FDA.

In 2019, the FDA reaffirmed the findings of its safety panel and literature review stating that the safety and effectiveness of multi-incision slings is well established.⁸ The FDA has not recalled or published warnings against the multi-incision midurethral sling. Most experts who deal with female stress urinary incontinence are supportive of the use of the mesh midurethral sling and the majority of women who have had one placed are satisfied.

Does a midurethral sling cause cancer?

There is no evidence the midurethral sling causes cancer. Two published studies with over 10,000 patients found no increase in cancer in patients who underwent midurethral sling surgery compared to the general population.^{9,10}

Does a midurethral sling cause any other diseases?

There is no evidence that polypropylene mesh or midurethral sling cause other diseases.

Where can I find more information on this?

- Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction. SUFU patient resources. Available at: <https://sufu.org/resources/patients.aspx>
- American Urogynecologic Society. AUGS Patient Fact Sheets. Available at: <https://www.augs.org/patient-fact-sheets/>
- 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>
- American Urological Association. AUA position statement on the use of vaginal mesh for the surgical treatment of stress urinary incontinence (SUI). Available at: <https://www.auanet.org/guidelines/use-of-vaginal-mesh-for-the-surgical-treatment-of-stress-urinary-incontinence>
- Urology Care Foundation. Answering your patients' questions: Surgical mesh sling surgery for stress urinary incontinence. Available at: <http://www.urologyhealth.org/>

References

1. 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.
2. Kobashi KC, Albo ME, Dmochowski RR, et al. *Surgical treatment of female stress urinary incontinence: AUA/SUFU guideline*. J Urol. 2017;198(4):875-883.
3. 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 <https://www.gov.uk/government/publications/vaginal-mesh-implants-summary-of-benefits-and-risks> . Accessed November 19, 2020.
4. 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.
5. Khan ZA, Nambiar A, Morley R, et al. *Long-term follow-up of a multicentre randomised controlled trial comparing tension-free vaginal tape, xenograft, and autologous fascial slings for the treatment of stress urinary incontinence in women*. BJU Int. 2015;115(6):968-77.
6. Berger AA, Tan-Kim J, Menefee SA. *Long-term risk of reoperation after synthetic mesh midurethral sling surgery for stress urinary incontinence*. Obstet Gynecol. 2019;134(5):1047-55.
7. Labrie, J., et al., *Surgery versus physiotherapy for stress urinary incontinence*. N Engl JMed. 2013;369(12):1124-33.
8. 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 November 19, 2020.

9. Chughtai B, Sedrakyan A, Mao J, et al. *Challenging the Myth: Transvaginal Mesh is Not Associated with Carcinogenesis*. J Urol. 2017;198(4):884-889.
10. King AB, Zampini A, Vasavada S, et al. *Is there an association between polypropylene midurethral slings and malignancy?* Urology. 2014;84(4):789-92.

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.

Copyright October 2021