AUGS
Advancing Female Pelvic Medicine and Reconstructive Surgery

SUFU
SOCIETY OF URODYNAMICS, FEMALE PELVIC MEDICINE & UROGENITAL RECONSTRUCTION

Frequently Asked Questions by Providers
Mid-urethral Slings for Stress Urinary Incontinence

Mid-urethral Slings were first performed in Europe in the early 1990s. The FDA approved the first mid-urethral sling (MUS) for use in the United States in 1998. Since that time over 3 million mid-urethral slings have been sold world-wide. Full length mid-urethral slings are considered safe and effective by the US Food and Drug Administration (FDA).

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 MUS. In 2013, the FDA further updated its position noting that "the safety and effectiveness of multi-incision slings is well established in clinical trials that followed patients up to one year."

After the FDA issued its initial statements, additional information appeared in the media, including some lawyer advertisements related to transvaginal mesh. Because mesh is used in both procedures (transvaginal mesh for prolapse and MUS for stress urinary incontinence) there may be some questions about the use of mesh.

The purpose of this Frequently Asked Questions document is to provide factual information for healthcare providers who are involved in the care of women considering such treatment.

Does the evidence indicate that mid-urethral slings are effective for the treatment of SUI?

A broad evidence base including high quality scientific papers in medical journals in the US and the world supports the use of mid-urethral slings as a treatment for SUI [1]. There are greater than 2000 publications in the scientific literature describing mid-urethral slings in the treatment of SUI. These studies include the highest level of scientific evidence in the peer reviewed scientific literature [1]. 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 mid-urethral slings, as well as comparing MUS to other established SUI procedures, have consistently demonstrated its clinical effectiveness [1-4] and patient satisfaction [4]. Among historical SUI procedures, the MUS has been studied as long in follow-up after implantation as any other procedure and has demonstrated superior safety and efficacy. This includes a recent 17 year follow-up study. [5]. No other surgical treatment for SUI before or since has been subject to such extensive investigation.

Does the evidence indicate that mid-urethral slings are safe in the treatment of SUI?

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. The difficulties and complications associated with mid-urethral slings are similar in character to that seen with non-mesh procedures (bladder outlet obstruction, urinary tract injury, dyspareunia, pain, etc.) with the exception of vaginal mesh exposure and mesh perforations into the urinary tract.

What is the material used for mid-urethral slings and have studies shown the material to be safe?

Currently available mid-urethral slings are composed of macroporous, knitted, monofilament polypropylene, sometimes known as "Type I" meshes. 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 five decades, in millions of patients in the US and the world. As the knitted form, polypropylene mesh is the consensus material as a graft augmentation layer for hernia repairs in a number of areas in the human body and has significantly and favorably impacted the field of hernia surgery. [6, 7] 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 [5].

Are all mid-urethral slings currently available in the US made of the same type of material?

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

Does the MUS mesh made of polypropylene degrade over time?

Polypropylene is a stable and well-accepted biomaterial with a history of over five decades of use in mesh implants. In recent years, concerns regarding implanted polypropylene degradation have been raised as a result of very highmagnification images that show portions of some explanted synthetic meshes with “cracked” surfaces.[8] These surface changes were further hypothesized to lead to adverse clinical outcomes, though this is not supported by the extensive peer-reviewed literature related to polypropylene mesh repairs. Prospective studies have followed patients with implanted mid-urethral slings for 17 years and show excellent durability and safety of the procedure. [5]

Is there scientific evidence that the mesh used in polypropylene mid-urethral slings causes cancer in humans?

Tumors related to the implantation of surgical grade polypropylene for mid-urethral slings in humans have never 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 world-wide. The possibility that biomaterial prosthetic devices could cause tumors or promote tumor growth has been the focus of extensive research by both clinicians and biomaterial researchers. [9, 10]. It is known that tumor formation related to biomaterials in animals is largely dependent on the physical, not the chemical configuration of the implant, with smooth large surface areas (discs and thin sheets) being potentially carcinogenic, and irregular disrupted surfaces (e.g. those that contain pores as in meshes) lacking carcinogenicity [10, 11].

Has there been an FDA recall of mid-urethral slings or the mesh material?

None of the FDA communications regarding mesh used in pelvic reconstructive surgery were related to a recall nor did they suggest that the material or implantation of mid-urethral slings were dangerous, or should be stopped.

Has the FDA warned against surgical placement of mid-urethral slings?

The mid-urethral sling was not the subject of the 2011 FDA Safety Communication, “Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Vaginal Placement for Pelvic Organ Prolapse.”[12] 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 2013, the FDA website stated clearly that: “The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year.” [13]. The FDA has specifically exempted full-length mid-urethral slings from the need for additional mandated research.

What is a 522 study and does it involve mid-urethral slings?

A 522 study refers to a specific section of the FDA regulatory framework wherein a commercial entity is required to perform additional post-marketing research following its regulatory approval by the FDA. Once 522 studies are mandated, they are subject to FDA oversight. Completion and review of these studies by the FDA is a requirement for continuing the sales and marketing of such products by the commercial entity under FDA scrutiny. 522 studies have been mandated for certain mesh products including some single incision slings (“mini-slings”). Currently available multi-incision mid-urethral slings are not subject to 522 studies.

The information above is intended to provide patients and physicians with general information, and is not intended to substitute for the treating physician's clinical judgment. The treating physician should make all treatment decisions based upon his or her independent judgment and the patient's individual clinical presentation.

Our Organizations

The *American Urogynecologic Society (AUGS)*, founded in 1979, is a non-profit organization representing more than 1,700 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.

SUFU, the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction, is a 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 and pelvic floor dysfunction, 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 500 members.

This FAQ statement was drafted by an AUGS/SUFU MUS task force composed of Charles Nager, Paul Tulikangas, and Dennis Miller from AUGS and Eric Rovner and Howard Goldman from SUFU. This FAQ statement was approved by both the AUGS Board of Directors and the SUFU Board of Directors.

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