

## **Frequently Asked Questions by Patients**

### ***Mid-urethral Slings for Stress Urinary Incontinence***

#### **What is a mid-urethral sling (MUS)?**

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

The surgery is done through a small incision in the vaginal wall 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 mesh are passed out incisions in the groin or above the pubic bone. Using absorbable suture, the vaginal incision is closed covering the sling.

#### **Are mid-urethral slings safe?**

The mid-urethral sling is considered safe and effective by the US Food and Drug Administration (FDA). As with any surgery, complications can occur but they are typically minor and can usually be repaired.

#### **Has the mid-urethral sling been recalled by the FDA?**

The current knitted polypropylene mid-urethral sling has not been recalled by the FDA. The full-length knitted polypropylene mid-urethral sling has been reviewed by the FDA and found to be safe and effective.

#### **What sort of evidence supports the efficacy and safety of the mid-urethral sling?**

The mid-urethral sling procedure is the most studied surgery to treat stress urinary incontinence and there have been over 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 mid-urethral sling's safety and efficacy – both found the procedure to have a low complication rate and a high success rate. Other large scientific studies from around the world have supported the safety and efficacy of the mid-urethral sling.

#### **How long have the mid-urethral slings been used?**

The mid-urethral sling was first performed in Europe in the early 1990s. The FDA approved the first mid-urethral sling for use in the United States in 1998. Since that time over 3 million mid-urethral sling procedures have been performed world-wide.

A peer-reviewed scientific article reported on the safety outcomes of the mid-urethral sling in Sweden over a 17 year period. It found a high satisfaction rate and no serious long-term adverse events related to the mid-urethral sling.

## **Are there other options to treat stress urinary incontinence?**

There are non-surgical treatments for stress urinary incontinence including behavioral techniques and pelvic floor muscle exercises. A recent scientific study found the mid-urethral sling to have a higher cure rate for stress urinary incontinence than pelvic floor physical therapy.

In office procedures for the treatment of stress urinary incontinence include the injection of a bulking substance into the urethral lining to treat stress urinary incontinence. While not as effective nor as durable as the surgical stress urinary incontinence treatments it is useful as an alternative in certain circumstances.

Alternative surgical treatment options to the mid-urethral sling have been performed by surgeons for over 100 years. Such procedures include operating through abdominal or vaginal incisions. Even today, in limited circumstances, such procedures may be considered by your doctor as a treatment for stress urinary incontinence. In general however, the mid-urethral sling has been found to be as or more effective than any of these procedures and is as durable (the surgery maintains its favorable effects over a longer period of time). In addition, 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 mid-urethral sling than for any of these surgical procedures.

## **What about the advertisements about vaginal mesh and slings?**

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 mid-urethral sling. 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. The media has also reported issues related to transvaginal mesh. Because mesh is used in both procedures (transvaginal mesh for prolapse and the mid-urethral sling for stress urinary incontinence) there may be some confusion about the use of mesh. As we have noted, transvaginal mesh is currently under further study by the FDA but with respect to the mid-urethral sling, the FDA has determined that no further study is necessary.

## **What is the difference between a mid-urethral sling and vaginal prolapse mesh?**

A mid-urethral sling is used to treat stress urinary incontinence. A vaginal prolapse mesh is placed through a vaginal incision to correct a vaginal bulge (ex. cystocele, rectocele or dropped uterus). Vaginal prolapse mesh is larger and placed in a different location than the mid-urethral sling mesh.

## **Does a mid-urethral sling cause cancer?**

There is no evidence that any women have developed cancer as a result of a mid-urethral sling.

## **Does a mid-urethral sling cause any other diseases?**

There is no evidence that polypropylene mesh or mid-urethral sling causes other diseases.

*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 Urology 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.

Disclosures: Dr. Nager is a principal investigator in the NICHD/NIH Pelvic Floor Disorders Network which is conducting an FDA recommended randomized trial involving transvaginal mesh for prolapse and the NICHD/NIH through a public/private cooperative arrangement has received partial financial support from Boston Scientific Corporation for this study. Dr Miller receives consulting fees and royalties from Boston Scientific for prolapse mesh. Drs. Tulikangas, Rovner, and Goldman have no disclosures.