Surgical Mesh for Stress Urinary Incontinence (also known as Sling Surgery)

The Urology Care Foundation and the American Urological Association (AUA) are concerned that patients may be confused about the use of surgical mesh to treat SUI. Surgical mesh is used to treat other health problems, such as hernias. The U.S. Food and Drug Administration (FDA) has issued safety statements on the use of mesh in other surgeries. But surgical mesh “sling” surgery continues to be a standard treatment for SUI.

SUI – WHAT EVERY PROVIDER NEEDS TO KNOW

Stress Urinary Incontinence (SUI) is urine leakage during activities that result in increased abdominal pressure, such as sneezing, coughing, laughing, physical exercise, lifting, bending and even changing positions.

SUI is a very common condition – 1 out of 3 women have SUI.

- Less than half of women who have urinary incontinence have discussed their symptoms with their health care provider.
- Any amount of leakage of urine is abnormal.
- Untreated, SUI can have significant impact on quality of life.
- Women have both non-surgical and surgical options to treat SUI.

For women choosing to undergo surgery, the sling procedure using synthetic polypropylene mesh is the most common surgery currently performed for SUI.

AUA and other leading urological subspecialty societies support the use of mesh slings.

- The American Urological Association advises doctors that synthetic mesh slings are a suitable treatment option for women with SUI, stating that “extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI.”
- The American Urogynecologic Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) have reiterated that they “support the use of the midurethral sling in the surgical management of stress urinary incontinence.”

SUI is different from Overactive Bladder (OAB, or Urgency Incontinence), which is leakage that occurs with a sudden urge to urinate. Many patients have Mixed Incontinence, which includes a combination of both SUI and OAB.

SYMPTOMS

- Mild incontinence is light leakage with vigorous activity such as exercise or from sneezing, laughing, coughing or lifting.
- Moderate/more severe incontinence is leakage associated with many different types of movement such as standing up, walking or bending over. Typically, patients use absorbent pads for protection from urine loss.

Risk factors for SUI include:

- age
- Caucasian or Hispanic race
- obesity
Untreated, SUI can have a significant impact on a patient’s quality of life, affecting day-to-day activities, participation in sports, and sexual activity, and can result in embarrassment and isolation. Consequently, it is important for the health care provider to discuss these issues with the patient to determine how bothered she is by the condition. It is also important to dispel some common myths associated with SUI (such as “SUI is a normal part of aging”). The goal of any treatment for urine leakage is to improve the patient’s quality of life. In most cases, great improvements or cure of urine leakage is possible.

SUI TREATMENTS

There are non-surgical strategies to help treat and manage SUI, including:

• pelvic floor muscle training
• lifestyle changes such as maintaining a healthy weight, smoking cessation and fluid and diet management
• absorbent pads
• urinary control devices such as pessaries or occlusive devices

For some people, these options may not be enough, and they may choose to have surgery. Current surgical options include:

• sling surgery
• bladder neck suspension (also called retropubic suspension or colposuspension)
• urethral bulking injection (helps better close off the urethra during times of increased pressure, significantly less effective than other surgeries)

WHAT IS SURGICAL MESH?

Today, mesh slings are the most common surgery used to treat female SUI worldwide. During this surgery, a strip of material (a “sling”) is placed under the bladder neck or urethra. The sling improves support of the bladder neck and/or urethra to help prevent urine leakage. Slings can be made from one’s own tissue (autologous graft), donor tissue (typically skin or fascia) or surgical mesh. Synthetic surgical mesh is used in the treatment of a number of health problems, most commonly for hernias. Today, surgical mesh is made of Type I, macroporous, monofilament and non-carcinogenic polypropylene.

SURGICAL MESH IS A STANDARD TREATMENT FOR SUI

Mesh sling surgery is a less invasive surgery than other options, and patients tend to recover quicker than with the alternative surgeries to correct SUI. (These alternatives include bladder suspension procedures – used in about 5% of surgeries – and slings that are constructed using the patient’s own tissue.) The AUA’s guidelines continue to list mesh slings as a “standard” treatment for SUI. In its
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SUI Guidelines (www.AUAnet.org/education/guidelines/incontinence.cfm), the AUA points to many scientific studies that support the use of mesh slings to treat SUI.

There are three kinds of mesh slings – transobturator, retropubic and mini-slings. All of the slings are safe and effective in treating SUI. Since mini slings are newer, studies to assess how well they work in the long-term are ongoing.

All surgeries carry a risk of side effects. Side effects can result from sling surgery, no matter what type of sling is used. These side effects can include difficulty voiding, or even inability to void in rare cases. Pelvic pain and/or pain with intercourse can occur, rarely, following sling surgery, and in certain cases might require sling excision. The FDA found that other long-lasting side effects from treating SUI with mesh seem to be rare.

Exposure of the mesh into the vagina after surgery is a side effect that happens about 2% of the time and is unique to the use of synthetic mesh. In most cases, exposure may be treated effectively in a fairly straightforward manner. However, some women with exposure do require further surgery.

A consultation with a urologist or other female pelvic medicine reconstructive surgeon is encouraged to help inform your patient about her options, including the risks and benefits of different treatments.

RECENT FDA SAFETY STATEMENTS ABOUT SURGICAL MESH

The Urology Care Foundation and the American Urological Association are concerned that patients are confused about the use of surgical mesh to treat SUI versus the different use of surgical mesh to repair pelvic organ prolapse (POP). (POP can be a serious health problem in which female pelvic organs - such as the uterus or bladder - fall into the patient's vagina. This can cause a vaginal bulge and often a sense of pressure or discomfort.)

POP and SUI are different health issues with different surgical treatments. The surgeries that use mesh to treat each health issue have their own unique risks and benefits.

Mesh used for POP repair must help support the “fallen” or “dropped” female pelvic organs continuously. Mesh to treat SUI only has to support the urethra and only during “stress” activity, such as coughing, laughing or exercising. Therefore, mesh used to treat SUI is different than mesh for POP repair. SUI mesh is smaller and is placed in a different location than mesh used to repair POP.

In 2011 and 2013, the FDA stated concerns about the use of transvaginal mesh to repair POP (http://1.usa.gov/1HghbDi). More recently, the FDA indicated that mesh for SUI does not carry the same risk as transvaginal mesh for POP repair. In 2016, the FDA put transvaginal mesh for POP in a higher risk category than mesh for SUI. Read the FDA's final rule at: http://1.usa.gov/1ne31wL. The FDA clearly states that this rule does not apply to mesh for SUI.

Mesh slings used to treat SUI are generally recognized to be safe, and long-lasting side effects are rare. Mesh slings are a standard treatment for SUI.

IF A PATIENT HAS ALREADY HAD SURGERY WITH MESH TO TREAT SUI DO THEY NEED TO HAVE IT REMOVED?

Surgical mesh is designed to be a permanent implant. If a patient has had this surgery and is not having any side effects, there is no need to remove the mesh. Mesh removal could have its own side effects, including injury to tissues near the mesh or recurrent incontinence.
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MORE INFORMATION FOR HEALTH CARE PROVIDERS:

American Urological Association
Position Statements on the Use of Vaginal Mesh for the Surgical Treatment of SUI and POP
www.AUAnet.org/about/vaginal-mesh-for-sui.cfm
Guideline for the Surgical Management of Female SUI
www.AUAnet.org/education/guidelines/incontinence.cfm

SUFU and AUGS
Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) and American Urogynecologic Society (AUGS) Position Statement on Mesh Midurethral Slings (MUS) for Stress Urinary Incontinence:
http://www.sufuorg.com/resources.aspx

U.S. Food and Drug Administration
Considerations About Surgical Mesh For SUI
http://1.usa.gov/1ukqsEx
Information for Health Care Providers for SUI
http://1.usa.gov/11j4G9F

Urology Care Foundation
SUI Monograph and SUI Pocket Reference
www.UrologyHealth.org/SUI, click on “for Health Care Providers.”
Answering Your Patient’s Questions: Surgical Mesh for Stress Urinary Incontinence
www.UrologyHealth.org/MeshQ

MORE INFORMATION FOR PATIENTS:

SUFU and AUGS

U.S. Food and Drug Administration
Information for Patients
http://1.usa.gov/14eIwX8

Urology Care Foundation
For referral to a urologist:
www.UrologyHealth.org/FindAUrologist
Choose “incontinence” as a “special interest area” to find urologists who are interested in treating SUI.

It’s Time to Talk about SUI campaign
Surgical Mesh for SUI Fact Sheet
www.UrologyHealth.org/Mesh

For more information, contact:

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UrologyHealth.org

You may download this and print this fact sheet yourself from UrologyHealth.org/MeshHCP. For copies of other printed materials about urologic conditions, visit UrologyHealth.org/Order or call 800-828-7866.