Stress Urinary Incontinence Sling FAQs for Patients

Q: What is stress urinary incontinence and is it a common problem?

A: Stress urinary incontinence (SUI) is loss of urine that occurs at the same time as physical activities that increase abdominal pressure (such as sneezing, coughing, laughing, and exercising). These activities can increase the pressure within the bladder, which behaves like a balloon filled with liquid. The rise in pressure can push urine out through the urethra, especially when the support to the urethra has been weakened; this is what we call stress urinary incontinence. Approximately 1 out of 3 women over the age of 45, and 1 out of every 2 women over 65 have SUI.

Q: What are surgical treatment options for stress urinary incontinence?

A: Surgeons have developed different techniques for supporting the bladder back to its normal position. The three main types of surgery are: retropubic suspension and two types of sling procedures.

• Retropubic suspension uses surgical threads called sutures to support the bladder neck. In this operation, the surgeon makes an incision in the abdomen a few inches below the navel and then secures the threads to strong ligaments within the pelvis to support the urethral sphincter. This common procedure is often done at the time of an abdominal procedure, such as a hysterectomy.

• Sling procedures are performed through a vaginal incision. The traditional sling procedure uses a strip of your own tissue called fascia to cradle the bladder neck. Other slings may consist of donor natural tissue or synthetic material. The surgeon ties both ends of the sling to the pubic bone or ties them in front of the abdomen just above the pubic bone.

• Mid-urethral slings are newer procedures that you can have on an outpatient basis. These procedures use synthetic mesh materials that the surgeon places midway along the urethra. The two general types of mid-urethral slings are retropubic slings, such as the transvaginal tapes (TVT), and transobturator slings (TOT). The surgeon makes small incisions behind the pubic bone or just by the sides of the vaginal opening as well as a small incision in the vagina. The surgeon uses specially designed needles to position a synthetic tape under the urethra. The surgeon pulls the ends of the tape through the incisions and adjusts them to provide the right amount of support to the urethra.

Q: How do I know if a sling is a good option for me?

A: This is a decision that you should make in consultation with your doctor. You should discuss all of your options and determine which treatment is most appropriate for your specific medical situation. This is a personal choice that your doctor should be ready to discuss with you.

Q: How long is the sling surgery?

A: In most cases, the surgery should last less than 30 minutes. If your doctor recommends, the procedure can be performed under local anesthesia with IV sedation. Sling procedures are frequently outpatient procedures, in which case you may be returning home the same day of surgery. Many times, the sling is part of another procedure and you may need additional surgery to support a dropped bladder, uterus or rectum. Your doctor will discuss this with you.

Q: What is a Public Health Notification?

A: A Public Health Notification is an important message from the FDA's Center for Devices and Radiological Health to the health care community describing a risk associated with the use of a medical device and providing recommendations on its use.

Q: What did the FDA say in its October 20, 2008 Public Health Notice?

A: On October 20, 2008, the FDA issued a Public Health Notification (PHN) regarding potential complications associated with transvaginal placement of surgical mesh to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). The PHN provided recommendations and encouraged physicians to seek specialized training in mesh procedures, to advise their patients about the risks associated with these procedures and to be diligent in diagnosing and reporting complications.

Q: What has happened since the 2008 PHN?

A: In July 2011, the FDA issued an update to the October 2008 PHN. In this update, the FDA maintained that adverse events for POP mesh repair are not rare, as previously reported, and questioned the relative effectiveness of transvaginal mesh as a treatment for POP as compared to non-mesh surgical repair.

On September 8-9, 2011, the FDA convened an Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee to further address the safety and effectiveness of transvaginal surgical mesh used for repair of POP. The panel recommended to the FDA that slings for the treatment of SUI are properly classified by the FDA with respect to risks and benefits offered. Regarding standard retropubic and transobturator slings, the panel concluded that no additional post-market surveillance studies are necessary. Regarding mini-slings, the panel recommended pre-market studies for new devices and additional post-market studies.

Q: Has the FDA recalled slings?

A: No, the FDA has not recalled slings.

Q: I have a sling implanted for bladder leakage. Should I have it removed?

A: As with all important medical decisions, you should consult with your physician. There is no need to remove your sling if you are satisfied with your surgery and are not having complications or symptoms. Because a sling integrates with your own tissues, removal may cause complications or symptoms. The FDA recommends you continue with your annual and other routine check-ups and follow-up care. Patients should notify the surgeon if complications develop (persistent vaginal bleeding or discharge, pelvic or groin pain during sex).