PATIENT

Frequently Asked Questions

Transvaginal Surgical Mesh for Pelvic Organ Prolapse

WHAT IS PELVIC ORGAN PROLAPSE AND HOW IS IT TREATED?

Q: What is pelvic organ prolapse and is it a common problem?

A: Pelvic organ prolapse (POP) occurs when the tissues that hold the pelvic organs in place become weak or stretched. Thirty to fifty percent of women may experience POP in their lifetime with 2 percent developing symptoms. When POP happens, the organs bulge (prolapse) into the vagina and sometimes prolapse past the vaginal opening. More than one pelvic organ can prolapse at the same time. Organs that can be involved in POP include the bladder, the uterus, the rectum, the top of the vagina (vaginal apex) after a hysterectomy, and the bowel.[1] Risk factors for developing POP include increasing age, pregnancy, childbirth, obesity, and genetics.[2] In total, women have an estimated 11 percent lifetime incidence of surgery to repair POP or SUI.[3]

Q: How is transvaginal surgical mesh used in the treatment of POP?

A: Surgical mesh is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material or biologic material. In urogynecologic procedures, transvaginal surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse.[1]

RECENT COMMUNICATIONS FROM THE FDA.

Q: What is a Public Health Notification?

A: A Public Health Notification (PHN) 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 to avoid or reduce the risk.[4]

Q: Has the FDA issued a PHN concerning transvaginal surgical mesh for POP?

A: Yes, on October 20, 2008, the FDA issued a PHN regarding serious complications associated with transvaginal placement (meaning placement through the vagina) of transvaginal surgical mesh to treat POP and stress urinary incontinence (leakage of urine during moments of physical activity, such as coughing, sneezing, laughing, or exercise.[8]) The PHN provided recommendations to physicians including to seek specialized training in transvaginal mesh procedures, to advise their patients about the potential for serious complications associated with these procedures and to be vigilant for potential complications from the mesh.

Q: What has happened since the 2008 PHN?

A: In July 2011, the FDA issued an update to the October 2008 PHN.[8] In this update, the FDA maintained that complications for POP mesh repair are not rare, as previously reported, and questioned the relative effectiveness and safety of transvaginal surgical 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 examined the use of transvaginal surgical mesh products to treat both POP and SUI and also examined how transvaginal surgical mesh used for POP is currently regulated by the FDA. Currently the FDA is considering whether to reclassify transvaginal surgical mesh products from a Class II to a Class III device.

Also, the FDA continues to assess the safety and effectiveness of transvaginal surgical mesh devices. Manufacturers will be required to submit study plans to the FDA that address specific safety and effectiveness concerns related to transvaginal surgical mesh devices for POP and single-incision mini-sling devices for SUI. Data from the studies will enable the FDA to better understand the safety and effectiveness profiles of these devices.[5]

Q: What does reclassification from a Class II to a Class III device mean? Is it the same as a recall?

A: Reclassification is not the same as a recall. A recall is when a product is removed from the market or a correction is made to the product because it is either defective or potentially harmful. The FDA has stated they do not intend to remove the class of transvaginal surgical mesh from the market.

A reclassification is a change of regulatory requirements necessary to place a product on the market. Currently Class II devices receive "clearance" from the FDA demonstrating they are substantially equivalent to a currently marketed device. With this process, there are no new questions posed regarding safety or effectiveness as compared to the currently marketed device. Class III devices receive "approval" from the FDA after manufacturers demonstrate a specific device is safe and effective with data.[6]

Q: Are transvaginal surgical mesh products still cleared by FDA to treat POP?

A: Yes.

TREATMENT OPTIONS FOR POP

Q: Are there any non-surgical options for the treatment of POP?

A: Depending on the severity and the type of prolapse, your physician will discuss the different treatment options you may want to consider. Pelvic floor exercises known as Kegels, and/or the use of a pessary (a removable device that is placed into the vagina) are non-surgical options for the treatment of POP.

Q: When is surgery usually recommended to treat POP? What are examples of surgeries that are performed to treat POP?

A: If non-surgical treatments do not provide sufficient relief of your symptoms and your POP continues to cause pain, functional problems with bowel and bladder functions or if it interferes with your sexual activity, you may choose to discuss surgical options with your doctor. The goal of any type of surgical treatment for POP is to repair the supporting tissue of the prolapsed organ or vaginal wall using either the patient's own tissues or a surgical mesh. Surgeries can be performed either through the abdomen or the vagina. In addition surgery may be performed laparoscopically (repairs are made with instruments inserted through a few small abdominal incisions).

Surgical procedures that use patients' own tissues and ligaments without a transvaginal surgical mesh to treat POP include McCall culdoplasty, uterosacral ligament fixation, and sacrospinous ligament fixation.

Surgical procedures that use surgical mesh to treat POP via an abdominal incision include sacrohysteropexy or sacralcolpopexy.

POP can also be repaired surgically using transvaginal surgical mesh. The transvaginal mesh is inserted through the vagina to reinforce the weakened vaginal wall to repair pelvic organ prolapse.[1]

If a physician determines that the patient's uterus is prolapsing into the vagina, the surgical removal of the uterus (hysterectomy) may be recommended as a treatment option for POP.

Your doctor can provide you with additional details regarding these procedures. Be sure to discuss all of your options with your physician to determine which treatment plan is most appropriate for your specific medical situation.

Q: When is surgical mesh used in POP surgery and, what if it is to be used in my surgery?

A: Depending on your individual situation, your physician may recommend the use of surgical mesh that is placed vaginally or abdominally to treat POP. Please talk to your doctor regarding the appropriate option for you.

Q: Why should I consider transvaginal surgical mesh for my POP repair?

A: You should decide if transvaginal surgical mesh is the right choice for you in consultation with your physician. Your physician should explain all of your options and determine which treatment plan is most appropriate for your specific medical situation.

Q: What are the benefits and the risks of using transvaginal surgical mesh? How likely is it that a repair could be successfully performed without using transvaginal surgical mesh?

A: As with any procedure, some patients will have success while others will not. It is difficult to estimate your specific results. Your physician will explain all of your options and determine which treatment plan is most appropriate for your specific medical situation.

Q: Will my partner be able to feel the transvaginal surgical mesh during sexual intercourse?

A: Your partner should not be able to feel the transvaginal surgical mesh during sexual intercourse. Exposure of the mesh or erosion can occur in some women[7]. Men may experience irritation and pain to the penis during sexual intercourse when the mesh is exposed in mesh erosion.[1]

Q: What if the transvaginal surgical mesh comes through my vaginal wall?

A: Exposure of the mesh or mesh erosion can occur.[7] Treatment of this complication may include an additional surgical procedure.[1] Your physician will decide the best course of treatment for you if mesh erosion should occur. Transvaginal surgical mesh exposure and pain can occur years after initial mesh placement. Therefore, it is important to continue with your annual and other routine check-ups and follow-up care.

Q: What can I expect during recovery?

A: Every patient's recovery experience is unique and you should consult with your physician as to what he or she expects in your case. Your doctor will determine which kind of anesthesia will be used during your surgery, the length of time you may be hospitalized after the surgery, your need for additional medication (for example antibiotics) following the surgery and whether you will have to go home with a catheter (a flexible plastic tube that drains urine from your bladder).

After undergoing POP surgery, you may feel sore. Notify your physician immediately if you have pain with urination, bleeding, painful sexual intercourse, severe pain, defecatory or other problems after surgery. Please consult with your physician on activities to avoid during recovery.

Q: I have a transvaginal surgical mesh implanted for POP. Should I have it removed?

A: As with all important medical decisions, you should consult with your physician. There is no need to take additional action if you are satisfied with your surgery and are not having complications or symptoms.[1] The FDA recommends you continue with your annual and other routine check-ups and follow-up care.[1] You should notify your physician if complications such as persistent vaginal bleeding or discharge, pelvic or groin pain or pain during sex continue after your surgical follow-up appointment.[1]

Q: Which specific complications should I report after transvaginal mesh surgery?

A: Generally, your physician will schedule follow-up visits after your surgery. You should call your physician immediately if you have pain with urination, bleeding, painful sexual intercourse, severe pain, defecatory or other problems after surgery.

Known risks of surgical procedures for the treatment of pelvic organ prolapse include the following: adhesion formation, mild to severe bleeding (hematoma, perforation of vessels), constipation, complete failure of the procedure resulting in recurrent pelvic organ prolapse, dyspareunia, de novo prolapse of an untreated compartment, fecal incontinence, foreign body reaction, infection, graft erosion, graft extrusion, graft migration, nerve damage, obstruction of the ureter, pain, perforation of: bladder, bowel, ureter, urethra, and other pelvic structures, urinary tract infection, vaginal contracture, voiding dysfunction, and wound dehiscence.

Q: What if the transvaginal mesh surgery doesn't improve my POP?

A: If the transvaginal mesh surgery doesn't improve your symptoms, your physician may continue to evaluate you. Improvement in symptoms does not always occur after POP surgery. Your physician may recommend additional treatment, which may include another surgical procedure.

Q: If I have a complication related to the transvaginal surgical mesh, how likely is it that it could be removed and what could be the consequences?

A: Your physician will explain the risks and benefits associated with transvaginal surgical mesh placement and whether or not the mesh should be or can be removed in your specific case. Removal of mesh due to mesh complications may involve multiple surgeries and may impair your quality of life. Complete removal of mesh may not be possible and may not result in complete resolution of complications, including pain.[1]

Q: If a transvaginal surgical mesh is to be used in my surgical POP repair, will my physician have information on the product to be implanted?

A: Yes. Ask your physician to give you a copy of any patient information that he/she may have for the product to be implanted and keep it in your personal surgical file.

Q: What if any additional information should I keep in mind after having transvaginal mesh surgery?

A: After surgery the FDA recommends:[1]

- Continuing with your annual and other routine check-ups and follow-up care.
- Notifying your health care provider if you have complications or symptoms, including persistent vaginal bleeding or discharge, pelvic or groin pain or pain with sex, that last after your follow-up appointment.
- Letting your health care provider know you have surgical mesh, especially if you plan to have another surgery or other medical procedures.
- Talking to your health care provider about any questions you may have.

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1 FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm262435.htm. Accessed January, 10, 2012.

2 Klauschie JL. Cornella JL. Surgical treatment of vaginal vault prolapse: A historic summary and review of outcomes. *Female Pelvic Med Reconstr Sur* 2012;18:8-15

3 Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence *Obstet Gynecol*. Apr 1997;89(4):501-6.

4 FDA. Public Health Notifications. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/default.htm. Accessed January 10, 2012

5 Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse July 2011. http://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf. Accessed 1-11-11

6 Committee on Gynecologic practice. Committee opinion no. 513: vaginal placement of synthetic mesh for pelvic organ prolapse. *Obstet Gynecol* 2011;118(6):1459-64.

7 Bot-Robin V., Lucot JP, Giraudet G, Rubod C, Cosson M. Use of vaginal mesh for pelvic organ prolapse repair : a literature review. *Gynecol Surg*2011Sept DOI 10.1007/s10397-011-0702-8

8 FDA. Public Health Notifications. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm

NOTES:

American Medical Systems, Inc.
U.S. Headquarters
10700 Bren Road West
Minnetonka, MN 55343
U.S.A.
U.S. Toll Free: 800 328 3881
Tel: + 952 930 6000
Fax: + 952 930 6157
www.AmericanMedicalSystems.com

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