Trans-Vaginal Mesh Overview

Historical Overview

Surgical mesh is a synthetic, permanent material made from polypropylene. It is stronger than the body's natural tissue and is frequently used to repair weakened tissue. Surgical mesh has been used since the 1950s to strengthen abdominal hernia repairs. In the 1970s gynecologists began using mesh products to repair pelvic organ prolapse (POP) in procedures done through abdominal incisions. In the 1990s gynecologists began using mesh for surgical treatment of stress urinary incontinence (SUI) and in pelvic organ prolapse (POP) repair procedures done through the vagina.

Over the past several years the FDA has received on-going reports of complications following the use of mesh in gynecologic surgery. This led the FDA to conduct a systematic review of the scientific literature to learn more about the safety and effectiveness of mesh in surgery for POP and SUI. Based on evaluation of adverse event reports and assessment of the scientific literature, the FDA determined that there is not conclusive evidence that using transvaginally placed mesh in POP repairs improves outcomes and it may expose patients to greater risk. They did, however, feel that mesh for SUI and abdominally placed mesh for POP repair do not expose patients to undue risks and that outcomes are improved.

The focus of the FDA's patient safety advisory, the new regulations being considered, and the class-action lawsuits being advertised on television is transvaginal mesh for POP repair, not transabdominal mesh for POP or mesh for SUI.
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm

□ **Stress incontinence:** Surgical repair of SUI can be performed through an abdominal incision, using sutures (Burch urethropexy), or through a vaginal incision, by placing a biologic or synthetic "sling" (e.g., surgical mesh) under the urethra to help prevent urinary loss during physical activity.

We feel that the mesh-specific risks of using a synthetic sling to treat SUI are well justified. TVT and TOT (the SUI procedures we perform using mesh) have a 15-year track record. Their efficacy is equal to or better than the alternatives, the recovery is much quicker, and the overall risks and complication rates are much lower. Mesh for SUI is widely accepted in the gynecologic community and surgeons continue to use it as their procedure of choice. The average reported rate of mesh erosion at one year following SUI surgery with mesh is approximately 2 percent.
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm284109.htm

□ **Mesh placed abdominally/laparoscopically:** Surgical mesh can be placed through the abdomen (transabdominally) in a procedure known as sacral colpopexy. High success rates have been reported over the last 30-40 years and sacral colpopexy has become accepted in the gynecologic community as an effective surgical means to correct POP.

Abdominal POP surgery using mesh (sacral colpopexy) appears to result in lower rates of mesh complications compared to transvaginal POP surgery with mesh, with average vaginal mesh erosion rates of around 4 percent. This erosion rate is even lower if the cervix is left in place as a barrier.

Recently surgeons have begun performing sacral colpopexy via laparoscopy. This has resulted in the same long-term success rates as the abdominal procedure, but with quicker recovery times and even fewer complications.

□ **Transvaginal Mesh:** Based on favorable experiences using mesh for stress incontinence and for sacral colpopexy, surgeons began incorporating mesh into transvaginal surgery. The placement of mesh is intended to increase the longevity of POP repairs. Over time, surgical mesh products for transvaginal POP repair became incorporated into "kits" that included tools to aid in the delivery and insertion of the mesh.

Transvaginally placed mesh is associated with a higher complication rates than traditional vaginal surgery or sacral colpopexy. In particular, these products are associated with serious adverse events, including vaginal mesh erosion (also called exposure, extrusion or protrusion), a complication which can require multiple surgeries to repair and may result in continued sequelae (e.g., pain) even after mesh removal. Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair, particularly for transvaginal apical and posterior repair. While the literature suggests an anatomic benefit to anterior repair with mesh augmentation, this anatomic benefit may not result in superior clinical outcomes, and the associated risk of adverse events should be considered.
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345201.htm

□ **RECOMMENDATIONS FOR PATIENTS**

The FDA recommends that women considering surgery for pelvic organ prolapse do the following:
Before surgery:

- Be aware of the risks associated with transvaginal POP repair.
- Know that having a mesh surgery may increase the risk for needing additional surgery due to mesh-related complications. In some patients, repeat surgery may not resolve complications.
- Ask their surgeons about all POP treatment options, including surgical repair with or without mesh and non-surgical options, and understand why their surgeons may be recommending treatment of POP with mesh.

After surgery:

- Continue with annual and other routine check-ups and follow-up care. Patients do not need to take action if they are satisfied with their surgery and are not having complications or symptoms.
- Notify their health care providers if they develop symptoms, including persistent vaginal bleeding or discharge, pelvic or groin pain or pain with sex, that last after the last follow-up appointment.
- Let their health care providers know if they have surgical mesh, especially if planning to have another related surgery or other medical procedures.
- Ask their surgeons at their next routine check-up if they received mesh for their POP surgery if they do not know if mesh was used.

Dr. Nosti reviewed the contents of this document and provided me with a copy

_____

Patient Signature Date