

AUGS Transvaginal Mesh Informed Consent Toolkit

Patient Background Information

Rationale for Transvaginal Mesh in Surgery for Pelvic Organ Prolapse (POP)

Surgery for POP is very common with approximately one in ten women having such procedures during their lifetime. Many of these women have symptoms that indicate the procedure has not worked the way it should. If POP occurs (or recurs) because there is excessive tension on vaginal tissues and the support they provide, it would then seem logical to reinforce those tissues, so they are able to withstand such tension. Some surgeons choose to consider using mesh to give this reinforcement; for instance, abdominal hernias are often repaired using mesh because doing so reduces the chances that the hernia will come back. Although the data isn't always clear or easy to interpret, it appears that there are situations where the use of mesh reduces the chances of POP coming back (surgical failure). However, these advantages must be weighed against the possibility of complications related to the use of mesh.

One particular type of mesh, polypropylene, has been used both in abdominal hernia repairs and in mid urethral slings, which showed good results. These meshes had been approved for transvaginally placed mid-urethral slings and, subsequently approved for POP procedures. This process did not require controlled clinical trials in human subjects because they were considered "substantially equivalent" in safety and effectiveness to other mesh devices in the market.

Transvaginal Mesh Devices and Kits

As use of transvaginal mesh for POP repair started to gain popularity, a variety of companies, with the help of surgical consultants, then produced a variety of transvaginal "mesh kits" which were marketed to gynecologists and urologists. Most of these kits are intended to replace weakened vaginal tissue with mesh. There is a wide variety of such kits currently available, with different anatomic characteristics, insertion techniques, and fixation devices. There are perceived advantages and disadvantages of the various kits that have been used for marketing purposes. Some surgeons prefer to use mesh using techniques that do not involve the use of these kits.

Surgeon Training and Experience

In POP surgery, as well as surgery in general, there are data that demonstrate that more experience and training of the surgeon correlates with better patient results and outcomes. Some of the gynecologists and urologists who have chosen to use vaginal mesh were not specialists in reconstructive surgery. Instead, they have attended training courses, sometimes less than one day's duration, sponsored by industry, and designed to teach the basic rationale for mesh, the potential complications of the procedures (methods to avoid these and how they might be managed) and how to place it. Often, there is little discussion of the judgment necessary to decide who would or would not benefit from these procedures, or which patients might be more likely to experience a complication. Instruction on which specific defects of pelvic support are or are not corrected by the various procedures are also inadequate or omitted at times and there has been little guidance regarding the importance of post-surgery follow-up of patients.



Advancing Female Pelvic Medicine
and Reconstructive Surgery

For more information, visit the American Urogynecologic Society physician site at www.augs.org/informedconsent or the patient site at www.voicesforpfd.org.

Overview of Risks and Considerations

Although few data currently exist as to who are the best patients for transvaginally placed mesh, ACOG and AUGS recommend that mesh be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures. The approach to the repair of POP should take into account the patient's medical and surgical history, severity of prolapse, and patient preference after education regarding the benefits and risks of the surgical and nonsurgical alternatives.

- **Mesh exposures or erosions** – incidence 2-17%. Most of these problems do not include an infection of the mesh; some mesh exposures respond to observation and/or topical medications, but many require a small operation with anesthesia to treat. Erosions probably occur less frequently when the patient's vaginal wall is healthy and if the procedure is performed correctly by a surgeon with extensive experience in pelvic reconstructive surgery.
- **Bleeding requiring transfusion plus or minus other measures** – incidence reported as high as 2-4% in some trials, less than 1% in others.
- **Infection** – Serious infections are uncommon with modern mesh materials. Minor superficial or incisional infections may be managed with antibiotics; however, infections involving the mesh itself usually require removal of all mesh that is infected and that does not have tissue ingrowth.
- **Injury of bladder or rectum** – reported to occur in 2-4% of these procedures. These can usually be repaired at the time; however, often, the mesh should not be placed after such injuries. When an injury is not recognized or if there is an infection or healing problem, it could lead to serious infection or melding between the bladder and the vagina (fistula).
- **Deaths associated with bleeding or organ injury** have been reported but are very rare, and pertain more to how the mesh was implanted rather than the kind of mesh used.
- **Damage to the nervous system with pain or occasional motor dysfunction** – incidence is rare (may be as high as 2%). When symptoms are associated with a focal area of mesh attachment and are disabling, stitch removal or removal of part of mesh is generally necessary. Removal or revision may not entirely resolve these problems.
- **Chronic pain or pain with intercourse or vaginal exams, etc.** This may be due to stricture of the mesh, bunching up of mesh, fibrosis or to unknown factors which could be related to the either the surgical procedure, an unusual reaction of the patient's tissue to the mesh, or possibly to an action of the mesh itself. The true incidence of these problems is not known, but it is suspected to be low, as they have not been reported in most of the clinical trials. However, many surgeons who receive referrals from other surgeons see quite a few patients with these problems (though it is important to realize these problems can happen from any kind of surgery, including surgery that doesn't use mesh).
- Adverse events requiring surgery are more common with mesh procedures than with non-mesh procedures; mesh exposure or erosion injuries caused by instruments used to insert the mesh are unique to these procedures. Other complications can also occur with non-mesh procedures for POP. ***When surgeons recommend mesh use to individual patients, it is because they believe that the individual's benefit from that procedure probably outweighs the risks.***



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Recent FDA Action

In the summer of 2011, the FDA issued a Statement of Concern regarding the use of transvaginally placed mesh used to correct POP and stress urinary incontinence. The concern was based on a significant increase in reported complications from 2008 to 2010 as compared to the previous 5-year period. This information came from the Manufacturers and Users Device Experience (MAUDE) database, which is known to be under reported by surgeons who are not required by the FDA to report complications. Admittedly, this complication increase could be explained by the large increase in procedures performed (approximately 75,000 in 2010). The FDA also stated that their concern was increased because of some long-term, life-altering complications, such as chronic pain and sexual dysfunction.

The FDA also performed a review of research on these procedures and concluded that there was not enough evidence to support mesh use over existing native tissue repairs. They did admit that more benefit with mesh might be seen if the patient groups were followed for longer periods of time. All of the reviewed research was from one year post-surgery follow-up studies.

The FDA held an investigative public meeting in August 2011, which included presentations from women who had undergone the mesh procedures with good and bad outcomes, various “medical experts,” representatives from professional societies including ACOG, AUA, AUGS, SUFU, and SGS, representatives from the companies that manufacture and sell the mesh products, and other interested parties. Litigation attorneys were present.

An expert panel discussed the issues (pros and cons) and the FDA made its determinations. It was concluded that there was not yet enough data to support that, for these transvaginal mesh procedures for POP, risk was greater than benefit, and because there were many good outcomes and subgroups of patients who apparently had favorable stories to share that most of the mesh products should not be taken off the market. It was decided that the approval process for new mesh products would change and require that the manufacturers conduct and report on additional research for traditional repairs with longer durations of post-surgery follow up and that certain mesh products in existence would need varying degrees of research based on their outcomes. It was also recommended that placement of transvaginal mesh for pelvic organ prolapse should be used cautiously by experienced surgeons with extensive training in pelvic surgery.

On January 4, 2012, the FDA announced that they would be requiring additional research to address specific safety and effectiveness concerns related to surgical mesh devices for POP and single-incision mini-sling devices for stress urinary incontinence. The research collected from these studies will enable the FDA to better understand the safety and effectiveness profiles of these devices. Updates on the research will be available on the [FDA website](#) and made public as it becomes available.