

**Society of Gynecologic Surgeons (SGS) Executive Committee Statement Regarding the FDA Communication:**

**Surgical placement of mesh to repair pelvic organ prolapse imposes risks**

The FDA recently released a Safety Communication regarding transvaginal placement of surgical mesh for pelvic organ prolapse. The leadership of SGS encourages its members to review all of the reports, as well as the thoughtful statements recently circulated by individual SGS members through email.

(Press Release: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm262752.htm>  
 FDA Safety Communication: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>)

SGS members have indicated that they would like a document produced by the Society to help interpret the above communication and provide recommendations to its members. In addition, the FDA documents will likely affect patients who have had mesh procedures for prolapse who may not totally understand the implications of the report and may be calling physicians with questions. To this end, the Executive Committee of SGS, a group generally representative of its members, has developed the following statement.

**Background:**

The main impetus for the current FDA document was a 5-fold increase in the number of reported adverse events (AEs) following the placement of transvaginal mesh for prolapse repair in the time period from 2008 through 2010. There were 1503 AEs reported during this period. Most reported complications were mesh erosions or exposures. Other complications included pain, dyspareunia, bleeding, infection, organ perforation and urinary problems. There were three deaths reported –two related to bowel perforations and one to hemorrhage. This AE data was obtained from the Manufacturer and User Device Experience (MAUDE) database for medical device reports. Reporting AE's in this database is not required of physicians, but is required by the manufacturers of these devices. The FDA listed several factors that could otherwise affect the increase in number of reported AEs including an increase in the use of mesh (a change in the denominator ) and an increase in marketing due to introduction of new meshes. In 2010, there were ~75,000 transvaginal procedures performed using mesh. Of note, a "Statement of Concern" had been issued by the FDA in 2008.

**Summary of FDA conclusions:**

The FDA performed a systematic review of the literature from 1996-2011 and concluded that there was a lack of evidence to support the premise that transvaginal mesh augmented repairs for pelvic organ prolapse were more effective when compared to traditional non-mesh procedures for the apical and posterior compartments. In addition, there are risks associated with mesh repairs that do not exist for non-mesh repairs. Finally, mesh use for the anterior compartment may result in improved anatomic cure, but there was a lack of evidence to support improved subjective outcomes, although admittedly, there is no long-term Level 1 comparative objective or subjective outcome data. These findings, conclusions and recommendations are all in line with the SGS Systematic Review Group's findings published in 2007.<sup>1</sup>

Of note, these findings do not necessarily apply to midurethral slings or the use of synthetic mesh products in abdominal sacral colpopexy, which are supported by level I evidence to be effective for the treatment of stress urinary incontinence and apical prolapse, respectively. However, increasing complications have been reported with continued longer-term surveillance of these two procedures and the FDA notes that it is continuing to review these outcomes and associated complications.

**The FDA Summary Statements on AEs seen with transvaginal placement of mesh for prolapse repair are listed below :**

- 1) Mesh procedures are subject to unique complications that are not seen with non-mesh procedures
- 2) AEs associated with transvaginally placed mesh can be life- altering for some women. Sequelae (e.g., pain) may continue despite mesh removal.
- 3) Mesh- associated complications are not rare. The most common mesh-related complication is vaginal mesh erosion. Based on data from 110 studies including 11,785 women, approximately 10% of women undergoing transvaginal POP repair with mesh experience mesh erosions within 12 months of surgery.
- 4) More than one half of the women with mesh erosions require a second excisional procedure in the operating room. Some require two to three procedures.
- 5) Mesh contractions, causing vaginal shortening, tightening, and/or vaginal pain in association with vaginal mesh placement is increasingly reported in the literature.
- 6) New onset SUI has been reported to occur more frequently following mesh augmented vaginal repair compared to traditional repair without mesh.
- 7) Transvaginal mesh procedures to correct apical prolapse are associated with a higher rate of complication requiring reoperation, and reoperation for any reason, compared to traditional vaginal surgery or sacral colpopexy.
- 8) Abdominal POP surgery using mesh (sacral colpopexy) appears to result in lower rates of mesh complications compared to transvaginal POP surgery with mesh, with the median vaginal mesh erosion rate reported at 4 percent within 23 months of surgery.

Comments: The complications unique to mesh and its placement are erosions, exposures, and trocar injuries. Mesh exposure or erosion (which are often used interchangeably) are by far the most frequently occurring complication and explain the increased reoperation rates. While occasionally the management of erosion/exposure can be difficult, most are easily managed, especially by experienced surgeons. The potentially life altering complications (chronic pain, dyspareunia, vaginal shortening, stricture formation, and agglutination) are relatively rare based on reports in clinical trials, but may be more common in overall practice. Many of the AEs associated with transvaginal mesh use may be due to lack of surgical expertise, individual patient factors, or, possibly, inherent properties of the mesh. Some of these AEs, including pain, agglutination and strictures, can also occur with native tissue repairs.

In general, the FDA's findings regarding AEs are also consistent with the SGS Systematic Review Group's review on mesh adverse events.<sup>2</sup>

### Summary

In summary, SGS is in agreement with the interpretations and recommendations made in the FDA Safety Communication by Dr Maisel and colleagues, which are consistent with our own SRG's findings and practice recommendations. The fact that several clinical trials and individual surgeon observations revealed that some traditional non-mesh vaginal repairs had unacceptably high failure rates and the fact that low density, monofilament polypropylene meshes (which were approved by the FDA (510) K process for transvaginal procedures) exhibited relatively low AE rates when used in hernia repairs, sacral colpopexies and midurethral slings have led to increased development and use of transvaginal mesh procedures. These procedures have yielded mixed results which may be highly surgeon-dependent. The current literature indicates that the use of mesh placement in the transvaginal spaces should not be widespread. Ideally data from past and future high quality long term clinical trials, designed to critically evaluate the benefits and safety of these new technologies, will guide the decision making process. The general consensus is that this reservation should not apply to midurethral sling procedures or sacral colpopexies utilizing the same mesh materials, but further longer term evaluations of all of these procedures is important. For now, thoughtful, discriminant use of transvaginal mesh to augment vaginal defects should be performed by trained surgeons with experience in complex reconstructive surgery, and

only on patients who are perceived to have an unacceptable risk of clinical failure when other procedures are performed.

We are supportive of extensive primary and secondary education of surgeons. This should include credible and comprehensive instruction of surgical principles, as well as the various procedure techniques, indications, contraindications, and the management of adverse events. We should all follow outcomes when we employ new procedures, and should feel comfortable about benefit versus risk before employing them. It is important that patients are informed of the risks and benefits of any surgical procedure as well as the specific potential adverse events associated with transvaginal mesh use, including outcomes that may still be unclear and require further investigation. Alternative treatments should be explained.

As expressed in our Mission Statement we as a Society will continue to strive to promote the highest standards for gynecologic surgical care for women and that advances in surgical methodologies are introduced in a safe, effective and ethical manner. SGS will ensure that our members will be represented at the upcoming FDA panel meeting in September regarding these issues.

1. Sung VW, Rogers RG, Schaffer JI, et al. Graft use in transvaginal pelvic organ prolapse repair: a systematic review. *Obstet Gynecol* 2008;112:1131-42.

2. Abed H, Rahn DD, Lowenstein L et al. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. *Int Urogynecol J Pelvic Floor Dysfunct* 2011; 22(7):789-98.