

OBSTETRICS & GYNECOLOGY DEVICES PANEL

September 8-9, 2011

Panel Discussion Questions

Day-1 *Surgical Mesh for Repair of Pelvic Organ Prolapse (POP)*

Vaginal Placement of Surgical Mesh for POP Repair

Medical devices are classified (i.e., Class I, Class II, and Class III) according to their risk and the level of regulatory control necessary to provide adequate assurance of their safety and effectiveness. The following questions are intended to assist the FDA in identifying the safety or effectiveness concerns associated with vaginal mesh used for POP repair and determining whether the evidence shows that the clinical benefits outweigh the risks.

1. Risk-Benefit of Vaginal Mesh for POP repair

- a. *Safety of Vaginal Mesh used for POP repair.* Based on a review of the published literature and an evaluation of its Manufacturer and User Facility Device Experience (MAUDE) database, the FDA has identified numerous peri-operative and long-term risks associated with vaginal mesh for POP repair.

Peri-Operative Risks

- Organ perforation
- Bleeding (including hemorrhage/hematoma)

Long Term Risks

- *Mesh exposure into vagina.* Clinical sequelae include pelvic pain, infection, dyspareunia (painful sex for patient or partner), vaginal bleeding, vaginal discharge, and the need for additional corrective surgeries.
- *Mesh erosion into the bladder or rectum.* Clinical sequelae include pelvic pain, infection, dyspareunia, fistula formation and the need for additional corrective surgeries (possibly including suprapubic catheter, diverting colostomy).
- *Other risks that can occur without mesh erosion.* These risks include pelvic pain, infection, dyspareunia, urinary problems, vaginal scarring/shrinkage, recurrent prolapse, neuro-muscular problems.

Please comment on the accuracy of this list and whether it captures the most serious risks associated with vaginal mesh used for POP repair. Discuss the incidence and severity of these adverse events. Please discuss if there is reasonable assurance of the safety of vaginal mesh for POP repair.

In answering this question, please consider the following factors:

- pelvic compartment for repair, i.e., anterior, posterior, apical, or multi-compartment
- previous and concomitant surgeries
- patient factors
- surgical technique and expertise
- limited patient follow-up, typically no more than 6 months to a year

- b. *Effectiveness of vaginal mesh used for POP repair.* The FDA believes that the available scientific evidence does not demonstrate that vaginal mesh used for POP repair provides clinical benefit compared to surgical repair of POP without using mesh. *In light of the scientific evidence, please discuss if there is a reasonable assurance of effectiveness for vaginal mesh for POP repair.*

In answering this question, please consider the following factors:

- pelvic compartment for repair, i.e., anterior, posterior, apical, or multi-compartment
 - clinical relevance of anatomic outcomes (e.g., POP-Q score, or prolapse above and below the hymen) in relation to patient satisfaction outcomes (e.g., QoL instrument)
 - whether use in certain sub-populations (e.g., higher stage prolapse or recurrent prolapse) changes the clinical benefit profile
 - duration of patient follow up
 - synthetic v. non-synthetic
 - other factors?
- c. Based on your assessment of the safety and effectiveness of these devices, please discuss whether the evidence shows that the clinical benefits of using vaginal mesh for POP repair outweigh the risks associated with its use.

2. Reclassification of Vaginal Mesh for POP Repair

- a. Given what is known about the safety and effectiveness of vaginal mesh for POP repair, should clinical studies be required for premarket evaluation? If yes, please describe the appropriate study design, including patient selection/exclusion, outcome measures, follow-up duration, and – especially – what type of control arm, if any, is needed.
- b. Please discuss whether one or more of the Class II special controls listed below would provide reasonable assurance of the safety and effectiveness of vaginal mesh for POP repair.
- performance standards
 - postmarket surveillance
 - patient registries
 - guidelines (*including guidelines for submitting clinical data, labeling*)

NOTE: If the panel recommends a premarket clinical study in the context of a special controls guideline, this study must conform to the 510(k) regulatory standard of *substantial equivalence*.

- c. Please discuss whether vaginal mesh for POP repair should remain in Class II (Special Controls) or be reclassified into Class III (Premarket Approval).

3. Need for Postmarket Studies

The FDA is concerned that the safety and effectiveness of currently marketed vaginal mesh for POP repair are not adequately understood. The FDA believes that manufacturers of such products should conduct 522 postmarket surveillance studies of devices on the market to address these outstanding concerns.

Note: *Mandating postmarket surveillance studies could begin in parallel with reclassification from Class II to Class III, but could still be implemented if these devices remain Class II. If reclassification occurs, the FDA believes that the postmarket surveillance studies could be designed to satisfy the requirements of future PMAs.*

Please state if you agree with the FDA's assessment. If you agree, please discuss the type of clinical study that should be required for vaginal mesh for POP repair that is already on the market. Please consider the following (below):

- a. How should the study address important co-factors such as, whether this is a primary or recurrent prolapse, the stage of prolapse, concomitant surgeries, the anatomic compartment repaired, surgeon experience, other patient selection criteria?
- b. What are the most important outcome measures to evaluate, primary and secondary?
- c. What is the appropriate duration for patient follow-up?
- d. Should these studies have a control arm, and if so, what are the optimal comparators (e.g., mesh-to-mesh, mesh-to-no mesh, vaginal-to-vaginal, vaginal-to-abdominal, etc.)? If a control arm is needed, should the study be randomized?

Abdominal Placement of Surgical Mesh for POP Repair

4. The FDA believes that the safety and effectiveness of *abdominal* placement of surgical mesh for POP repair, e.g., sacrocolpopexy for apical prolapse, is well-established. Please state if you agree with the FDA's assessment. If not, please discuss the following:
 - a. Should future premarket submissions for mesh products indicated for abdominal sacrocolpopexy be supported with clinical performance data? If yes, please discuss the type of clinical performance data that should be requested. Please consider patient selection/exclusion (e.g., concomitant surgeries), outcome measures, follow-up duration, and controls.
 - b. Should manufacturers of currently marketed mesh products indicated for sacrocolpopexy conduct 522 postmarket surveillance studies? If yes, please discuss the type of clinical study that should be conducted. Please consider patient selection/exclusion (e.g., concomitant surgeries), outcome measures, follow-up duration, and controls.