Surgical Mesh for Transvaginal Repair of Pelvic Organ Prolapse in the Anterior Vaginal Compartment

Obstetrics and Gynecology Devices Panel

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Panel Scope

- General issues panel meeting
- Device under consideration:
  - Surgical mesh placed transvaginally in the anterior vaginal compartment to treat pelvic organ prolapse (POP)
- Devices outside the scope of today's meeting:
  - Surgical mesh placed transvaginally in the posterior vaginal compartment to treat POP
  - Surgical mesh placed abdominally to treat POP
  - Mesh for stress urinary incontinence

2011 Panel Meeting

- September 8, 2011 Panel Meeting
  - Discussed the safety and effectiveness of mesh for POP
- 2011 Panel Recommendations
  - Issue postmarket surveillance (522) study orders
  - Reclassify transvaginal POP mesh to higher risk category (class II to III)

522 Orders

- FDA issued 131 separate 522 orders to 34 manufacturers starting in 2012
- 522 orders requested:
  - Collection of safety and effectiveness outcomes
  - Follow up at 12, 24, and 36 months
  - Comparison of mesh to native tissue repair
- 522 study could be designed to support premarket approval (PMA) application if FDA reclassified surgical mesh for transvaginal repair of POP

Reclassification to Class III

- Class II devices
  - 510(k) pathway
  - Demonstration of substantial equivalence
- Class III devices
  - Premarket approval (PMA) pathway
  - Independent demonstration of safety and effectiveness
  - Establish favorable benefit/risk
- Extensive regulatory process
  - Proposed (2014) ➡ Final (2016) ➡ PMAs required (2018)

Currently Marketed Devices

- Three devices currently on the market
  - Boston Scientific Uphold LITE
  - Boston Scientific Xenform
  - Coloplast Restorelle DirectFix Anterior
- All indicated for anterior/apical compartment repair
- 522 studies for marketed devices currently ongoing

Panel Recommendations

- Panel recommendations apply to:
  - 522 studies for currently marketed devices
  - Future PMA applications for devices of this type
- FDA will use Panel's recommendations to:
  - Evaluate the safety and effectiveness of individual devices placed in the anterior/apical compartment
  - Determine if the benefit/risk profile of each device supports premarket approval

Panel Questions

1. Should mesh be more effective than native tissue repair and at what timepoint?
2. Should both anatomic and subjective outcomes be used to assess effectiveness?
3. What are the types of adverse events that should be used to evaluate safety and how should those adverse events be assessed?
4. Should the adverse event profile of mesh be similar to native tissue repair and at what timepoint?
5. What are the effect of concomitant procedures and a patient's surgical/medical history on safety and effectiveness outcomes?
6. What factors determine whether a patient undergoes a mesh versus a native tissue repair?
7. What is the effect of surgeon experience on safety and effectiveness outcomes?
8. How should FDA assess the overall benefit/risk of surgical mesh placed transvaginally in the anterior vaginal compartment to treat POP?

Panel Charge

- FDA is not asking the Panel to:
  - Determine safety and effectiveness of currently marketed devices
  - Determine safety and effectiveness of surgical mesh placed in the anterior compartment as a device type
  - Whether surgical mesh placed in the anterior compartment should continue to be on the market
- FDA is asking the Panel how to evaluate surgical mesh placed in the anterior compartment for prolapse repair
- FDA requests the Panel focus their discussion on the general population of women who are candidates for transvaginal surgical repair of POP

Data Presented to Panel

- Not intended to be representative of any specific device or device type
- Provides context around how safety and effectiveness are typically assessed
- Provides key considerations that affect safety and effectiveness outcomes
- Individual device characteristics can affect safety and effectiveness
  - Considered as part of FDA review of individual device
  - Class III PMA devices ⇨ Each device must independently demonstrate safety and effectiveness

Stakeholder Perspectives

- Perspectives from all stakeholders
  - Patients
  - Physicians
  - Industry
  - Professional societies
  - FDA
- Panel should consider all stakeholders when making recommendations

Agenda

- Open public hearing
- FDA presentation
- Industry presentations
- Professional society presentations
- Panel deliberations
- Panel questions

FDA Team

- Michael Bailey, Ph.D.
- Kelly Colden, M.D., MPH
- Jacqueline Cunkelman, M.D., MPH
- Ann Ferriter
- Benjamin Fisher, Ph.D.
- JoAnn Fujikawa, RN
- Monica Garcia, Ph.D.
- Angie Lee, M.D.
- Sherry Liu
- Cheryl Mackey
- Ellen Olson, Ph.D.
- Allison O'Neill, Ph.D.
- Gunja Pathak, Ph.D.
- Yanping Qu, Ph.D.
- Catherine Ricketts, RN
- Jason Roberts, Ph.D.
- Charles Viviano, M.D., Ph.D.
- Evella Washington
- Joyce Whang, Ph.D.

Thank You

- Patients
- Physicians
- Industry
- Professional societies
- Panel members

For your time, expertise, and sharing your experience today