



# Developing of the Pelvic Floor Disorder Registry (PFDR)

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# Outline

- Overview of Pelvic Floor Disorders (PFD)
- Treatment options
- Concern with transvaginal mesh repair
- FDA actions
- Development of PFDR

# Female Pelvic Floor Disorders

- Incontinence (urinary or fecal)
- **Pelvic Organ Prolapse (POP)**
  - [Prolapse animation](#)
- Defecatory dysfunction
- Voiding dysfunction

# PFD prevalence

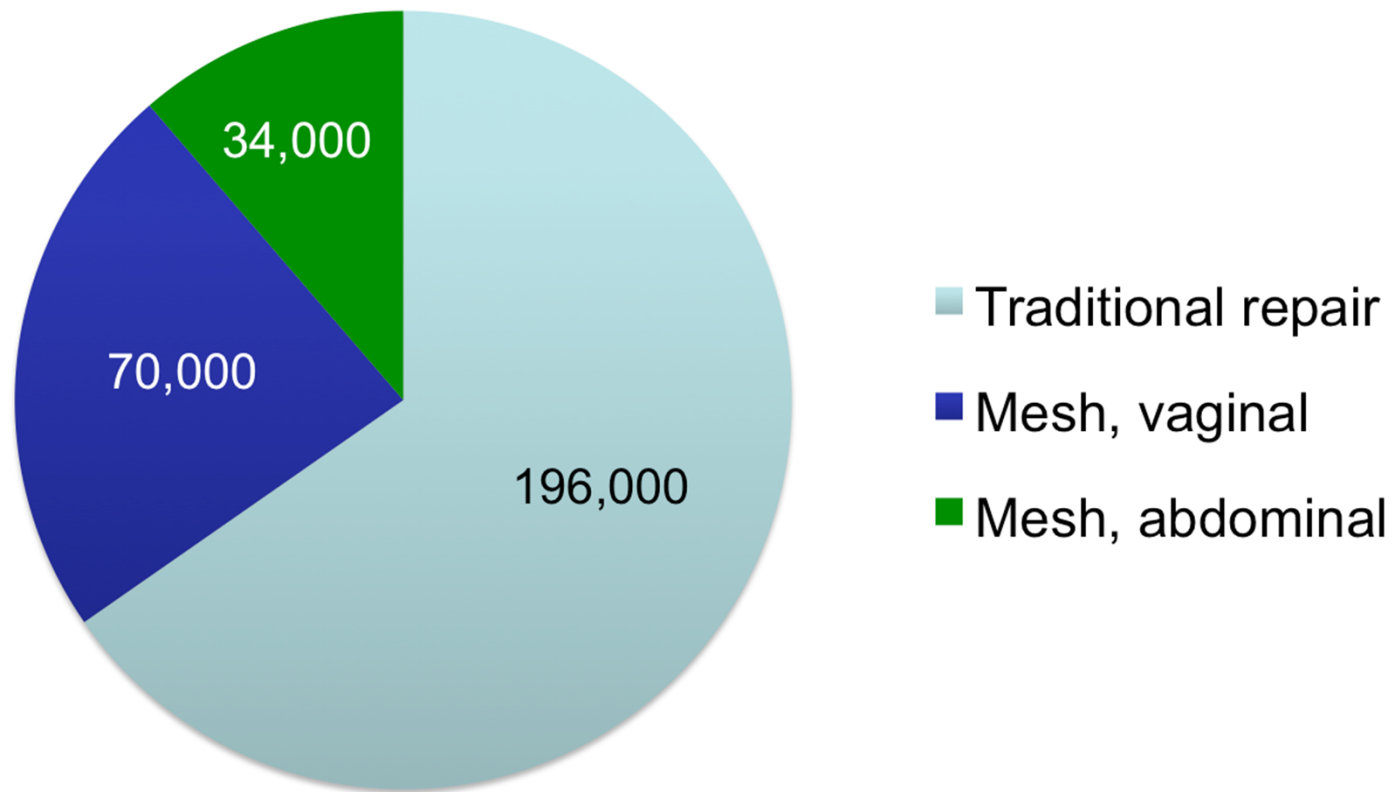
- Urinary incontinence (UI)- 27.6% (4.8-58.4%) of women have from of UI, with more than half comprised of SUI
- PFD- 1/4 women over the age of 60 have PFD, among women presenting for routine gynecology care 43%-76% have loss vaginal support, with 3%-6% having descent of organ beyond the hymen <sup>1-3</sup>
- 1/ 9 women will undergo surgery for UI and/or POP by age 80 <sup>4</sup>

# Treatment Options for POP

- Non Surgical
  - Pelvic Floor Exercises
  - Pessary
- Surgical
  - Done either through the vagina (transvaginal) or abdomen
  - Can be done using sutures (traditional repair) or with addition of surgical mesh
  - Surgical mesh can be a) non-absorbable synthetic b) absorbable synthetic c) biologic or d) composite

# POP Repair Surgeries - US Market 2010\*

*300,000 women<sup>5</sup>*



# Transvaginal Mesh: Timeline

	<b>Perigee (AMS)</b>	<b>Prolift (Ethicon)</b>	<b>Elevate (AMS)</b>	<b>UpHold (Bost Sci)</b>
Introduced in US	2004	2005	2008	2008
First Study	2004	2006	Feb 2012	May 2012

# Timeline of FDA concern

- July of 2011 an analysis of adverse events reported to the FDA and complications described in scientific literature, prompted FDA to release a Safety Communication to medical community and patients that:
  1. serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**; and
  2. it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair
- September 2011 FDA held Ob/Gyn Medical Device Panel for recommendations on the safety and effectiveness of surgical mesh used for POP





American  
Urogynecologic  
Society

Advancing Female Pelvic Medicine  
and Reconstructive Surgery

**The American College of Obstetricians and Gynecologists**  
*Women's Health Care Physicians*

# COMMITTEE OPINION

Number 513 • December 2011

## **Committee on Gynecologic Practice**

*This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.*

## **Vaginal Placement of Synthetic Mesh for Pelvic Organ Prolapse**

- Surgeons performing transvaginal placement of mesh for POP should undergo **training specific to each device and have experience with reconstructive surgical procedures** and a thorough understanding of pelvic anatomy.
- Transvaginal placement of mesh for POP should be **reserved for high-risk individuals in whom the benefits of mesh placement may justify the risk**, such as individuals with recurrent prolapse (particularly of the anterior compartment) or with medical co-morbidities that precluded more invasive and lengthier open and endoscopic procedures.
- ACOG & AUGS strongly support continued audit and review of outcomes, as well as the **development of a registry for surveillance for all current and future vaginal mesh implants.**

# Outcomes of Panel Meeting

- Jan. 2012 FDA ordered postmarket surveillance studies “522 studies”
  - Over 95 “522 studies” issued to over 34 manufactures of mesh for POP
  - Per the Panel’s discussion, assessment of adverse event reports submitted to the FDA, and evaluation of the published literature, the FDA is considering the recommendation that surgical mesh used for transvaginal repair POP be reclassified from Class II (low- to moderate-risk devices) to Class III (high-risk devices).

# 522 Summary – January 2012

- Data through 36 months post-implantation
  - Adverse events
  - Revision/re-surgery
  - Quality of Life
  - Effectiveness
  - 6, 12, 18, 24, 36 months
- Rates of events, by compartment
- Non-inferiority vs. similar surgeries without mesh
  - “native tissue”
- Comparison to no surgical intervention (QOL)

# PFDR- Development

- Collaborative effort to create national registry
- AUGS registry leadership and experts on content, research design, and implementation
- Industry partners, FDA, National Institute for Childhood Health and Human Development (NICHD), ACOG, Women's Health Registry Alliance, PFDRN Advisory Panel, Society for Urodynamics (SUFU), AUA

# Primary Objectives

- Evaluate the effectiveness, quality of life and safety associated with surgical options (transvaginal/transabdominal native tissue repair, transvaginal mesh repair and sacrocolpopexy) for POP
- Assess the effectiveness and quality of life associated with non-surgical management (pessary) for POP
- Provide a framework for clinical studies to be conducted within the registry, including industry-sponsored studies required to fulfill the FDA's request for postmarketing surveillance for transvaginal mesh for POP
- Allow healthcare providers to track surgeon volume, patient outcomes and quality measures and fulfill upcoming Centers for Medicaid and Medicare Services (CMS), Physician Quality and Reporting Systems (PQRS) and maintenance of certification requirements

# Levels of Participation-Overview

	LEVEL 1	LEVEL 2	LEVEL 3
Goal	Universal minimum data set	Expanded dataset	Specific study data collection
Description	Effectiveness, quality of life and safety	Level 1 plus condition specific QOL, POPQ, surgical details, etc	Level 1&2 plus Allows unique cohort studies (522 compliant)
Attributes	Minimal patient and provider burden	More detailed provider (i.e. POPQ) and patient data entry	Allows for additional study specific outcomes
Research questions	Epidemiologic Descriptive	Provides comparison group for level 3 & more detailed outcome comparison	Used for sponsored studies (i.e. NIH, post marketing surveillance, etc). Restricted access.

# Data Collection and Reporting

- Data will be collected after informed consent is obtained from levels 2 and 3
- Post intervention assessment will include patient-reported outcome assessment (PRO) via registry PRO system (ePRO)
- Level 1 and Level 2 data will be presented in aggregate giving efficacy and safety data for pre specified research questions
- Level 3 is industry specific and reported by individual companies to the FDA

# Registry Governance

- Registry Steering Committee (RSC)- AUGS appointed committee responsible for developing and implementing strategic goals for registry, and appointing a scientific sub-committee, that will approve use of data for research and publication



# Challenges

- Collaboration between multiple Industry partners
  - Outcomes
  - Data collection and how collected
  - Financial considerations
  - Data access
- Time
  - Multiple protocols having to be harmonized and done in timely fashion
- Encouraging surgeon participation
  - 522 studies
  - Quality measures, PQRS
  - Internal audit for credentialing
  - Maintenance of Certification for subspecialty
- Long-term patient follow-up
  - ePRO
- Multiple devices, multiple indications
- Generalist vs. Specialist

# Conclusion

- Will have a much needed national registry that will provide evidence for best medical practices for advancement of public health with respect to treatment modalities available for PFDs and specifically POP
- Resources:
  - <http://www.augs.org/p/bl/et/blogaid=59>
  - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm>

# References

1. Nygaard, I., Barber, M. D., Burgio, K. L., Kenton, K., Meikle, S., Schaffer, J. et al.: Prevalence of symptomatic pelvic floor disorders in US women
2. Ellerkmann, R. M., Cundiff, G. W., Melick, C. F., Nihira, M. A., Leffler, K., and Brent, A. E.: Correlation of symptoms with location and severity of pelvic organ prolapse. *Am J Obstet Gynecol*, 185: 1332, 2001
3. Swift, S. E.: The distribution of pelvic organ support in a population of female subjects seen for routine gynecologic health care. *Am J Obstet Gynecol*, 183: 277, 2000
4. Olsen AL et. al. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstet Gynecol* 1997; 89 (4); 501-6
5. Shah AD, Kohli N, Rajan SS, Hoyte L. The age distribution, rates, and types of surgery for pelvic organ prolapse in the U.S. *Int Urogynecol J Pelvic Floor Dysfunct* 2008;19:421-428