SESSION C4

Mesh Use in Surgery for Pelvic Organ Prolapse and Stress Urinary Incontinence
Jeffrey L. Clemons, MD

Session Description:

The use of mesh slings for stress incontinence and mesh implants for pelvic prolapse (abdominally placed versus vaginally placed) will be discussed, as well as the 2011 FDA warning about vaginally placed mesh for prolapse.

Learning Objectives:

Following my presentation, participants will be able to:
1. Describe the types of mesh slings for stress incontinence.
2. Discuss the pros and cons of abdominally placed mesh versus vaginally placed mesh for pelvic prolapse.
3. Describe the key points of the 2011 FDA warning on vaginally placed mesh.
Mesh Use in Surgery for Stress Urinary Incontinence & Pelvic Organ Prolapse

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Definitions

• SUI = Stress Urinary Incontinence
  ▪ Loss of urine associated with exertion
  ▪ Urethral weakness

• POP = Pelvic Organ Prolapse
  ▪ Hernia of uterus, bladder, rectum, or small bowel into the vagina
  ▪ Loss of pelvic support

Objectives:
Mesh for SUI & POP

• Describe the type of mesh used in SUI & POP
• Describe the risks and benefits of Abdominally v. Vaginally placed mesh in POP surgery, including unique morbidity from mesh.
• Discuss the 2011 FDA Warning on use of Vaginally placed mesh for POP
• Describe management strategies for mesh complications.
• List current recommendations for use of mesh

Definition:
Urinary Incontinence

• Involuntary loss of urine.
• Perceived as a problem by patient

Cystocele?
Rectocele?
Vault Prolapse?
Vaginal Vault Prolapse
Stage IV

POP-Q Staging of Prolapse
The leading edge of prolapse is ...

- Stage I
  - More than 1 cm ABOVE Hymen
- Stage II
  - -1 cm ≤ Hymen ≤ +1 cm
  - -1 cm: usually No symptoms
  - +1 cm: usually symptoms exist
- Stage III
  - More than 1 cm BELOW Hymen
- Stage IV
  - Complete prolapse -or-
  - Prolapse within 2 cm of TVL

“Vaginal Mesh” Has Many Interpretations

- Mesh slings for SUI
  - TVT slings, TOT slings
- Abdominally or Laparoscopically placed mesh implants for POP
  - Sacral colpopexy
- Vaginally placed Mesh implants for POP
  - Trans Vaginal Mesh “kits” (TVM)
  - for Cystocele, Rectocele, Uterine prolapse

2011 FDA Warning on Vaginally Placed Mesh for POP

- Complications are Not Rare
- Most common complications:
  - mesh erosion, pain, infection, dyspareunia (female or male pain), vaginal bleeding, organ perforation, urinary & bowel problems
- FDA Warning did Not apply to:
  - Slings for SUI
  - Abdominally placed mesh for POP

Aftermath of 2011 FDA Warning on TransVaginal Mesh for POP

- Multiple legal & lawsuit ads on TV & internet
- Sep 2011:
  - FDA Ob-Gyn Advisory Panel meeting, rec that all Trans Vaginal Mesh (TVM) products be reclassified as Class III (needs pre-market approval)
- Jan 2012:
  - FDA required 3-yr studies on all TVM products
  - Many TVM products withdrawn:
    - Prolift, Apogee, Perigee, Pinnacle, Avaulta, Prosima
- Still available: Elevate, Uphold

POP & SUI
Epidemilogy
POP & SUI: Epidemiology

- Annually, in US, surgery for:
  - POP = 200,000 women
  - SUI = 100,000 women
    - (Boyles, 2003, Oliphant, 2010)
- 11-12% Lifetime risk of surgery by age 80, for POP and/or SUI
  - (Olsen, 1997 & Fialkow, 2008)
- 30% of those undergoing surgery had Recurrent POP and/or SUI
  - (Olsen, 1997)

Risk Factors for POP & SUI

- Childbirth
- Aging & Atrophy
  - Atrophy of pelvic floor muscles & endopelvic fascia
- Poor Collagen
  - POP with more Type III collagen (weaker)
- Prior prolapse surgery
- Obesity
- Chronically increased intra-abdominal pressure
  - Constipation, Chronic cough, Heavy Lifting
- Hysterectomy
- Menopause / Estrogen deficiency
- Family History of Prolapse
Levator Ani Atrophy

10 control women “V”

10 POP women “U”

L Hoyte, AJOG, 2001

- Women with POP (v. Controls)
  - Increased type III collagen
  - Increased MMP-2 & MMP-9 activity
- Weaker Collagen & Elastin in POP

Moalli, Obstet Gynecol 2005;106:953-962
Ewies, H Repro 2003;18:2189-195
Gabriel, Int Urogyn J 2006;17:478-482
Phillips, BJOG 2006;113:39-46

Risk Factors for Recurrent POP after Vaginal Surgery

- Risk Factors for Failure:
  - Age < 60 yr at surgery
  - Stage 3-4 POP
  - Obesity
  - ? Occupational Straining?

Mesh for POP & SUI: How did we get here?

SUI
- Kelly plications (1913)
- Fascia slings (1908)
- MMK (1949)
- Burch (1961)

POF
- A&P repairs (1910)
- McCall culdoplasty (1957)
- Utero-Sacral Lig. Susp.
- Sacrospinous Lig. Susp. & Iliococcygeus Muscle Susp (1970)
- open Sacral Colpocoxpy (Mesh) (1970)

Mesh for POP & SUI: How did we get here?

- Slings: 1990’s – 2000’s:
  - Fascia (autograft), cadaver (allograft),
    various meshes (mersilene, marlex, gore-tex)
  - ProteGen mesh sling – SUI
    - Introduced in early 90’s, recalled late 90’s
  - Mid Urethral Slings introduced 1999-2000
    - TVT sling (excellent, copied by many)
    - IVS Tunneler & OB Tape slings (poor, withdrawn)
  - TOT slings introduced 2003-04
    - Mostly equivalent to TVT sling

Mesh for POP & SUI: How did we get here?

- 2004: Vaginal mesh kits introduced, based on…
  - Success of polypropylene mesh slings (TVT and TOT)
    - Cure rates of 80-90%
  - 510-K Approval process - no need for outcome data
  - High “Objective” failure rates for POP surgery
    - Sutured repair & biologic grafts, failure rates of 15-45%
  - POP-Q exam (1997)
    - Failure = stage 2 POP: -1 / 0 / +1, Is -1 cm really a failure?
  - Need for minimally invasive option
    - Robotic SC did not start until around 2007
    - Decrease risk of recurrence 50-75% with mesh
However, Vaginal Mesh placed Vaginally is NOT the same as Vaginal Mesh placed Abdominally or Abdominal Wall Mesh

<table>
<thead>
<tr>
<th>Issues in Vaginally Placed Mesh for POP</th>
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<tbody>
<tr>
<td>• Vagina: clean-contaminated surgery</td>
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<tr>
<td>• Vaginal Mucosa</td>
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<tr>
<td>▪ Thin tissue layer</td>
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<tr>
<td>▪ Vaginal incision does not always heal over mesh</td>
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<tr>
<td>• Larger piece of mesh next to vagina</td>
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<tr>
<td>▪ 20 - 40 cm² for POP repair v. 2 cm² for sling</td>
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<tr>
<td>• Attachment sites for Vaginal mesh</td>
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<tr>
<td>▪ Muscle instead of bone</td>
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<tr>
<td>▪ Mesh to muscle can cause pain</td>
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<tr>
<td>▪ difficult to access, with trocars</td>
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<td>▪ hemorrhage &amp; visceral injury</td>
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<table>
<thead>
<tr>
<th>Expert Opinions, 2002-08</th>
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<tbody>
<tr>
<td>• Cochrane '02:</td>
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<tr>
<td>▪ “use of synthetic mesh might reduce the risk of prolapse recurrence”</td>
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<td>• Fenner '06:</td>
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<tr>
<td>▪ “the indiscriminate use of grafts in POP is inappropriate at this time”</td>
</tr>
<tr>
<td>▪ “limited to carefully selected patients”</td>
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<tr>
<td>• Baessler '06:</td>
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<tr>
<td>▪ “Until data on the safety and efficacy of synthetic mesh in POP emerge, its routine use outside trials cannot be recommended”</td>
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<tr>
<td>• 2005 IUGA grafts roundtable, '06:</td>
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<tr>
<td>▪ “With few exceptions the current expansion of graft utilization in POP is not a product of evidence-based medicine”</td>
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<tr>
<td>• Graft Use - SGS Systematic Review Group, ’08</td>
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<tr>
<td>▪ “Overall, the existing evidence is limited to guide decisions regarding whether to use graft materials in transvaginal prolapse surgery”</td>
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<tr>
<td>• Clinical Guidelines - SGS Systematic Review Group, ’08</td>
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<tr>
<td>▪ “Based on the overall low quality of evidence, only weak recommendations could be provided”</td>
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<td>• Feiner ’08: Efficacy and safety of transvaginal mesh kits</td>
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<td>▪ “an increasing # of women require surgical intervention for mesh-related complications”</td>
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<table>
<thead>
<tr>
<th>Vaginal Mesh: Where are we now?</th>
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<tbody>
<tr>
<td>• 2008: FDA Warning on Vaginal Mesh</td>
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<tr>
<td>▪ MAUDE Database - “over 1000” complications</td>
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<tr>
<td>▪ Recommendations to physicians on training and informed consent</td>
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<tr>
<td>• 2011: FDA Update Warning on Vaginal Mesh</td>
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<tr>
<td>▪ 2,874 more complications reported</td>
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<td>▪ Systematic reviews on Transvaginally placed Mesh for POP repair show limited benefit</td>
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<tr>
<td>▪ TVM products reclassified as Class III (game changer)</td>
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<tr>
<td>• All TVM companies must conduct 3-year studies</td>
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<td>• Need to show efficacy and safety</td>
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<table>
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<th>Mesh Complications</th>
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<tr>
<td>• 2% - Slings</td>
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<tr>
<td>▪ 1% mesh erosion, 1% too tight</td>
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<tr>
<td>• 3% - Abdominally placed Vaginal mesh</td>
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<tr>
<td>▪ Sacral Colpopexy, robotic, laparoscopic</td>
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<tr>
<td>▪ 3% Mesh erosion</td>
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<tr>
<td>• 20-30% - Vaginally placed Vaginal mesh</td>
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<tr>
<td>▪ Mesh “Kits” – Class Action Lawsuits</td>
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<tr>
<td>▪ 10-15% mesh erosion</td>
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<td>▪ 10-15% pain, dyspareunia, bowel or bladder dysfunction</td>
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Revisiting POP Surgery Outcomes

- **Ant.Repair, RCT of 3 techniques** (Weber, AJOG, 2001)
  - Cure: stage 0 / 1 (failure = stage 2, or -1 cm)
    - AR: 70% failed
    - AR + vicryl mesh: 58% failed
    - "ultralateral" AR: 54% failed

- **Re-evaluation 10 years later** (Barber, AJOG, 2011)
  - Cure: composite outcome
    - No prolapse beyond hymen (> 0 cm, i.e. -1 or 0 is OK)
    - Absence of POP symptoms
    - No retreatment
    - Only 12% failed, only 1% had repeat POP surgery

Slings

- Mid-urethral mesh slings
- Gold standard treatment for SUI
- TVT = TOT
  - High Efficacy
  - Low Complications
  - Easy, standardized surgery
- Mini-slings (single incision) - less effective

Types of Vaginal Mesh Implants

- Slings for Stress urinary incontinence
- Abdominally placed mesh for Vaginal Prolapse
- Vaginally placed mesh for Vaginal Prolapse

Stress Urinary Incontinence

- Involuntary loss of urine
- absence of a bladder spasm
- during a physical stress

- Lack of urethral support or strength
- Triggers: laugh, cough, sneeze, exercise,
- Severe: standing up, bending over, lifting
Normal Urethral Support

Damaged Urethral Support

Backboard effect of vaginal wall

Cough Stress Test: Spurt of Urine

SUI Surgical Treatment

Vaginal:
- Kelly plication with Anterior repair
- Transvaginal needle suspension
  - Easy, fast, but less effective

Abdominal:
- Burch or MMK Retropubic urethropexy
- Traditional bladder neck Sling
  - More difficult, longer surgery, more effective

Mid Urethral sling
  - Easy, fast, standardized, highly effective

Kelly plication with Anterior repair

Vaginal Needle Urethropexy
Burch Urethropexy

Traditional Bladder Neck Sling

Mid Urethral Slings

TVT - type  TOT - type

Key Features of Mid Urethral Slings

- Needles / Trocars
  - Placement of sling with minimal dissection
- Polypropylene mesh
  - “Grabs” onto tissue – no need to anchor
  - Porous – allows tissue in-growth
  - Some products use different mesh or biologic
- Mid-urethral location
- Tension-free

Polypropylene Mesh

- Porous: allows tissue in-growth
- Retropubic: TVT, Sparc, Advantage
- Trans-Obturator: Monarc, Obtryx, TVT-O

Probability of Cure / Dry (48 months)

AUA Outcomes of Surgery for Female Stress Incontinence

Leach et. al. 1997
Retropubic Mid Urethral Slings

**Good**
- TVT
- Advantage
- Sparc

**Bad**
- IVS Tunneler
- OB Tape

Mid Urethral Sling Location

- Meatus
- Midurethra
- Bladder neck

1 cm

TVT Technique

TVT Anatomy

TVT Sling

TVT Sling
Inferior Epigastric Vessels
Obturator vessels
Ext. Iliac Vessels

Cystotomy

The BEST Surgery for Stress Incontinence

1. Burch vs. TVT Midurethral sling:
   - no difference in cure rates, quality of life, or sexual function outcomes
   - MUS has shorter OR time, faster recovery
   - Advantage MUS

2. Burch vs. pubovaginal sling:
   - PV sling had better subjective cure rates
   - PV sling had higher rates of retention requiring return to the operating room
   - No advantage

3. Pubovaginal sling vs. TVT MUS:
   - MUS had better subjective cure outcomes
   - Advantage MUS

4. Retropubic vs. Transobturator MUS:
   - TVT v. TOT
   - No difference in cure, quality of life, or sexual function outcomes
   - TVT has better cure rate in women with intrinsic sphincter deficiency (severe SUI)
   - TVT: less sling erosion, less groin/leg pain, less vaginal perforation
   - TOT: less voiding dysfunction, less OAB symptoms, less blood loss
The BEST Surgery for Stress Incontinence

5. Mini-slings vs. MUS:
   - significantly higher cure rates for MUS
   - Advantage MUS
   - Midurethral slings are the BEST surgical treatment for SUI
     - v. Burch, Mini-Sling, Pubo-Vaginal sling
   - TVT and TOT both excellent

Types of Vaginal Mesh Implants

- Slings for Stress urinary incontinence
- Abdominally placed mesh for Vaginal Prolapse
- Vaginally placed mesh for Vaginal Prolapse

Vaginal Vault Suspension: Abdominal v Vaginal

- Abdominal / Laparoscopic / Robotic
  - Sacral colpopexy - mesh
  - Uterosacral Ligament colpopexy - suture
- Vaginal:
  - Uterosacral Ligament colpopexy - suture
  - Sacrospinous Ligament colpopexy - suture or mesh
- Cystocele or Rectocele repair
  - Suture or Mesh

Normal Pelvic Support

Cystocele

Uterine Prolapse
Sutured Vaginal Apex Repairs

- Utero-Sacral ligament colpopexy
- Sacrospinous ligament colpopexy

Utero-Sacral & Sacrospinous Ligaments

Utero-Sacral Ligament Colpopexy

Sacral Colpopexy
Uphold Vaginal Mesh

Anterior Prolift

Posterior Prolift


• Apex: ASC is superior to SSLC
  • Less Recurrent Vault prolapse (RR = 0.23)
  • Less Dyspareunia (RR = 0.39)
  • No difference in reoperation rates
  • SSLC was faster and less expensive

• Anterior vagina: Vaginal Mesh v Native tissue
  • Mesh has better anatomic outcomes
  • Equal subjective & QOL outcomes

• Posterior Vagina: Vaginal Mesh v Native tissue
  • No data

Properties of Mesh and Grafts used in Vaginal Surgery
The Ideal Mesh for Vaginal POP Surgery

- Polypropylene, Monofilament
- Lightweight, Knitted
- Large Pores for tissue ingrowth (> 1000 microns)
- Large Interstitial pores (50-200 microns) to prevent infection
- High efficacy
- Near zero foreign body complication profile
- Mesh not palpable
- Maintenance of vaginal elasticity and function
- NEED DATA ON OUTCOMES!! (Anatomic & Functional)

Available Biologic Grafts & Synthetic Meshes

- **Biologic**
  - SOME will undergo autolysis, especially processed grafts.
  - ALL are remodeled / replaced with endogenous collagen.
  - If wound breaks down, vagina WILL heal over graft (except Pelvicol).
  - Autologous
    - Rectus Fascia & Fascia Lata
  - Allografts
    - Cadaveric Dermis (Alloderm) & Cadaveric Fascia Lata (Tutoplast)
  - Xenografts
    - Porcine dermis - cross-linked (Pelvicol), not cross-linked (Inte-Xen)
    - Porcine intestine (SIS)
    - Bovine pericardium (Veititas)
- **Synthetic**
  - Permanent mesh: (Polypropylene, Mersilene, Marlex)
  - Scar forms through the mesh, graft not replaced.
  - Risk of Mesh erosion, vagina WILL NOT heal over graft (wound revision)
  - Absorbable mesh: (Vicryl, Dexon)

Host Response to Graft & Mesh Materials

- **Encapsulation**
  - Collagen and connective tissue surround implant
  - High risk of Infection and/or Erosion
- **Resorption / Autolysis**
  - Material is degraded & replaced by host tissue
  - Incorporation
    - Infiltration by host cells, with neovascularization and collagen deposition throughout the mesh
- **Complications:**
  - Exposure (asymptomatic, may heal)
  - Erosion (exposed mesh, symptomatic)
  - Infection (vaginal discharge, odor, erosion)
Resorption
Porcine Dermal Graft Implanted into Rabbit Vagina
Degrades at 9 months

- Replacement of vaginal PelviSoft (PS) porcine dermal xenograft with host collagen
- Graft remnants are visible histologically, but graft not identified at necropsy.
- Graft degradation occurred in 70% of animals
  - Partial = 40%
  - Complete = 30%

Incorporation
Polypropylene Mesh Incorporates into Rabbit Vagina at 9 months

- Encapsulation of polypropylene fibers (*) with collagen
- Vagina (A) & Abdomen (B) - same animal
- Mild inflammatory reaction to mesh
- Host tissue incorporates into mesh
- FBGC, foreign body giant cell; SM, smooth muscle.
- Mesh erosion rate: 27% (n=22)

Scaffolding for Tissue Remodeling

- Porosity allows the growth of fibroblasts around monofilaments.

Fibroblasts & Collagen, after 4 months, Human Vagina

Mesh v. Biologic

- Slings:
  - 30-40% Failure rates from Allograft & Xenograft slings
  - 10-15% Failure rates from Autograft and polypropylene mesh slings
- Abdominal Sacral Colpopexy:
  - 40% Failure rates from Allografts (cadaveric fascia lata)
  - 10% Failure rates from Polypropylene Mesh

Implant Summary:
Slings & Sacral Colpopexy

- Autografts:
  - Slings: Excellent outcomes (SISTER study, UITN)
  - POP surgery: graft size issues & morbidity of harvest site
- Allografts:
  - Poor outcomes in ASC and slings – graft is resorbed
- Xenografts:
  - Poor outcomes in ASC and slings – graft is resorbed
- Absorbable Synthetic Mesh:
  - No data, but Mesh will disappear
- Permanent Synthetic Mesh:
  - Monofilament, large pore, knitted, polypropylene mesh:
  - Standard for Slings & Sacral Colpopexy (CARE Trial, PFDN)
- What about Vaginal POP surgery?
Vaginal Surgery Options for POP

- Sutured repair
  - High failure rates with strict definitions of cure
  - Low failure rates with better definition of cure
- with Biologic graft
  - No to limited benefit
- with Mesh
  - Some benefit with cystocele
  - No benefit with rectocele or vaginal apex

Biologic Grafts for Vaginal POP Repair

- Cystocele – limited benefit
- Rectocele – No benefit
- Vaginal apex – no benefit

Permanent Synthetic Meshes

- Marlex
- Prolene
- Mersilene
- Gore-tex

Permanent Synthetic Mesh: Basic Characteristics

1. Material
   - Polypropylene (current Meshes on market)
   - Polytetrafluoroethylene (Gore-Tex)
   - Polyester (Mersilene)
2. Fiber Arrangement
   - Monofilament
   - Multifilament
3. Structural Weave
4. Pore Size

Meshes and their properties
(adapted from Baessler and Maher, Current Opinion in Ob/Gyn, 2006)

Pores and Interstices:

- Pore Size (red line)
  - Large pores: scaffolding for tissue ingrowth
  - Small pores: no ingrowth; encapsulation occurs
- Infection
  - Bacteria < 1 um
  - Leukocytes 9-15 um, Macrophages 16-20 um
  - Pore size > 50 um required to allow penetration by Leukocytes & Macrophages
- Interstices between filaments (inside red circle)
  - < 10 um allows Bacteria to pass, but not Leukocytes & Macrophages
Multifilament Mesh & Infection

- ASC & mesh erosions
  - Mersilene – Infections occur, entire mesh may need to be removed
  - Polypropylene – Infections uncommon; partial resection of mesh
- Suture erosions (knots) common with multifilament suture
  - Uncommon with monofilament suture
- Gore-tex mesh slings
  - 40% wound infection, 22% removal rate (Weinberger, 1995)
- Protegen mesh slings
  - Woven polyester mesh treated with bovine collagen
  - Multiple infections & removals, resulted in 1999 FDA recall
- IVS Tuneller
  - Woven polyester mesh, Multiple infections, no longer marketed

Monofilament Polypropylene Mesh: Inert to infection

- An inoculum of Staph aureus into grafted monofilament Polypropylene mesh (rat model)
  - No bacterial growth at 4 days evaluation
  - No inhibition of fibroblastic growth
- Large pores allow early inflammatory cell migration and first line defense through macrophages.

Various Polypropylene Meshes: All with pore size > 1000 um

- AMS Apogee™ Mesh (22x)
- Avaulta Solo™ Mesh (18x)
- Prolift™ Mesh (18x)

Available Polypropylene Monofilament Meshes

<table>
<thead>
<tr>
<th>Mesh Density</th>
<th>Macro Pores</th>
<th>Interstitial Pores</th>
<th>Fiber Diameter</th>
<th>Thickness</th>
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</thead>
<tbody>
<tr>
<td>Gynemesh</td>
<td>44 g/m²</td>
<td>2500 x 1700 um</td>
<td>50-200 um</td>
<td>94 um</td>
</tr>
<tr>
<td>Avaulta</td>
<td>34 g/m²</td>
<td>1600 um</td>
<td>50-200 um</td>
<td>119 um</td>
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<tr>
<td>Apogee</td>
<td>24 g/m²</td>
<td>50-200</td>
<td></td>
<td></td>
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<tr>
<td>Novasilk</td>
<td>21 g/m²</td>
<td>1100 um</td>
<td>50-200 um</td>
<td>90 um</td>
</tr>
<tr>
<td>Smartmesh</td>
<td>19 g/m²</td>
<td>1800 um</td>
<td>100 um</td>
<td>80 um</td>
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The Ideal Mesh for Vaginal POP Surgery

- Polypropylene, Monofilament
- Lightweight, Knitted
- Large Pores for tissue ingrowth (> 1000 microns)
- Large Interstitial pores (50-200 microns) to prevent infection
- High efficacy
- Near zero foreign body complication profile
- Mesh not palpable
- Maintenance of vaginal elasticity and function
- NEED DATA ON OUTCOMES!! (Anatomic & Functional)


- Apex: ASC is superior to SSLC
  - Less Recurrent Vault prolapse (RR = 0.23)
  - Less Dyspareunia (RR = 0.39)
  - No difference in reoperation rates
  - SSLC was faster and less expensive
- Anterior vagina: Vaginal Mesh v Native tissue
  - Mesh has better anatomic outcomes
  - Equal subjective & QOL outcomes
- Posterior Vagina: Vaginal Mesh v Native tissue
  - No data
### CARE Trial: ASC

- **RCT**, stage 2-4 POP, ASC +/- Burch
- 95% cure rate for POP
  - Robotic SC
- **Adverse Events:** UroGyn MHS
  - 6% mesh / suture erosion rate
  - 7% ileus or SBO
  - 1.5% had surgery for SBO
  - 10% wound complications
  - 8% rehospitalized (within 3 mo.)
- This is the Gold Standard for POP repair.

### Apical repairs

- **Vaginal Repair**: Mesh v. No mesh
  - No RCT’s or comparative studies
  - Only small-medium case series
  - Very limited data
- **Sacral Colpopexy** v. Vaginal Mesh repair
  - 1 RCT...

### Total Vaginal Mesh versus Sacral Colpopexy

- **1 RCT**
- ≥ stage 2 vaginal vault prolapse
- Lap SC (53), TVM (55), 2 yr f/u
- Lap SC better than TVM
  - Higher anatomic success rate, 77% v 43%
  - Lower reoperation rate, 5% v 22%

### Anterior wall: Synthetic Mesh v. No mesh

- **7 RCT’s:**
  - Anatomic benefit with mesh
    - Failure rate: 7-19% (mesh) v 28-59% (no mesh)
  - POP Symptom outcomes: similar
- Mesh erosion rate: 3-17%
- Dyspareunia rates: worse with mesh
- SUI outcomes: similar - worse with mesh

### Anterior wall RCT’s: Synthetic Mesh v. No mesh

- **Hiltunen (2007)**, RCT, POP-Q stage 2 or worse
  - Anterior colporrhaphy (n=96)
  - Same, Augmented with polypropylene mesh (n=104)
  - Excluded: SUI surgery, ASC, SSLF
- **Lower failure rate with mesh** (≥ Stage 2 POPQ, at 1 yr, Aa or Ba):
  - 7% v 39% (p<.001)
  - At 2 yr: 11% v 41% (p<.001) (Nieminen, 2008)
- **Adverse events:**
  - Mesh exposure rate 17%
  - Symptomatic outcomes: No difference at 1 yr
  - At 2 yr: mesh with less bulge symptoms, less dyspareunia
### Anterior wall RCT’s: Synthetic Mesh v. No mesh

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>POP-Q stage</th>
<th>Procedures</th>
<th>Lower failure rate with mesh</th>
<th>Adverse events</th>
<th>Symptomatic outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nguyen (2008)</td>
<td>RCT</td>
<td>2 or worse</td>
<td>Anterior colporrhaphy (n=38)</td>
<td>13% v 45% (p&lt;.001)</td>
<td>Mesh exposure 5%</td>
<td>No difference</td>
</tr>
<tr>
<td></td>
<td>Same, Augmented</td>
<td></td>
<td>Same, Augmented with Perigee polypropylene mesh (n=37)</td>
<td></td>
<td>Dyspareunia: 9% mesh, 18% no mesh</td>
<td>Prolapse and Urinary symptoms</td>
</tr>
<tr>
<td>Sivaslioglu (2008)</td>
<td>RCT</td>
<td>2 or worse</td>
<td>Anterior colporrhaphy (n=38)</td>
<td>9% v 28% (p&lt;.001)</td>
<td>Adverse events:</td>
<td>No difference</td>
</tr>
<tr>
<td></td>
<td>Same, Augmented</td>
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<td>Same, Augmented with Perigee polypropylene mesh (n=37)</td>
<td></td>
<td>Mesh exposure 7%</td>
<td></td>
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<td></td>
<td>Dyspareunia: 5% mesh, 0% no mesh</td>
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</tr>
<tr>
<td>Carey (BJOG, 2009)</td>
<td>RCT</td>
<td>2 or worse</td>
<td>Anterior &amp; Posterior colporrhaphy (n=70)</td>
<td>19% v 34% (p=.07)</td>
<td>Adverse events:</td>
<td>No difference</td>
</tr>
<tr>
<td></td>
<td>Same, Augmented</td>
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<td>Same, Augmented with polypropylene mesh (n=69)</td>
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<td>Mesh exposure 5.6%</td>
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<td></td>
<td></td>
<td>Dyspareunia: 17% mesh, 15% no mesh</td>
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</tr>
<tr>
<td>Altman (NEJM, 2011)</td>
<td>RCT</td>
<td>2 or worse</td>
<td>Anterior colporrhaphy (n=189)</td>
<td>18% v 52% (p&lt;.001)</td>
<td>Adverse events:</td>
<td>No difference</td>
</tr>
<tr>
<td></td>
<td>Anterior Prolift (n=200)</td>
<td></td>
<td></td>
<td></td>
<td>Mesh exposure 3%</td>
<td></td>
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<td></td>
<td>Dyspareunia: 7% mesh, 2% no mesh</td>
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<td></td>
<td>Reoperation: 6% mesh, 0.5% no mesh</td>
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<tr>
<td>Vollebregt (BJOG, 2011)</td>
<td>RCT</td>
<td>2 or worse</td>
<td>Anterior colporrhaphy (n=64)</td>
<td>9% v 59% (p&lt;.05)</td>
<td>Adverse events:</td>
<td>No difference</td>
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<tr>
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<td>Same, Augmented</td>
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<td>Same, Augmented with polypropylene mesh (Avaulta) (n=61)</td>
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<td>Mesh exposure 4%</td>
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<td></td>
<td>Dyspareunia: de novo: 15% mesh, 9% no mesh</td>
<td>Persistent Baseline: 80% Mesh, 20% no mesh</td>
</tr>
<tr>
<td>Menefee (2011, Ob Gyn)</td>
<td>RCT</td>
<td>2 or worse</td>
<td>Anterior colporrhaphy</td>
<td>18% v 46% demis (p=0.015)</td>
<td>Adverse events:</td>
<td>No difference</td>
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<td>v 58% AR (p&lt;0.002)</td>
<td>Mesh exposure 14%</td>
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<td></td>
<td>Dyspareunia: 9% mesh, 16% no mesh</td>
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<td></td>
<td></td>
<td></td>
<td>Symptomatic outcomes: No difference</td>
<td>Prolapse and Urinary symptoms</td>
</tr>
</tbody>
</table>
Sexual Function after Anterior Mesh Repair

- Case series: Variable results in SF
  - Improved FSFI, 96 women, (Hoda, 2011)
  - Worsened FSFI, 152 women, (Long, 2011)
  - Improved PISQ-12, Ethicon study (Roy, 2012)
  - Improved FSFI, 70 women, (Kuhn, 2009)
  - Worsened PISQ-12, 84 women (Altman, 2009)

- RCT's: Worse sexual function with mesh
  - AR: improved SF, 18% worse
  - AR + mesh: not improved SF, 43% worse
    - Vollebregt (2012, J Sex Med)
  - AR: improved PISQ 12 subscales
  - AR + mesh: worsened subscales
    - Milani, 2011

Posterior Mesh Repair: Case Series

<table>
<thead>
<tr>
<th>Author</th>
<th>Mesh</th>
<th>#</th>
<th>F/U</th>
<th>Cure</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dwyer</td>
<td>Polypropylene</td>
<td>50</td>
<td>29 m</td>
<td>100%</td>
<td>12% erosion 1 RV fistula</td>
</tr>
<tr>
<td>Miliani</td>
<td>Polypropylene</td>
<td>31</td>
<td>17m</td>
<td>100%</td>
<td>6.5% erosion 69% dyspareunia</td>
</tr>
<tr>
<td>Lim</td>
<td>Composite</td>
<td>78</td>
<td>36m</td>
<td>78%</td>
<td>30% erosion 27% dyspareunia</td>
</tr>
<tr>
<td>de Tayrac</td>
<td>Polypropylene</td>
<td>26</td>
<td>23m</td>
<td>92%</td>
<td>12% erosion 8% dyspareunia</td>
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<tr>
<td>Watson</td>
<td>Polypropylene</td>
<td>9</td>
<td>29m</td>
<td>89%</td>
<td>none</td>
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<tr>
<td>Mercer-Jones</td>
<td>Polypropylene &amp; Vicryl</td>
<td>24</td>
<td>12m</td>
<td>91%</td>
<td>8% rectal injury 4% dysparenia</td>
</tr>
</tbody>
</table>

Posterior wall, Synthetic Mesh v. No mesh

- No RCT’s on PR only
- 3 RCT’s on native tissue v mesh reported outcomes on post vag wall
  - 2 showed no difference
- No benefit from mesh in PR
  - Lack of data

Mesh Kits

- What about the Mesh Kits?
  - Prolift: Apogee, Perigee, Elevate
  - Avaulta: Pinnacle, Uphold
- Nearly all large case series (a few RCT)
  - Failure rate: approx 10%
  - Mesh erosion rate: 5-15%
  - Major complications: 4%

Complications: Injuries from Prolift

- Registry involving 248 subjects with 6 month f/u
  - Anterior = 106 (2 bladder, 1 urethra, EBL>1000 ml)
  - Posterior = 71 (3 rectal)
  - Combo ant/post = 20 (1 bladder, 1 rectal)
  - Total repair = 51 (2 bladder, 3 EBL >500ml)
- Complications
  - Major = 11 (4%) (10 visceral injuries)
  - Minor = 36 (12%) (UTI, retention, fever)

Altman et al. AJOG 2007;109:303-8
More Mesh Kit complication rates
Abul-Fattah et al. BJOG 2008 115:22-30

- Retrospective cohort, 3 centers, n = 329
  - Prolift – 76%, Apogee/Perigee – 24%
- Perioperative complications
  - Bladder injury 1.5% (n=5)
  - Rectal injury 1.2% (n=4)
  - Life threatening hemorrhage 0.6% (n=2)
- Delayed complications
  - Buttock pain 5.6%
  - Vaginal erosion 10%
  - Bladder erosion 0.3% (n=1)
  - Necrotizing fascitis 0.6% (n=2)

Mesh Kits

- Most is data relatively “early”
- Potential complications 15-25%
  - Visceral injuries (bladder, rectum): 3-4%
  - Mesh erosion: 10%
  - Dyspareunia: 10%
  - Chronic pelvic pain
  - Major bleeding (<1%) in the retropubic space, ischiorectal fossa, branches of the pudendal

  - What about the Anatomy & Trocars?

Right Obturator Foramen

The mean distance between the anterior superior trocar and the obturator canal was 2.5 cm (95% CI 2.2 – 2.8 cm).

Right Space of Retzius

The mean distance between the anterior inferior trocar and the obturator canal was 3.0 cm (95% CI 2.5 – 3.4).

Posterior Trocar: Passes Near the Inferior Rectal vessels

Schematic of Left Hemipelvis

The mean distance between the posterior trocar and pudendal vessels exiting from Alcock’s canal was 2.6 cm (95% CI 2.3 – 3.0)
In 12 out of 16 passes, the trocar was within 1 cm of the nearest branch of the inferior rectal vessels, which is a branch of the pudendal with a mean distance of 0.9 cm (95% CI: 0.7 – 1.1).

Anatomic Relationships

- Bladder and Rectum - susceptible to injury
- Obturator & Pudendal vessels
  - at risk of injury
  - 1-3 cm away from the passage of trocars

Bladder or Rectal Injury

- Recognized in OR
  - If bladder, close injury, could still place mesh
    (if injury not touching mesh)
  - If rectum, close injury, do NOT place mesh
    (unless well separated)
- Diagnosed postop
  - Return to OR to remove mesh
  - If bladder, close injury, place Foley x 2 weeks
  - If rectum, likely need Temporary Colostomy, allow to heal with fistula x 2 mo, repair fistula, confirm healing, take down colostomy

Vascular Injury

- Fluid resuscitation & blood products
- Option 1 – Return to OR
  - Vaginal vs. Abdominal / Retropubic approach
  - Exposure of bleeding vessel & ligation
  - Floseal™ or similar product can be helpful
  - Packing as last resort
- Option 2 – Interventional radiology
  - Targeted embolization vs. bilateral hypogastric embolization
  - May eventually need return to OR for evacuation of hematoma

Complications

- How do you manage…
- Bladder or Rectal injury
- Vascular injury
- Dyspareunia
- Mesh Erosion
Vaginal Mesh Erosion

Vaginal Mesh Erosions

Mesh Erosion near Vaginal Apex

Dissect Vagina Off of Mesh

Dissect Mesh Off of Bladder

Removal of Vaginal Mesh
Exposed Mesh: after Resection

Simple Closure of Vaginal Epithelium

Dyspareunia and/or Mesh Erosion

- Remove mesh out to the mesh arms at the sidewall
  - Midline vaginal incision
  - Dissect vagina off of mesh
  - Incise mesh in midline
  - Dissect mesh off of bladder or rectum
- Prepare to ligate bleeders at sidewall
- Have Floseal available
- If there is a mesh erosion, dissection is similar to Fistula repair
- May need postop Pelvic Floor Physical Therapy

Key points of Mesh Excision

- Cystoscopy or proctoscopy at beginning & end
- Lateral dissection of vaginal epithelium off of mesh out to the sidewall
- Mobilization of superior and inferior portions of the mesh off underlying viscera
- Midline transection of the mesh
- Dissection of mesh flap as lateral as possible
- Concomitant POP repair as needed

Mesh Anterior Repairs

Summary

- Native tissue repairs
  - Recurrent POP is common, but overstated?
- Mesh repairs offer promising Anatomic results
  - Morbidity of mesh erosion
  - Dyspareunia & pelvic pain rates
  - Similar subjective outcomes
- Full-thickness dissection
- Extensive lateral dissection - to paravaginal space
- Use Trocars? or Suture to pelvic muscles?
- Long-term data still needed.
### Apical Vaginal Mesh Repairs

**Summary**
- Sacral colpopexy (Abd mesh):
  - Gold standard for apical POP, high success rates
  - Mesh erosion occurs 1-5%
  - Less invasive techniques (Laparoscopy, Robot)
- Traditional vaginal repairs (suture)
  - High success rate
- Apical vaginal mesh repairs
  - Traditional anchor points (SSL)
  - Blind trocar penetration near rectum
  - No data to suggest benefit

### Posterior Vaginal Mesh Repairs

**Summary**
- Traditional native tissue repairs have high (80-90%) success rate
- Posterior Vaginal Mesh
  - Repairs are easy to perform
  - Simply suture to levators and perineal body
  - Can attach mesh to SSL if apical support needed
  - No data to suggest benefit with mesh

### FDA Approval for Devices

- Much less strict than with drugs
  - Marketing allowed if the device is “substantially equivalent” to other devices on the market
  - 510 K Process
- Outcome Data not required
  - Does not assure efficacy or safety
- Be careful if Early adopter
  - Best to wait for Outcome Data

### FDA Warning, October 20, 2008

- Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence
- Over the past three years, FDA has received over 1,000 reports from nine surgical mesh manufacturers of complications that were associated with surgical mesh devices used to repair POP and SUI.
- These mesh devices are usually placed transvaginally utilizing tools for minimally invasive placement.

### FDA Warning: Complications

- The most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence.
- There were also reports of bowel, bladder, and blood vessel perforation during insertion.
- In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia.
2008 FDA Warning: Physician Recommendations

- Obtain specialized training for each mesh placement technique, and be aware of its risks.
- Be vigilant for potential adverse events from the mesh, especially erosion and infection.
- Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.
- Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
- Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall (in POP repair).
- Provide patients with a written copy of the patient labeling from the surgical mesh manufacturer, if available.

Pre-op Counselling with Vaginal Mesh Cases

Risks of the procedure include, but not limited to:
- bleeding, transfusion
- infection
- post-op or chronic pain
- need for re-operation
- injury to the adjacent organs
  - bowel, bladder, ureters, vascular
- persistence or recurrence of condition
- voiding dysfunction
- prolonged bladder catheter use
- poor wound healing
- erosion of any implant used
- dyspareunia
- vaginal scarring or narrowing

2011 FDA Warning on Transvaginal Mesh for POP

- July 13, 2011 - Updated warning released
- Complications from Transvaginal mesh (TVM) for POP repair are NOT RARE
  - 2005-2007, “over 1000” adverse events reported
  - 2008-2010, 2,874 additional reports
- Most common:
  - mesh erosion, pain, infection, dyspareunia (female or male pain), bleeding, organ perforation, urinary problems

2011 FDA Warning on Transvaginal Mesh for POP

- Systematic Review, 1996-2011:
  - TVM for POP repair does NOT improve Symptomatic results or QOL versus traditional repair
  - TVM introduces Risks Not present in non-mesh repair
  - Abdominal mesh (Sacral Colpopexy) has lower rates of mesh complications than TVM
  - No evidence of benefit for TVM repair of the vaginal apex or posterior vagina

2011 FDA Warning on Transvaginal Mesh for POP

- Mesh Erosion
  - Most common complication of TVM
- Can require multiple surgeries to repair
- Debilitating for some women
- Repeat surgeries do not always resolve
- Mesh Contraction
  - Previously unidentified risk of TVM
- Vaginal shortening, tightening, & pain

2011 FDA Warning: Same 2008 Physician Recommendations

- Obtain specialized training for each mesh placement technique, and be aware of its risks.
- Be vigilant for potential adverse events from the mesh, especially erosion and infection.
- Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.
- Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
- Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall (in POP repair).
- Provide patients with a written copy of the patient labeling from the surgical mesh manufacturer, if available.
### New Physician Recommendations

- Recognize that in most cases, POP can be treated successfully without mesh.
- Choose mesh surgery only after considering all surgical and non-surgical alternatives.
- Consider that abdominal mesh has lower mesh complications rates than TVM.
- Inform the patient about the risks and benefits of non-surgical options, non-mesh surgery, and abdominally placed mesh.
- Ensure the patient understands the postoperative risks and complications of mesh surgery as well as limited long-term outcomes data.

### Aftermath of 2011 FDA Warning on TVM for POP

- Multiple legal & lawsuit ads soon followed
- Sep 2011:
  - FDA Ob-Gyn Advisory Panel meeting, rec that all TVM products be reclassified as Class III (needs pre-market approval)
- Jan 2012:
  - FDA required 3-yr studies on all TVM products (focus on AE’s & QOL)
- July 2012:
  - 4 Gynecare mesh products withdrawn:
    - TVT Secur, Prosim, Prolift, & Prolift + M.

### Choosing a Surgery

#### What Now?

- Pessaries are safe & effective
- Sacral colpopexy is effective for apical prolapse
  - min invasive options exist (robotic laparoscopic)
- Native tissue repairs are effective and have high patient satisfaction
- Compared with native tissue repair, TVM for anterior vaginal prolapse reduces anatomic recurrence but subjective outcomes are the same
- Mesh exposure will occur in 10% of TVM cases.
AUGS Survey: Mesh Use for POP & SUI

- Transvaginal mesh use decreased
  - 40% reported decreased use
  - 12% stopped use
  - However, still used by 61%
- Transabdominal mesh not decreased
  - No change (62%)
  - Increased use (12%).
- Mesh slings - No change
  - Only 6 mo after 2011 FDA Warning

My Apical Repair Recommendations (most will need apical support)

- Transvaginal (USLC, SSLC)
  - Concurrent Hysterectomy Primary POP
  - Moderate POP (stage 2-3) High surgical risk
- Sacral Colpopexy (robotic, laparoscopic, open)
  - Prior Hysterectomy Severe POP (stage 3-4)
  - Recurrent POP Occupational heavy lifting
- Colpocleisis
  - Older, no longer sexually active
- Avoid Vaginal Mesh

Candidates for TransVaginal Mesh or Biologic Graft

- Need for Extra-Peritoneal repair
- Recurrent anterior vaginal prolapse
  - especially if has good apical support
- Unable to accomplish repair without causing vaginal stenosis
  - Cystocele, with prior Hysterectomy
  - Upper Rectocele
- Best if Older, not sexually active
- Do NOT use if she has a Chronic Pain disorder

Conclusions

- Slings
  - Gold standard for SUI
- Vaginal sutured repair
  - Best choice for moderate POP with uterus
- Sacral colpopexy (Robotic)
  - Best choice for severe or recurrent POP, or with prior hysterectomy, or with occupational heavy lifting
- Vaginal Mesh repair
  - more complications, similar results

The End
<table>
<thead>
<tr>
<th>Utero-Sacral Ligament</th>
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</thead>
<tbody>
<tr>
<td>Vaginal Suspension</td>
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</tbody>
</table>

![Image of Utero-Sacral Ligament and Vaginal Suspension](image_url)