Mesh Use in Vaginal Surgery for Pelvic Organ Prolapse

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Objectives:
Vaginal Mesh for POP

- Describe the properties of mesh
- Describe the risks and benefits of mesh in POP repair, including unique morbidity from mesh.
- Discuss the 2011 FDA Warning
- Describe management strategies for mesh complications.
- List current recommendations for use of mesh
POP Epidemiology

- Annually, 200,000 women undergo inpatient procedures for POP in US, 1979-97
  - (Boyles, 2003)

- Lifetime risk of surgery by age 80, for POP and/or SUI: 11-12%
  - (Olsen, 1997 & Fialkow, 2008)

- 30% of those undergoing surgery had Recurrent POP and/or SUI
  - (Olsen, 1997)
Risk Factors for POP

- 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 Muscles

Ischial spine
Levator Ani Atrophy

10 control women

10 women with Prolapse

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
Gabriel, Int Urogyn J 2006;17:478-482
Ewies, H Repro 2003;18:2189-195
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?
Levels of Vaginal Support & Implant Attachment Sites

- **Level 1** = Apical vagina, level of ischial spines
  - USL, SSL, SC

- **Level 2** = Mid-vagina, to levator ani
  - Paravaginal repair

- **Level 3** = Distal vagina, fused to Introitus with urethra & perineal body

DeLancey, 1992
Vaginal Mesh: How did we get here?

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

POP
- A&P repairs
- McCall culdoplasty / USLC (1957)
- 1970’s:
  - Sacrospinous & Iliococcygeus Susp
  - Mesh: Abd Sacral Colpopexy
Vaginal Mesh: How did we get here?

- 1990’s
  - Slings: Fascia (autograft), cadaver (allograft), various meshes (mersilene, marlex, gore-tex)
  - ProteGen mesh sling – SUI
    - Introduced in early 90’s, recalled late 90’s
  - Minimally invasive slings developed
    - Introduced to US around 1999-2000
    - TVT sling (excellent, copied by many)
    - IVS Tunneler & OB Tape slings (poor, withdrawn)
  - TOT slings introduced 2003-4
Vaginal Mesh: How did we get here?

- 2004: Vaginal mesh kits introduced, based on...
  - Success of polypropylene mesh slings (TVT and TOT)
  - High “Objective” failure rates for POP surgery
    - Sutured repair & biologic grafts
  - 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, Mesh in the Vagina is NOT the same as Mesh in the Abdominal Wall
Issues in the Transvaginal Placement of Grafts or Mesh

• Vagina cannot be sterilized
  – clean-contaminated surgery

• Vaginal Mucosa
  – Thin overlay with no real fascial layer

• Attachment sites are difficult to access

• Complex 3-D architecture and vector forces

• Sexual, Bladder, & Bowel function
Vaginal Mesh: Where are we now?

• 2008: FDA Warning on Vaginal Mesh
  – “over 1000” complications reported to MAUDE Database
  – Recommendations to physicians on training and informed consent

• 2011: FDA Update Warning on Vaginal Mesh
  – 2,874 more complications reported
  – Systematic reviews on Transvaginally placed Mesh for POP repair show limited benefit
  – TVM products reclassified as Class III (game changer)
    • All TVM companies must conduct 3-year studies
Properties of Mesh and Grafts used in Vaginal Surgery
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 (Veritas)

- **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)
Encapsulation of Mesh

Host Tissue

Mesh
Human Fascia Lata
(freeze-dried, gamma-radiated)
Implanted in a Rabbit Vagina
Degrades at 12 weeks

(Walter, IUJ, 2005)

<table>
<thead>
<tr>
<th>Week</th>
<th>n</th>
<th>Inflammatory response</th>
<th>Graft integrity</th>
<th>Graft Neovascularization</th>
<th>Host collagen deposition</th>
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<tbody>
<tr>
<td>2</td>
<td>3</td>
<td>Increased acute</td>
<td>Preserved</td>
<td>Peripheral</td>
<td>Focal</td>
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<tr>
<td>4</td>
<td>2</td>
<td>Decreased acute</td>
<td>Preserved</td>
<td>Peripheral</td>
<td>Focal</td>
</tr>
<tr>
<td>8</td>
<td>2</td>
<td>Continued decreased</td>
<td>Fibers losing</td>
<td>Diffuse</td>
<td>Marked linear infiltration</td>
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<td></td>
<td></td>
<td>acute; increased chronic</td>
<td>orientation</td>
<td></td>
<td></td>
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<tr>
<td>12</td>
<td>2</td>
<td>Decreased chronic</td>
<td>No identifiable graft</td>
<td>Diffuse</td>
<td>Complete replacement by linear fibrils</td>
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</tbody>
</table>
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%

Pierce, et al. AJOG, 2009
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%, “mesh degradation” rate: 7% (n=22)

Pierce, et al. AJOG, 2009
Scaffolding for Tissue Remodeling

- Porosity allows the growth of fibroblasts around monofilaments.

Fibroblast growth with collagen deposition at polypropylene mesh interstices at 128 days from implantation for cystocele repair.
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

Culligan, Obstet Gynecol, 2005
Simsiman, AJOG, 2005
Fitzgerald
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?
Biologic Grafts for Vaginal POP Repair

• Overall assessment of data:
  – Numerous case series
    • Benefits claimed, no control group
  – Very limited Level 1 Evidence (RCT’s)
    • Cystocele: 3 conflicting studies, no benefit overall
    • Rectocele: 1 study, no benefit
  – Limited to No Benefit
Cystocele: Biologic graft v. No graft

- Gandhi (2005) RCT
  - Anterior colporrhaphy, ‘ultralateral’ technique (n=78)
  - Tutoplast Augmentation (solvent dehydrated human fascia lata) (n=75)
  - No significant difference (13 mo, failure > stage 2 or grade 2)
  - 21% (graft) v. 29% (traditional) (p=.25)

- Meschia (2007) RCT
  - Traditional repair (n=103) v Pelvicol Augmentation over plication (n=98)
  - Lower Failure rate with biologic graft (1 yr, point Ba ≥ -1 on POPQ)
  - 7% (graft) v. 19% (traditional) (p=.02)

- Guerette (2009) RCT
  - Traditional repair (n=35) v Bovine pericardium graft (n=37)
  - No significant difference (1 yr, point Ba ≥ -1 on POPQ)
  - 14% (graft) v. 22% (traditional) (p=.54)

- Meta-analysis - No Difference
Rectocele: Biologic graft v. No graft

- Paraiso (2006) - the only RCT on Biologic graft in Posterior wall
  - posterior colporrhaphy (n = 37)
  - Site-Specific repair only (n = 37);
  - S-S repair augmented by porcine SIS graft (Fortagen, n = 32)

- Higher failure rate with graft (defined as Bp > -2, at 1 yr)
  - 46% biologic graft v. 22% S-S repair v. 14% post colp (p=.02)

- Symptom outcomes – no difference between groups
  - Defecatory dysfunction: all 3 improved
  - Sexual function: all 3 improved
  - Dyspareunia: no difference

- Conclusion: No benefit, possibly Worse Anatomic outcome, with biologic graft, posterior vagina
Absorbable Synthetic Mesh for Vaginal POP Repair

- Absorbable mesh will break down after several weeks

- Conflicting results from 2 RCT’s
  - Weber, AJOG, 2001 - no benefit with cystocele
  - Sand, AJOG, 2001 - benefit with cystocele
  - Meta-analysis – no benefit

- Overall, limited data. Not used.
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
(adopted from Baessler and Maher, Current Opinion in Ob/Gyn, 2006)

Meshes:
- **Knitted monofilament mesh**
  - Type I mesh
  - Large pores, good elasticity
- **Knitted multifilament mesh**
  - Type II mesh
  - Small interstices, reduced elasticity
- **Non-knitted, non-woven mesh**
  - Type III mesh
  - Large pores, small interstices, restricted elasticity
**Amid Classification of Mesh**

(From Amid, *Langenbecks Arch Chir*, 1994)

Meant for hernias, not the vagina. Macroporous by this definition is too small of a pore.

<table>
<thead>
<tr>
<th>Type</th>
<th>Pore size</th>
<th>Filament</th>
<th>Component</th>
<th>Trade name</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Macroporous (&gt;75 microns)</td>
<td>Mono</td>
<td>Polypropylene</td>
<td>Gynemesh, Avaulta, etc.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hybrid</td>
<td>Polypropylene/Polyglactin 910</td>
<td>Vypro</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Multi</td>
<td>Polyglactin 910</td>
<td>Vicryl</td>
</tr>
<tr>
<td>II</td>
<td>Microporous (&lt;10 microns)</td>
<td>Multi</td>
<td>Expanded PTFE</td>
<td>Gore-Tex (25% erosion)</td>
</tr>
<tr>
<td>III</td>
<td>Macroporous, with multifilament interstices &lt; 10 microns</td>
<td>Multi</td>
<td>Polyethylene, Polypropylene</td>
<td>Mersilene, ObTape &amp; IVS Tunneler off market</td>
</tr>
<tr>
<td>IV</td>
<td>Submicronic</td>
<td>Mono</td>
<td>Silicone</td>
<td>Not for GYN</td>
</tr>
</tbody>
</table>
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.

Barbolt. Int Urogynecol J 2006;17:S26-S30
Various Polypropylene Meshes:
All with pore size > 1000 um

- AMS Apogee™ Mesh (22x)
- Avaulta Solo™ Mesh (18x)
- Prolift™ Mesh (18x)
<table>
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<tr>
<th>Available Polypropylene Monofilament Meshes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Gynemesh</strong> (Ethicon)</td>
</tr>
<tr>
<td>44 g/m²</td>
</tr>
<tr>
<td><strong>Avaulta</strong> (Bard)</td>
</tr>
<tr>
<td><strong>Apogee</strong> (AMS)</td>
</tr>
<tr>
<td><strong>Novasilk</strong> (Coloplast)</td>
</tr>
<tr>
<td><strong>Smartmesh</strong> (Mpathy)</td>
</tr>
</tbody>
</table>
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)
Possible POP Indications for Vaginal Grafts or Mesh

- Stage 3-4 (severe) prolapse
- Obesity
- Age < 60 -or- Physically active
- Recurrent prolapse
- Poor tissue quality
  - Inadequate Site-specific repair
- Unable to accomplish Colporrhaphy or Levator plication without vaginal stenosis
  - Cystocele, with prior Hysterectomy
  - Upper Rectocele
- Need for Extra-Peritoneal repair
Levels of Vaginal Support & Implant Attachment Sites

- **Level 1** = Apical vagina, level of ischial spines
- **Level 2** = Mid-vagina, to levator ani
- **Level 3** = Distal vagina, fused to Introitus with urethra & perineal body

DeLancey, 1992
Vaginal Vault Suspension: Abdominal v Vaginal

• Abdominal:
  – Sacral colpopexy - mesh
    • Open
    • Laparoscopic +/- Robotic
  – Uterosacral Ligament colpopexy (AUSLC) - tissue

• Vaginal:
  – Uterosacral Ligament colpopexy (USLC) - tissue
  – Sacrospinous Ligament colpopexy (SSLC) - tissue
Possible uses of Vaginal Mesh

• Total Vaginal Mesh POP repair instead of:
  – Sacral colpopexy
  – U-S ligament suspension
• Cystocele repair with mesh
• Rectocele repair with mesh
• With or without Kits / Trocars
Cochrane Review: POP Surgery

• 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
Total Vaginal Mesh versus Sacral Colpopexy

• 1 RCT
  – Maher, AJOG, 2011; 204:360.e1-7.
• ≥ 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%
Goal for Vaginal Mesh POP Repair

• ASC cure rate = 95%
• ASC complications
  – mesh erosion rate = 0.5% - 5%
  – ileus/SBO rate = 6%
  – Major re-operation rate = 1.5%
  – hemorrhage / transfusion rate = 4%
  – Visceral injury rate = 5%

• Vaginal Mesh
  – Cure rates attainable
  – Complication rates will be the issue
  – Let’s take a look
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
  – No RCT’s
### ASC Review & Complications

- **Wound (infection, hematoma)**: 4.6% (0.4% - 20%)
- **Hemorrhage or transfusion**: 4.4% (0.2% - 17%)
- **Cystotomy**: 3.1% (0.4% - 16%)
- **Enterotomy or proctotomy**: 1.6% (0.4% - 3%)
- **Ureteral injury**: 1.0% (0.8% - 2%)
- **Postoperative ileus**: 3.6% (1.1% - 9%)
- **DVT or PE**: 3.3% (0.4% - 5%)
- **Reoperation for SBO**: 1.1% (0.6% - 9%)
- **Incisional hernia repair**: 5.0% (0.4% - 15%)

*Nygaard et al. Obstet Gynecol 2004;104:805-823*
CARE Trial: ASC

- RCT, stage 2-4 POP, ASC +/- Burch
- 95% cure rate for POP
- Adverse Events:
  - 6% mesh / suture erosion rate
  - 20% nausea, emesis, bloating, ileus
  - 7% ileus or SBO (1.5% had surgery for SBO)
  - 10% wound complications
  - 8% rehospitalized (within 3 months surgery)

- This is the Gold Standard for POP repair.

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## Apical Mesh Repairs: Case series

<table>
<thead>
<tr>
<th>Author</th>
<th>Mesh</th>
<th>#</th>
<th>Follow-up</th>
<th>Cure</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Lo</td>
<td>Polypropylene</td>
<td>15</td>
<td>35m</td>
<td>100%</td>
<td>16.7% dysp. 6.7% erosion</td>
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<td>Rutman</td>
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<td>Shah</td>
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ASC Review & Graft materials

- 2004: Systematic review (38 years) on ASC
- “Success” 78-100%
- Worse outcomes with biologic grafts vs. mesh
- Overall synthetic mesh erosion rates: \(3.4\%\)
  - Polytetrafluoroethylene PTFE (Teflon) \(5.5\%\)
  - Polyethylene (Marlex) \(5.0\%\)
  - Expanded PTFE (Gore-Tex) \(3.4\%\)
  - Polyethylene terephthalate (Mersilene) \(3.1\%\)
  - Polypropylene mesh \(0.5\%\)

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</tbody>
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Anterior Vaginal Mesh Repair
Anterior Prolift
Body of bladder removed + hysterectomy
Anterior Vaginal Wall Mesh Support

Bladder neck

Ischial spines
Anterior Vaginal Wall Mesh Support
Trocar site placement & mesh location
Anterior wall:
Synthetic Mesh v. No mesh

- 3 of 4 RCT’s: Anatomic benefit with mesh
  - Failure rate: 7-19% (mesh) v 28-45% (no mesh)
  - Mesh erosion rate: 5-17%
  - Dyspareunia rates similar
  - Postop Symptom outcomes similar

- Several large case series
  - Failure rate 10%
  - Mesh erosion rate 5-15%
<table>
<thead>
<tr>
<th>Author</th>
<th>Mesh</th>
<th>#</th>
<th>F/U</th>
<th>Cure Rate</th>
<th>Mesh Erosion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flood (1998)</td>
<td>Polypropylene</td>
<td>142</td>
<td>38m</td>
<td>100%</td>
<td>2%</td>
</tr>
<tr>
<td>Dwyer (2004)</td>
<td>Polypropylene</td>
<td>64</td>
<td>29m</td>
<td>94%</td>
<td>5%</td>
</tr>
<tr>
<td>de Tayrac (2006)</td>
<td>Polypropylene</td>
<td>63</td>
<td>37m</td>
<td>89%</td>
<td>9%</td>
</tr>
<tr>
<td>de Tayrac (2007)</td>
<td>LW Polypro</td>
<td>143</td>
<td>13m</td>
<td>92%</td>
<td>6%</td>
</tr>
<tr>
<td>Migliari (1999)</td>
<td>Polypropylene</td>
<td>12</td>
<td>20m</td>
<td>100%</td>
<td>None</td>
</tr>
<tr>
<td>Nicita (1998)</td>
<td>Polypropylene</td>
<td>44</td>
<td>14m</td>
<td>90%</td>
<td>13%</td>
</tr>
<tr>
<td>Migliari (2000)</td>
<td>Hybrid mesh</td>
<td>15</td>
<td>23m</td>
<td>93%</td>
<td>None</td>
</tr>
</tbody>
</table>
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

- Nguyen (2008), RCT, POP-Q stage 2 or worse
  - Anterior colporrhaphy (n=38)
  - Same, Augmented with Perigee polypropylene mesh (n=37)

- Lower failure rate with mesh (≥ Stage 2 POPQ, at 1 yr):
  - 13% v 45% (p<.001)

- Adverse events:
  - Mesh exposure rate 5%
  - Dyspareunia: 9% mesh, 16% no mesh

- Symptomatic outcomes: No difference
  - Prolapse and Urinary symptoms
Anterior wall RCT’s: Synthetic Mesh v. No mesh

- Sivaslioglu (2008), RCT, POP-Q stage 2 or worse
  - Anterior colporrhaphy (n=38)
  - Same, Augmented with Perigee polypropylene mesh (n=37)

- Lower failure rate with mesh (≥ Stage 2 POPQ, at 1 yr):
  - 9% v 28% (p<.001)

- Adverse events:
  - Mesh exposure rate 7%
  - Dyspareunia: 5% mesh, 0% no mesh
Anterior wall RCT’s: Synthetic Mesh v. No mesh

- Carey (2009), RCT, POP-Q stage 2 or worse
  - Anterior & Posterior colporrhaphy (n=70)
  - Same, Augmented with polypropylene mesh (n=69)

- **Lower failure rate with mesh** (≥ Stage 2 POPQ, at 1 yr):
  - 19% v 34% (p=.07)

- Adverse events:
  - Mesh exposure rate 5.6%
  - Dyspareunia: 17% mesh, 15% no mesh

- Symptomatic outcomes: No difference
Rectocele Repair with Graft

Cuff and uterosacral ligaments
Iliococcygeus muscle
Puborectalis muscle
Pubococcygeus muscle
Perineal body
Posterior Prolift
Posterior wall,
Synthetic Mesh  v.  No mesh

• No RCT’s or comparative studies
• Only large case series…
### 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>17 m</td>
<td>100%</td>
<td>6.5% erosion, 69% dyspareunia</td>
</tr>
<tr>
<td>Lim</td>
<td>Composite</td>
<td>78</td>
<td>36 m</td>
<td>78%</td>
<td>30% erosion, 27% dyspareunia</td>
</tr>
<tr>
<td>de Tayrac</td>
<td>Polypropylene</td>
<td>26</td>
<td>23 m</td>
<td>92%</td>
<td>12% erosion, 8% dyspareunia</td>
</tr>
<tr>
<td>Watson</td>
<td>Polypropylene</td>
<td>9</td>
<td>29 m</td>
<td>89%</td>
<td>none</td>
</tr>
<tr>
<td>Mercer-Jones</td>
<td>Polypropylene &amp; Vicryl</td>
<td>24</td>
<td>12 m</td>
<td>91%</td>
<td>8% rectal injury, 4% dysparenia</td>
</tr>
</tbody>
</table>
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%
## Prolift Outcomes

<table>
<thead>
<tr>
<th>Author</th>
<th>N</th>
<th>F/U (mo)</th>
<th>Erosion</th>
<th>Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Van Raalte (2007)</td>
<td>349</td>
<td>6</td>
<td>1.4%</td>
<td>91%</td>
</tr>
<tr>
<td>Withagen (2007)</td>
<td>49</td>
<td>6</td>
<td>8%</td>
<td>NA</td>
</tr>
<tr>
<td>Belot (2004)</td>
<td>277</td>
<td>NA</td>
<td>12%</td>
<td>NA</td>
</tr>
<tr>
<td>Rechberger (2007)</td>
<td>112</td>
<td>6</td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>Manchana (2007)</td>
<td>101</td>
<td>5</td>
<td>6.6%</td>
<td>T 88%, A 96%, P 100%</td>
</tr>
<tr>
<td>Meshia (2007)</td>
<td>228</td>
<td>8</td>
<td>4.8%</td>
<td>75%</td>
</tr>
<tr>
<td>Abdel-fattah (2007)</td>
<td>143</td>
<td>3</td>
<td>12%</td>
<td>94%</td>
</tr>
<tr>
<td>Fatton (2007)</td>
<td>106</td>
<td>3</td>
<td>5%</td>
<td>95%</td>
</tr>
<tr>
<td>Altman (2008)</td>
<td>123</td>
<td>2</td>
<td>2%</td>
<td>T 88%, A 87%, P 91%</td>
</tr>
<tr>
<td>Hinoul (2008)</td>
<td>48</td>
<td></td>
<td>10%</td>
<td>A 96%</td>
</tr>
</tbody>
</table>
## Apogee / Perigee Outcomes

<table>
<thead>
<tr>
<th>Author</th>
<th>N</th>
<th>Follow-up</th>
<th>Erosion</th>
<th>Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gauruder-Burmester (2007)</td>
<td>120</td>
<td>13m</td>
<td>3%</td>
<td>93%</td>
</tr>
<tr>
<td>Kannan (2007)</td>
<td>102</td>
<td>3m</td>
<td>8%</td>
<td>97%</td>
</tr>
<tr>
<td>Moore &amp; Miklos (2006)</td>
<td>42</td>
<td>12m</td>
<td>7%</td>
<td>93%</td>
</tr>
<tr>
<td>Dietz (2006)</td>
<td>48</td>
<td>11m</td>
<td>10%</td>
<td>85%</td>
</tr>
<tr>
<td>Davila (2006)</td>
<td>177</td>
<td>1-9 m</td>
<td>14%</td>
<td>96%</td>
</tr>
<tr>
<td>Biller (2007)</td>
<td>104</td>
<td>7 m</td>
<td></td>
<td>96%</td>
</tr>
<tr>
<td>Sarsotti (2007)</td>
<td>47</td>
<td>14m</td>
<td>10%</td>
<td>86%</td>
</tr>
</tbody>
</table>
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?
The mean distance between the anterior superior trocar and the obturator canal was 2.5 cm (95% CI 2.2 – 2.8 cm).
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
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).
Left Pararectal Space
Anatomic Relationships


• Bladder and Rectum - susceptible to injury

• Obturator & Pudendal vessels
  – at risk of injury
  – 1-3 cm away from the passage of trocars
Complications

- How do you manage...
- Bladder or Rectal injury
- Vascular injury
- Dyspareunia
- Mesh Erosion
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
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
Vaginal Mesh Erosions
Mesh Erosion near Vaginal Apex
Dissect Vagina Off of Mesh
Dissect Mesh Off of Bladder
Removal of Vaginal Mesh
Dissect Exposed Mesh
Simple Closure of Vaginal Epithelium
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

- Anterior vaginal wall - Recurrent POP is common
- Mesh repairs offer promising Anatomic results
  - Morbidity of mesh erosion - unknown
  - Dyspareunia & pelvic pain rates - need more data
- Full-thickness dissection
- Extensive lateral dissection - to paravaginal space
- Use Trocars? or Suture to pelvic muscles?
- 3 RCT’s. More data still needed.
Apical Vaginal Mesh Repairs

Summary

• Sacral colpopexy: Gold standard for apical POP
  – Mesh erosion occurs 1-5%
  – Less invasive sacral colpopexy?? (Laparoscopy, Robot)
• Traditional vaginal repairs: good success rate
• Non-kit apical mesh repairs
  – Traditional anchor points (SSL)
  – Can do concomitant anterior or posterior POP repair
• Mesh kits: blind trocar penetration near rectum
• Need data
Posterior Vaginal Mesh Repairs

Summary

• Traditional repairs have acceptable success rate for most rectocele repairs
  – Have always been associated with dyspareunia
• Posterior Mesh repairs are easy to perform
  – Simply suture to levators and perineal body
  – Can attach mesh to SSL if apical support needed
• Mesh kits always attach apically
  – No Kit or trocars needed unless that occurs
• Need data.
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 Counseling 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.
2011 FDA Warning
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, Prosima, Prolift, & Prolift + M.
What Now?

• Pessaries are a safe & effective treatment
• Sacral colpopexy is effective for apical prolapse, and min invasive options exist
• 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 cases.
AUGS Survey: Mesh Use for POP Repair
POP Repair Recommendations

- Most will need an apical support procedure
- Transvaginal (USLC, SSLC)
  - Older
  - Primary POP, stage 2-3
  - Increased surgical risk
- Open or laparoscopic Sacral Colpopexy
  - Younger Prior Hysterectomy
  - Recurrent POP Primary POP, stage 3-4
  - Physically active Occupational heavy lifting
- Colpocleisis
  - Older, no longer sexually active
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

- Vaginal POP Mesh repair has more complications than traditional vaginal POP repairs and Abdominal mesh repair
- Early evidence to support use with cystocele repair
- Many risks to mesh & trocar use
- Counsel patients carefully
MultiCare Women’s Pelvic Medicine and Reconstructive Surgery

• Three Locations
  – **TACOMA**: Allenmore Medical Center/Building B, 1901 Union Avenue, Suite 2006
  – **OLYMPIA**: MultiCare Women’s Specialty Services, 3504 12th Ave NE
  – **PUYALLUP**: Good Samaritan Medical Building, 1450 5th St. SE, Suite 3200

• Referrals (253) 301-5120
• Physicians need to cut and paste the following link, into their browser, to access the CME post test. http://www.surveygizmo.com/s3/1155441/WCGRPT020713

• Achieve 80% correct answers and CME credit will be awarded. Certificate will be emailed within 21 business days.

• Non Physicians may follow the same process and receive a certificate of participation.