Grafts in Pelvic Reconstructive Surgery:
What Procedures and Which Graft

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GRAND ROUNDS
Department of Urological Sciences
May 6, 2009

Potential Conflict of Interest

Prior Research Grant
- COOK OB/GYN
- CR BARD

Former Consultant
- CR BARD
Learning Objectives

• Understand the rationale for development of grafts in pelvic reconstructive surgery
• Review established procedures using grafts and the benefits and risks
• Describe the physical properties and qualities of available graft materials
• Consider innovative applications for the use of synthetic grafts

Epidemiology of Reconstructive Surgery

• 11.2% lifetime risk of surgical intervention
• 29–40% of procedures require repeat surgery for failure within 3 years
  - 60% of recurrences at the same site
  - 32.5% at a different (occult support defect)

Possible Causes of Failure

- Anatomic
- Tissue Factors
- Environmental Factors
- Surgical Factors

Multiple studies show structurally altered collagen, elastin, smooth muscle in POP

Hernia Metaphore

- Incisional Hernia Multicenter Randomized Trial\(^1\)
  - 181 patients randomized — mesh vs. traditional repair
  - 3 year cumulative recurrence rates:
    - Primary repair: 24% vs. 43% (odds ratio 0.56, p<0.02)
    - First Recurrence: 20% vs. 58% (odds ratio 0.34, p<0.001)
    - Same group at 10 yrs: 32% vs. 63% (odds ratio 0.51, p<0.001)\(^2\)
- Cochrane Review 2002\(^3\)
  - Synthetic mesh vs. non-mesh: femoral/inguinal hernia
  - 20 randomized trials identified
  - No difference in complications
  - Recurrence mesh vs. non-mesh OR: 0.37 (95% CI 0.26-0.51)
- Conclusion: 50-75% risk of recurrence with mesh

\(^{3}\)Scott NW et al. Cochrane Rev 2003;CD002197

Prolift™
Now What?

- 60 y/o Asian s/p TVM repair with polypropylene mesh for procidentia (2006)
- Mesh erosion
  - Suburethral
  - X3 posterior wall
- Recurrent POP

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**U.S. Food and Drug Administration**

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**

Issued: October 20, 2008

**FDA Public Health Notification: 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.
Physicians should:

- 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.


Important Questions

- What surgeries are improved through the use of grafts?
- What grafts are most effective?
- Do grafts increase complications?
Pelvic Reconstructive Surgeries with Graft Materials

Traditionally use graft

• Suburethral sling
• Sacral colpopexy

Graft as innovation

• Anterior fascial replacement
• Posterior fascial replacement
• Total Vaginal Mesh procedures
Midurethral Sling: Paradigm Shift

**Tension Free Vaginal Tape**
- 10 years of R&D
  - Outpatient
  - Minimally Invasive
  - Tension free
  - Soft weave wide bore polypropylene
  - Olmsten & Petros 1996

**Transobturator Tape**
- Equivalent results
- Reproducible
- Easy to teach

De Leval 2005
Delorme 2003
Surgeons as Innovators

Most surgeons innovate on a daily basis, tailoring therapies and operations to the intrinsic uniqueness of every patient and their disease.

New Technologies: Spectrum of Adoption

Early Majority 34%  Late Majority 34%
Innovators 2.5%  Early Adopters 13%
Laggards 16%  Early Majority 34%

The Hype Cycle

Visibility

Technology Trigger  Trough of Disillusionment
Peak of Inflated Expectation  Plateau of Productivity
Slope of Enlightenment

"Mastering the Hype Cycle: How to Adopt the Right Innovation at the Right Time" Gartner Group 2008
Surgical Innovation: Historical Lessons

• Many more failures than successes

• Surgical innovations that withstand scientific scrutiny and the test of time are outliers

• Initial enthusiasm has no correlation with long-term success

Options for Surgical Graft

• Synthetic grafts
• Autologous grafts
  – Fascia lata
  – Rectus fascia
• Allogenic grafts
  – Fascia lata
  – Dermal grafts
• Xenografts
Misadventures with Synthetic Slings

- **Gore-Tex® (polytetrafluoroethylene)**

- **Mersilene® (polyester)**

- **Protegen® (woven polyester)**

- **OB Tape® (pressed polypropylene)**
The University of British Columbia

Synthetic Graft Materials

<table>
<thead>
<tr>
<th>Material</th>
<th>Brand</th>
<th>Permanent</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyglycolic acid</td>
<td>Dexon</td>
<td></td>
<td>$190</td>
</tr>
<tr>
<td>Polyglactin</td>
<td>Vicryl</td>
<td></td>
<td>$140</td>
</tr>
<tr>
<td>Polyethylene terphthalate</td>
<td>Morsilene</td>
<td>✓</td>
<td>$35-$100</td>
</tr>
<tr>
<td>Polypropylene</td>
<td>Marlex Prolene</td>
<td>✓</td>
<td>$65-$95</td>
</tr>
<tr>
<td>ePTFE</td>
<td>GoreTex</td>
<td>✓</td>
<td>$125-$170</td>
</tr>
<tr>
<td>Polypropylene</td>
<td>Gynemesh PS</td>
<td>✓</td>
<td>$295</td>
</tr>
</tbody>
</table>

The University of British Columbia

Mesh Erosion after Sacrocolpopexy
Surgical Technique: Partial Colpocelesis

Dissection/Excision

Surgical Goals
- Suture in mesh for traction
- Dissection of exposed mesh
- Excision of exposed mesh only

Layered Closure

Surgical Goals
- Interrupted sutures to invert field
- Closure of skin
Surgical Results for Mesh Erosion

<table>
<thead>
<tr>
<th>Partial Colpoclesis</th>
<th>1st</th>
<th>2nd</th>
<th>3rd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success</td>
<td>10 (50%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Failure</td>
<td>10 (50%)</td>
<td>8 (100%)</td>
<td>2 (100%)</td>
</tr>
<tr>
<td>Lost to f/u</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
<td>9</td>
<td>2</td>
</tr>
</tbody>
</table>

Overall Cure
* 50%

Failures
* 2nd & 3rd attempts all failed

Surgical Results for Mesh Erosion

<table>
<thead>
<tr>
<th></th>
<th>Partial Colpocleisis</th>
<th>Laparotomy/Excision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1st</td>
<td>2nd</td>
</tr>
<tr>
<td>Success</td>
<td>10 (50%)</td>
<td>0</td>
</tr>
<tr>
<td>Failure</td>
<td>10 (50%)</td>
<td>8 (100%)</td>
</tr>
<tr>
<td>Lost to f/u</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
<td>9</td>
</tr>
</tbody>
</table>

Overall Cure
- 79% (15/19 available for f/u)
- 26 surgeries (mean 1.7, R 1-4)

Failures
- 2 persistent mesh erosions
- 2 chronic smas tracts


Conclusions

**Surgically managed mesh erosion**
- 79% cure
- 32% risk of major complication

**Partial Colpocleisis**
- ~50% cure rate
- less morbid

**Excision by Laparotomy**
- better results after failed partial colpocleisis
- Cure rate of 62%
- 75% major complications

**Risk Factors for failure**
- Smoking

Mesh Related Complications in Sacral Colpopexy

<table>
<thead>
<tr>
<th>Graft</th>
<th>No. papers</th>
<th>N</th>
<th>Erosion rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autologous</td>
<td>3</td>
<td>88</td>
<td>0</td>
</tr>
<tr>
<td>Allograft</td>
<td>3</td>
<td>88</td>
<td>0</td>
</tr>
<tr>
<td>Polypropylene</td>
<td>5</td>
<td>211</td>
<td>0.5%</td>
</tr>
<tr>
<td>Mersilene</td>
<td>8</td>
<td>811</td>
<td>3.1%</td>
</tr>
<tr>
<td>Gore-Tex</td>
<td>5</td>
<td>350</td>
<td>3.4%</td>
</tr>
<tr>
<td>Teflon</td>
<td>5</td>
<td>119</td>
<td>5.5%</td>
</tr>
<tr>
<td>Marlex</td>
<td>6</td>
<td>402</td>
<td>5%</td>
</tr>
</tbody>
</table>


Mesh Erosion in the CARE Trial

- 322 women randomized
  - Mean age = 61±10 yrs, median parity = 3
  - 93% white, 74% married, 77% BMI< 30
  - 93% 2-year follow-up
- 20 erosions (6%)
  - 3 suture erosions
  - 17 mesh erosions
  - Mean interval to erosion = 313 days (range 45-744)
Mesh Erosion in the CARE Trial

Demographic variables

- Current smoking
  - 5/20 (25%) erosion
  - 18/302 (6%) no erosion
  - OR = 5.2 (CI 1.7, 16.0)
- No other differences in demographic variables

Surgical variables

- Concurrent hysterectomy
  - 12/20 (60%) erosion
  - 71/302 (24%) no erosion
  - OR = 4.9 (CI 1.9, 12.4)
- No differences in:
  - Culdoplasty
  - Mesh configuration

Impact of Surgical Materials on Erosion

<table>
<thead>
<tr>
<th></th>
<th>Erosion N=20</th>
<th>No erosion N=302</th>
<th>% with Erosion</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Graft</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Braided Polyester (n=134)</td>
<td>10</td>
<td>124</td>
<td>7.5</td>
<td>0.49</td>
</tr>
<tr>
<td>Polypropylene (n=156)</td>
<td>8</td>
<td>148</td>
<td>5.1</td>
<td>0.49</td>
</tr>
<tr>
<td>Porcine dermis (n=22)</td>
<td>2</td>
<td>20</td>
<td>9.1</td>
<td>0.64</td>
</tr>
<tr>
<td>ePFTE</td>
<td>0</td>
<td>5</td>
<td>0</td>
<td>1.0</td>
</tr>
<tr>
<td>ePFTE + synthetic</td>
<td>4</td>
<td>12</td>
<td>25</td>
<td>0.012</td>
</tr>
<tr>
<td>Any ePFTE (n=21)</td>
<td>4</td>
<td>17</td>
<td>19</td>
<td>0.03</td>
</tr>
<tr>
<td><strong>Vaginal Suture</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Braided Polyester (n=38)</td>
<td>1</td>
<td>37</td>
<td>2.6</td>
<td>0.49</td>
</tr>
<tr>
<td>Polypropylene (n=9)</td>
<td>0</td>
<td>9</td>
<td>0</td>
<td>1.0</td>
</tr>
<tr>
<td>ePFTE (n=172)</td>
<td>15</td>
<td>157</td>
<td>8.7</td>
<td>0.003</td>
</tr>
</tbody>
</table>
**Mesh erosion**

**17 Mesh**

- **Office management**: 17
  - Resolved: 0
  - Persisted: 16

- **Surgical management**: 17
  - Resolved: 2
  - Persisted: 6

- **Lost to Follow-up**: 1
  - Persistent: 5

- **2nd Surgery**: 2
  - Resolved: 0
  - Persisted: 1

- **3rd Surgery**: 1
  - Resolved: 0
  - Persisted: 1

• Successful Office management = 0
• Successful Surgical management = 2
• Failed Surgical management = 9
• Lost to f/u = 6
Conclusions From CARE Trial

Patient modifiable risk factor
- Smoking

Surgeon modifiable risk factors
- Use of ePFTE mesh
- Concurrent hysterectomy

Impact of Vaginal Suture Choice on Erosion Rate following Sacrocolpopexy

<table>
<thead>
<tr>
<th>Suture</th>
<th>Interval</th>
<th>n</th>
<th>Erosion rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethibond</td>
<td>June 1996</td>
<td>161</td>
<td>3.7%</td>
</tr>
<tr>
<td></td>
<td>May 2001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PDS</td>
<td>Aug 2001</td>
<td>254</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>May 2006</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Objective: Reduce intensity and time of inflammatory period

Synthetic Grafts: Characteristics Impacting Tissue Integration

**Pore Size**
- Macroporous (Marlex, Prolene, Atrium)
- Mixed (Teflon, Mersilene, Surgipro)
- Microporous (Gortex)

**Fiber Type**
- Monofilament (Marlex, Prolene, Atrium)
- Multifilament (Mersilene, Gortex)
Commonly Used Synthetic Materials

- **Marlex®**
- **Prolene®**
- **Mersilene®**
- **Gore-Tex®**

**Stiffness**
- Determined by:
  - Weave
  - Fiber type
- Prolene > Marlex > Mersilene > Gore-tex
- May relate to risk of visceral erosion

The Duke Experience

3.3% Erosion rate
## Synthetic Graft Erosion Rate in Sacral Colpopexy

*Retrospective case series, n = 273*

<table>
<thead>
<tr>
<th>Technique</th>
<th>Erosion rate</th>
<th>Interval (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASC</td>
<td>3.2%</td>
<td>15.6 mo.s</td>
</tr>
<tr>
<td>ASCP</td>
<td>4.5%</td>
<td>12.4 mo.s</td>
</tr>
<tr>
<td>ASCP/vaginal sutures</td>
<td>16%</td>
<td>9.0 mo.s</td>
</tr>
<tr>
<td>ASCP/vaginal mesh</td>
<td>40%</td>
<td>4.1 mo.s</td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td><strong>5.5%</strong></td>
<td></td>
</tr>
</tbody>
</table>

Prevalence and timing of erosion determined by:
- Volume of graft material
- Amount of exposure to vaginal field

### Surgical Outcomes for Mesh Erosion by Procedure

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Partial Colpoclesis (n=21/8/2)</th>
<th>Laparotomy (n=8/2)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBL (cc)</td>
<td>84</td>
<td>378</td>
<td>0.012</td>
</tr>
<tr>
<td>Hospitalization (days)</td>
<td>0</td>
<td>4.2</td>
<td>0.001</td>
</tr>
</tbody>
</table>

**Complications**

- Vesicovaginal fistula: 0% vs. 9%
- Small bowel obstruction: 0% vs. 4.8%
- Sacral osteomyelitis: 0% vs. 4.8%

**Microbiology**

- 62% (13/19) cultures positive
- 3 cultures (+) for Actinomyces
- 1 pap with Actinomyces
- No MRSA or VRE

**Outcomes with Actinomyces (2/4)**

- 7 surgeries
- 50% cure

*Quiroz L, Cundiff GW. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Feb;19(2):261-6.*
Autologous Fascia Lata

Additional Procedure
- (30 – 45 min.)
- Separate incision
- Patient repositioning

Operative Site Complications
- Brown and Guster (2000)
  - 11% significant donor site pain at 6 weeks
- Walter et al. (2001)
  - 13% seroma
  - 7% wound infection
  - 15% significant symptoms
  - 13% unsatisfactory cosmesis

Biologic Graft Materials
- Allografts (Cadaveric)
  - Fascia Lata
  - Dura
  - Dermal Derivatives
- Xenografts (Farm Animals)
  - Porcine Small Intestinal Submucosa
  - Porcine Dermal Derivatives
  - Bovine Pericardium
### Allograft Materials

<table>
<thead>
<tr>
<th>Material</th>
<th>Brand</th>
<th>Permanent</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freeze-dried fascia lata</td>
<td>Bard Tissue banks</td>
<td>?</td>
<td>$325-1,200</td>
</tr>
<tr>
<td>Solvent dehydrated fascia lata</td>
<td>Tutoplast (Mentor)</td>
<td>?</td>
<td>$495-1,200</td>
</tr>
<tr>
<td>Dermal</td>
<td>Repliform (Alloderm) (Boston Scientific)</td>
<td>?</td>
<td>$200-400</td>
</tr>
</tbody>
</table>

### Disappointing Results for Surgery with Allografts

<table>
<thead>
<tr>
<th>Author</th>
<th>Procedure</th>
<th>Graft</th>
<th>n</th>
<th>Optimal Outcome</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gregory</td>
<td>ASC</td>
<td>Synthetic mesh</td>
<td>19</td>
<td>89%</td>
<td>0.06</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Freeze dried Fascia Lata</td>
<td>18</td>
<td>61%</td>
<td></td>
</tr>
<tr>
<td>Fitzgerald</td>
<td>ASC</td>
<td>Freeze dried Fascia Lata</td>
<td>54</td>
<td>57%</td>
<td>n/a</td>
</tr>
<tr>
<td>SUS</td>
<td>Freeze dried Fascia Lata</td>
<td>27</td>
<td>59%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Xenograft Materials

<table>
<thead>
<tr>
<th>Material</th>
<th>Brand</th>
<th>Permanent</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Porcine small intestine submucosa</td>
<td>SIS (Cook)</td>
<td></td>
<td>$600-1000</td>
</tr>
<tr>
<td>Bovine pericardium</td>
<td>Synovis</td>
<td></td>
<td>$700 (2 x 12)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$599 (4 x 7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$995 (6 x 8)</td>
</tr>
<tr>
<td>Porcine dermis</td>
<td>Pelvicol (Bard)</td>
<td>✔️</td>
<td>$265-700</td>
</tr>
</tbody>
</table>

### Posterior Fascial Replacement
**Posterior Facial Replacement**

<table>
<thead>
<tr>
<th>Author</th>
<th>Approach</th>
<th>N</th>
<th>F/U mo.s</th>
<th>Improvement</th>
<th>Mesh Erosion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kohli et al.</td>
<td>Vaginal – Pelvicol</td>
<td>30</td>
<td>13 (8-17)</td>
<td>93% (Ap&lt;0.5)</td>
<td>0%</td>
</tr>
<tr>
<td>Mercer-Jones et al.</td>
<td>Transperineal- Prolene mesh</td>
<td>24</td>
<td>12 (3-47)</td>
<td>91% symptom improvement</td>
<td>12%</td>
</tr>
</tbody>
</table>


---

**RCT for Rectocele Repair**

Traditional posterior colporraphy and site-specific rectocele repair result in similar anatomic and functional outcomes.

The addition of a porcine-derived acellular collagen matrix graft does not improve anatomic outcomes and may worsen them.

Cohort Study of Sacrocolpopexy

n = 259 subjects

Autologous

23 (9%)

Pelvicol

102 (39%)

Synthetics

134 (52%)

"Significant vaginal support defect" is defined as a symptomatic first degree or any second degree or third degree prolapse. Kaplan-Meier curves are illustrated.
Patient Demographics

<table>
<thead>
<tr>
<th></th>
<th>Synthetics n=134</th>
<th>Pelvicol n=102</th>
<th>Autologous n=23</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>59 ± 10.6</td>
<td>54 ± 13.4</td>
<td>53 ±11.1</td>
<td>0.002</td>
</tr>
<tr>
<td>Previous Hyst (n, %)</td>
<td>103 (77)</td>
<td>55 (54)</td>
<td>13 (56)</td>
<td>0.001</td>
</tr>
<tr>
<td>Previous ASC (n, %)</td>
<td>5 (3)</td>
<td>5 (5)</td>
<td>2 (9)</td>
<td>0.57</td>
</tr>
<tr>
<td>Menopause (n, %)</td>
<td>94 (70)</td>
<td>53 (52)</td>
<td>14 (61)</td>
<td>0.017</td>
</tr>
<tr>
<td>HRT (n, %)</td>
<td>49 (37)</td>
<td>35 (34)</td>
<td>11 (48)</td>
<td>0.478</td>
</tr>
</tbody>
</table>

Group Differences

- Synthetic group
  - Fewer hysterectomies (22% v. 36% and 35%, p=0.038)
  - Fewer sacrocolpoperineopexies, rectopexies, and sacrohysteropexies
- Similar intraop and postop complications
- Median length of stay (3 days)
- Mean postop follow-up (1.1 years)
**Anatomic Failures**

<table>
<thead>
<tr>
<th></th>
<th>Synthetics n=105</th>
<th>Pelvicol n=93</th>
<th>Autologous n=15</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior Compartment</td>
<td>1</td>
<td>6</td>
<td>0</td>
<td>0.073</td>
</tr>
<tr>
<td>Posterior Compartment</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0.691</td>
</tr>
<tr>
<td>Apical Compartment</td>
<td>1</td>
<td>10</td>
<td>1</td>
<td>0.011</td>
</tr>
<tr>
<td>Re-operations for apical failure</td>
<td>0</td>
<td>7</td>
<td>0</td>
<td>0.009</td>
</tr>
</tbody>
</table>

**Graft-related Complications by Graft Group**

<table>
<thead>
<tr>
<th></th>
<th>Synthetics n=134</th>
<th>Pelvicol n=102</th>
<th>Autologous n=23</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Granulation</td>
<td>8</td>
<td>9</td>
<td>4</td>
<td>0.169</td>
</tr>
<tr>
<td>Erosion</td>
<td>4</td>
<td>11</td>
<td>1</td>
<td>0.045</td>
</tr>
<tr>
<td>VV Fistula</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0.097</td>
</tr>
<tr>
<td>Sinus tract</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0.001</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td>22</td>
<td>6</td>
<td>0.004</td>
</tr>
<tr>
<td>Operations for GRC</td>
<td>7</td>
<td>5</td>
<td>2</td>
<td>0.761</td>
</tr>
</tbody>
</table>
Graft-related Complications

- Erosion rates and hysterectomy (p=0.067)
  - Concomitant hysterectomy (9.4%)
  - Without hysterectomy (3.5%)
  - Sacrohysteropexies excluded

- 5 of 14 (36%) surgical revisions required removal synthetic mesh from prior ASC
  - 3 Pelvicol
  - 2 Autologous

Re-operation by Graft Type

<table>
<thead>
<tr>
<th></th>
<th>Synthetic Mesh</th>
<th>Pelvicol ®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrent POP</td>
<td>1%</td>
<td>10%</td>
</tr>
<tr>
<td>Surgery for Recurrent POP</td>
<td>0%</td>
<td>7%</td>
</tr>
<tr>
<td>Graft Erosion</td>
<td>3%</td>
<td>11%</td>
</tr>
<tr>
<td>Surgery for Graft Erosion</td>
<td>1 surgery: 3%</td>
<td>1 surgery: 2%</td>
</tr>
<tr>
<td></td>
<td>2 surgeries: 2%</td>
<td>2 surgeries: 0%</td>
</tr>
<tr>
<td></td>
<td>Total = 5%</td>
<td>Total = 2%</td>
</tr>
</tbody>
</table>
In Vivo Tissue Response of Allografts

Society for Gynecologic Surgeons Systematic Review Group Guidelines

- Biologic grafts and absorbable synthetic grafts offer no advantage over native tissue repair for anterior or posterior vaginal wall.
- No data to guide recommendations regarding non-absorbable synthetic mesh in the posterior wall or for vaginal apical suspension.

Cystocele Repair

<table>
<thead>
<tr>
<th>Author</th>
<th>Mesh</th>
<th>F/U</th>
<th>Success</th>
<th>Erosion</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Julian 96</td>
<td>Marlex</td>
<td>12 m</td>
<td>100%</td>
<td>0%</td>
<td>25% subj. cure</td>
</tr>
<tr>
<td>Flood 98</td>
<td>Marlex</td>
<td>36 m</td>
<td>100%</td>
<td>2%</td>
<td>55% subj. cure</td>
</tr>
<tr>
<td>Mahler 00</td>
<td>Prolene</td>
<td>24 m</td>
<td>70%</td>
<td>0%</td>
<td>Mesh excised</td>
</tr>
<tr>
<td>Dupont 04</td>
<td>Prolene</td>
<td>26 m</td>
<td>90%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Ding 04</td>
<td>Prolene</td>
<td>27 m</td>
<td>85%</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>DeTora 06</td>
<td>Gynemesh</td>
<td>24 m</td>
<td>90%</td>
<td>0%</td>
<td></td>
</tr>
</tbody>
</table>

RCT of Mesh vs. No-Mesh for Cystocele Repair

- 202 women
  - Stage 2 or greater cystocele
    - no SUI
- Randomized to
  - Standard anterior repair
  - Polypropylene mesh overlay

RCT of Mesh vs. No-Mesh for Cystocele Repair: Reoperations

**Mesh group (n=104)**
- 1 (1%) apical prolapse
- 4 (3.8%) TVT
- 10 (9.6%) for mesh exposure

**No-Mesh group (n=97)**
- 6 (6%) cystocele repair with mesh +/- TVT

Pros of Mesh
- Fewer Stage 2 recurrences (6.7% vs. 38.5%)
- Fewer symptomatic cystocele recurrences (4% vs. 15%)
- Lower mean PVRs

Cons of Mesh
- Longer surgery
- Greater EBL
- Higher de novo SUI (23% vs. 10%)
- 18 of 104 mesh exposures: 4/18 symptomatic, 10/18 office resection, 7/18 persistent exposure at 12 months

Society for Gynecologic Surgeons Systematic Review Group Guidelines

- Biologic grafts and absorbable synthetic grafts offer no advantage over native tissue repair for anterior or posterior vaginal wall.
- No data to guide recommendations regarding non-absorbable synthetic mesh in the posterior wall or for vaginal apical suspension.
- It is suggested that non-absorbable synthetic mesh may improve anatomic outcomes of anterior vaginal wall repair, but there are trade-offs in regards to the risk of adverse events.


Systematic Review of Meshes in Cystocele Repairs

- 10 RCTs included with 1087 patients
- Risk of recurrence after one year (Odds Ratio [OR])
  - OR for biologic mesh 0.56 (0.34 – 0.92)
  - OR for synthetic mesh 0.44 (0.21 – 0.89)
- Number needed to treat (NNT) to prevent one recurrence at 1 yr
  - NNT for biologic mesh : 13 (6.5 – 85.3)
  - NNT for synthetic mesh : 6 (3.0 – 33.8)
- Despite an objective difference in anatomic outcomes favoring mesh, there was no difference in recurrent prolapse symptoms among patients.

Foon et al Int Urogynecol J 2008; 19:1697-706
The University of British Columbia

Systematic Review of Apical Prolapse Surgeries

249 articles
19 conference abstracts

160 articles excluded

89 articles
19 conference abstracts included

Traditional vaginal repairs
54 studies

Sacral colpopexy
43 studies

Vaginal mesh kits
24 studies


Complication Grade By Repair Group

<table>
<thead>
<tr>
<th>Complications</th>
<th>Traditional Vaginal Repairs</th>
<th>Sacral Colpopexy</th>
<th>Mesh Kits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7,827</td>
<td>5,695.5</td>
<td>3,425</td>
</tr>
<tr>
<td>F/U (mo)</td>
<td>32.6</td>
<td>26.2</td>
<td>17.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Complications</th>
<th>Mesh erosion Fistula</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dyspareuna</td>
</tr>
<tr>
<td>UTI</td>
<td>Visceral injury Wound</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>Mesh erosion Fistula</td>
</tr>
<tr>
<td>Dyspareuna</td>
<td>Dyspareuna</td>
</tr>
</tbody>
</table>
### Sexual Dysfunction After Trocar-Guided Transvaginal Mesh Repair

- Prospective multi-center study
- N = 105
- Validated sexual function questionnaire – PISQ-12
- Sexual function scores deteriorate 1 year after trocar-guided transvaginal mesh surgery:
  - primarily partner-related and behavioral emotive items
  - No change in dyspareunia

Altman et al Obstet Gynecol 2009; 113:127-33

<table>
<thead>
<tr>
<th></th>
<th>Traditional Vaginal Repairs</th>
<th>Sacral Colpopexy</th>
<th>Mesh Kits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>95% CI</td>
<td>Range</td>
</tr>
<tr>
<td>Total Complication rate</td>
<td>15.3</td>
<td>14.7-16.3</td>
<td>0-25.8</td>
</tr>
<tr>
<td>Reoperation for prolapse recurrence</td>
<td>3.9</td>
<td>3.5-4.4</td>
<td>0-29.1</td>
</tr>
<tr>
<td>Total Reoperation rate</td>
<td>5.8</td>
<td>5.3-6.3</td>
<td>0-29.2</td>
</tr>
</tbody>
</table>
TVM: Weighing benefits vs. risks

- Improved anatomic outcomes for anterior wall only
  - ? Clinically relevant
- Increased cost
- Mesh erosion rate 5-10%
- Increased reoperation rate
- Decreased sexual function

Graft Augmentation: Conclusions

Utility of Grafts in POP surgery
- Long-term cure rates for prolapse still suboptimal
- Grafts may improve surgical outcomes in some uses
- This must be balanced by the disadvantages of grafts:
  - Graft-related complications
  - Increased cost
  - Negative impact on functional outcomes

Choice of Graft
- Ideal graft material not identified
- The best graft may differ by site and use
- Prudent use of graft materials until more data is available