To Mesh or Not to Mesh
That is the question

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Disclosures

• Nothing to disclose
A New Subspecialty

• Gynecologic Urology
• Urogynecology
• FPMRS Female Pelvic Medicine and Reconstructive Pelvic Surgery
• FPMRS- Female Pelvic Mesh removal and some incontinence and Prolapse surgery
The Extremes

- 22-year-old G3 P3 initially desiring a tubal ligation
- doctor suggested that she has some mild prolapse and may well be better off with a hysterectomy
- she underwent a hysterectomy and total prolift
- now complaining of mesh erosion, pelvic pain, dyspareunia
- unable to have intercourse for over a year and unable to urinate or have a BM without great difficulty

Mesh Erosion
To Be or not to be........

• Hamlet’s dilemma: suicide or fight

• Hamlet’s: To be, or not to be: that is the question: Whether 'tis nobler in the mind to suffer the slings and arrows of outrageous fortune, Or to take arms against a sea of trouble......

• To act or not to act

To Mesh or not to Mesh
Why ask the question?

• 300,000 women suffering from pelvic floor disorders require surgical repair annually

• One third for recurrent prolapse

• Very little data on efficacy

• Sacrocolpopexy and sling established
Over the next 30 years the rate of women seeking care for pelvic floor dysfunction will double.

Luber K 2001

Cumulative incidence of primary operations for pelvic organ prolapse and urinary incontinence by age group (years)

Olsen et al 1997
Risk Factors for Recurrent POP

- Poor tissue
- Impaired healing
- Chronic increases in abdominal pressure
- High grade cystocele (any anterior compartment defect)
- Stage three or four genital prolapse
- Age > 60

Risk Factors for Recurrent POP

- Inappropriate choice of procedure
- Lack of surgical expertise (not taking care of all the prolapse at the time)
- Recurrent intra-abdominal pressure
- Poor patient selection
To Mesh or no to Mesh?
Why use a graft?

One in three patients will have recurrence for stress incontinence and POP.

Why grafts?

- Extrapolating from surgical success with hernia and success of TVT
- Grafts will improve the function of the repair
- Make the repair more durable
- Decreases operative time and improved return to function
Why Consider Adjunct of Material for Prolapse Repair?

• Variable success rates for using native tissue
• Up to 29% reoperation can we do better?
• One can repair or reattach defective connective tissue to strong structures however the repaired or connect it to she remains weak
• If pelvic muscles and nerves are damaged, native tissues may not prove to be supportive in the long run
• Risk factors which led to prolapse are still there

Situations in Which Graphs Reinforcement Might be Indicated

• Nonexistent or sub optimal autologous tissue
• Presence of a connective tissue disorder
• Likelihood of unavoidable stress on repair
• Need to branch a space
• Inadequate vaginal length of caliber
• Denervated pelvic floor
Mesh Proliferation

• FDA approval process via 510K allowed a new device to be substantially equivalent to a device already on the market
• In 2010 there were at least 100,000 pelvic organ prolapse repairs using surgical mesh
• 75,000 of there were transvaginal procedures
• 260,000 surgeries for stress incontinence

What Happened in the USA?

• rapid development of new materials, products and procedures
• rapid FDA approval process
• rampant marketing
• training inappropriate providers
• patient and market pressures
FDA safety communication communication

• Update on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse
  • July 2011
Complications of Mesh Placement

- mesh erosion
- pain
- infection
- bleeding
- dyspareunia
- man parunia
- organ perforation
- urinary problems
- recurrent prolapse
- vaginal scarring and shrinkage
- emotional problems
- neuro muscular problems

Range of Percentage of Mesh Related Complications

<table>
<thead>
<tr>
<th>Reported Complications</th>
<th>Range Based on Case Series (%)</th>
<th>Range Based on RCT (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesh Erosion (exposure)</td>
<td>1.18.8</td>
<td>5-19</td>
</tr>
<tr>
<td>Buttock, groin or pelvic pain</td>
<td>2.9-15</td>
<td>0-10</td>
</tr>
<tr>
<td>De novo dyspareunia</td>
<td>2.2-15</td>
<td>8-27.8</td>
</tr>
<tr>
<td>Reoperation</td>
<td>1.3-7.6</td>
<td>3.2-22</td>
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Various Studies Including Cochrane Database
Mesh Erosion

• Complication unique to mesh
• Can occur several years after the index procedure
• Vaginal pain is associated with shrinkage
• 11.7% of patients in large retrospective cohort reported pelvic pain with shrinkage based on ultrasound (Velemir et al 2010)
Life Altering Sequelae

• There is a small but significant number of patients who have refractory pain and dyspareunia

• Registries are needed to understand the number of mesh augmented patients who truly suffered

• Many physicians in the USA improperly trained and marketed in weekend courses for profit

Breaking news: 5.5 million awarded to transvaginal mesh victim

• on June 4, 2012 Ethicon announced it was removing the TVT Secur system and Prolift pelvic floor repair system from market

• 25,000 cases filed against American medical systems spent 1.2 billion 70% slings

• 1.3 billion so far against Johnson & Johnson for Prolift, Prolift M, TVT Secure and Prosima

• 119 million to settle close to 3,000 cases against Boston scientific mostly slings

• Over 500 million dollars against CR Bard
Anterior Colporrhaphy vs. Transvaginal Mesh for POP

- Multicenter RCT, N=389
- Stage 2 anterior POP
- Anterior Colporrhaphy versus Anterior Prolift
- Primary outcome (assessed at 12 months)
  - POPQ stage 0-1
  - absence of vaginal bulge symptoms
  - no other pop surgery performed
    - Altman NEJM 2011

Anterior Colporrhaphy vs. Transvaginal Mesh for POP

- Primary outcome: Mesh 60.8% vs AC 34.5%
  - p<.001 RR 3.6 95%CI 2.2-5.9
- Anterior mesh associated with:
  - greater OR time (20 min) and blood loss (50 cc)
  - more post op SUI: 12.3% vs. 6.3% p=.05
  - increase bladder perforations: 3.5% to 0.5% p=0.07
  - 3.2% risk of mesh exposure
  - no difference in sexual function
Anterior Colporrhaphy vs. Transvaginal Mesh for POP

• Quality-of-life questionnaires: no difference
• Reoperation rate POP 1.3 vs. 3%
  \[ \text{RR} \, 2.28 \, 95\% \, \text{CI} \, 0.93 \, \text{to} \, 5.10 \]
• Mesh **decr** objective failure rate 14 vs. 49%
  \[ \text{RR} \, 3.50 \, 95\% \, \text{CI} \, 2.71 \, \text{to} \, 4.52 \]
• Mesh **decr** subjective failure rate 17 vs. 28%
  \[ \text{RR} \, 1.62 \, 95\% \, \text{CI} \, 1.22 \, \text{to} \, 2.14 \]

Maher Cochrane 2012

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Anterior Colporrhaphy vs. Transvaginal Mesh for POP

• AC **decr**. de novo prolapse in apical and posterior compartment 9.5% vs. 17.7%
  \[ \text{RR} \, 0.49; \, \text{CI} \, 0.25-.97 \]
• Mesh erosion 10.4%
• Surgery for mesh erosion 6.3%
• Mesh associated with increased OR time and blood loss
• Mesh tendency towards greater cystotomy rate and de novo SUI

Maher Cochrane 2012
Summary Anterior Prolapse Repair

- at least 5 RCTs comparing polypropylene mesh to native tissue in the anterior compartment each showing increased anatomical and subjective outcomes superior for polypropylene mesh
- no difference in outcomes for QoL or reoperation rate for prolapse
- mesh group consistent increased operating time, blood loss, apical and or posterior compartment pelvic organ prolapse
- Mesh extrusion rate was 10.4% with 6.3% undergoing surgical correction
- superior anatomic outcome for the polypropylene mesh vs. Biological graph
- mesh exposure rate significantly higher for polypropylene mesh compared to biologic graft

Maher/Cochrane

Cochrane Review 2013

- Forty RCT reviewed 3773 Women
- Abdominal sacral colpopexy better than vaginal sacrospinous in terms of a lower recurrent vault prolapse (RR 0.23, 95% CI 0.07 to 0.77)

- No statistically significant difference in re-operation rates for prolapse (RR 0.46, 95% CI 0.19 to 1.11).

Maher
Cochrane Review 2013

• Anterior repair was associated with more recurrent cystoceles than polyglactin mesh inlay (RR 1.39, 95% CI 1.02 to 1.90) or porcine dermis mesh inlay (RR 2.72, 95% CI 1.20 to 6.14) data on morbidity outcomes were lacking
• Anterior repair associated with more anterior compartment failures than for polypropylene mesh repair (RR 2.14, 95% CI 1.23 to 3.74) or armed transobturator mesh (RR 3.55, 95% CI 2.29 to 5.51).

Maher

Posterior Vaginal Prolapse Repair

• Fascial plication posterior repair > objective outcome to site specific posterior repair Level 1 Paraiso, Level 2 Abramov (Grade B)
• Increased dyspareunia with levatoplasty (Grade C)
• Transvaginal approach superior to trans anal approach (grade A)
• No evidence any benefit mesh or biologic repair for posterior wall prolapse (Grade B)
• Bowel symptoms improve in most patients
• 11% of patients develop new symptoms (Grade B)
Biologic Graft in Posterior Compartment

• 3 comparative studies
• one RCT evaluated anatomical and functional outcomes
• no difference in symptomatic or functional outcomes
• *it is suggested that native tissue repair remains appropriate in posterior vaginal wall repair when compared with biologic graft (Weak)*

Significant Problems with the Mesh Literature

• There is a difference between what is supported and what is being seen in practice
• Likely to do with skill and experience of experts reporting findings
• Complications of the infrequent operators are not reported
• Large-scale long-term follow-up studies not funded by national agencies
ACOG Committee Opinion #513

• POP vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent POP (especially anterior compartment) or with medical comorbidities that preclude more invasive and lengthier open or endoscopic procedures.

ACOG Committee Opinion 2011

• The risk/benefit ratio for mesh-augmented vaginal repairs must balance improved anatomic support of the anterior vaginal wall against the cost of the device and increased complications such as mesh erosion, exposure or extrusion; pelvic pain; groin pain; and dyspareunia.
ACOG Committee Opinion #513

• Surgeons placing vaginal mass should undergo training specific to each device and have experience with reconstructive pelvic surgical procedures and a thorough understanding of pelvic anatomy.

• Compared with existing mesh products and devices, new products should not be assumed to have equal or improved safety and efficacy and less long-term clinical data are available.

ACOG Committee Opinion #513

• ACOG and a AUGS strongly support continued audit and review of outcomes, as well as development of a registry for surveillance of all current and future vaginal mesh implants.

• Rigorous comparative effectiveness randomized trials of synthetic mesh and native tissue repair and long-term follow-up are ideal.
ACOG Committee Opinion #513

• patients should provide informed consent after reviewing the risks and benefit of the procedure as well as discussing alternative repairs.

Conclusion

• Accumulating evidence does not reflect world complications being seen by FP MR specialist
• Vaginal mesh carry significant risk which may be irreversible
• Risk of native tissue repair are well established.
• Some evidence of an atomic benefit but no evidence of symptomatic or quality-of-life benefit
• Appropriate training is essential
Conclusions

• Only experienced pelvic reconstructive surgeons should attempt to use this material
• Surgeons should track and report outcomes
• Care should be taken to carefully evaluate new products on the market before introduction into widespread use
• Informed consent should include the surgeons experience familiarity and long-term studies before inserting a foreign body into the patient