

Mesh Use in Transvaginal Pelvic Organ Prolapse Repair



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Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee

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Disclosures

- I have no financial relationships with industry.

SRG Original review 2008

Reviews

Graft Use in Transvaginal Pelvic Organ Prolapse Repair

A Systematic Review

*Vivian W. Sung, MD, MPH, Rebecca G. Rogers, MD, Joseph I. Schaffer, MD, Ethan M. Balk, MD, MPH, Katrin Uhlig, MD, MS, Joseph Lau, MD, Husam Abed, MD, Thomas L. Wheeler II, MD, MSPH, Michelle Y. Morrill, MD, Jeffrey L. Clemons, MD, David D. Rahn, MD, James C. Lukban, DO, Lior Lowenstein, MD, MS, Kimberly Kenton, MD, MS, and Stephen B. Young, MD, for the Society of Gynecologic Surgeons Systematic Review Group**

OBJECTIVE: To estimate the anatomic and symptomatic efficacy of graft use in transvaginal prolapse repair and to estimate the rates and describe the spectrum of adverse events associated with graft use.

DATA SOURCES: Eligible studies, published between 1950 and November 27, 2007, were retrieved through Medline and bibliography searches.

METHODS OF STUDY SELECTION: To assess anatomic and symptomatic efficacy of graft use, we used transvag-

Clinical Practice Guidelines on Vaginal Graft Use From the Society of Gynecologic Surgeons

*Miles Murphy, MD, MSPH, for the Society of Gynecologic Surgeons Systematic Review Group**

OBJECTIVE: To develop guidelines regarding whether graft or native tissue repair should be done in transvaginal repair of anterior, posterior, or apical pelvic organ

recommendations was based on a modification of the Grades for Recommendation Assessment, Development, and Evaluation system.

Adverse events

Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review

Husam Abed · David D. Rahn · Lior Lowenstein ·
Ethan M. Balk · Jeffrey L. Clemons ·
Rebecca G. Rogers ·
For the Systematic Review Group of the Society of
Gynecologic Surgeons

Int Urogynecol J (2011) 22:789–798

791

Table 1 Comparison of rates of adverse events between non-absorbable synthetic and biological graft

Adverse event graft type	Number of studies	Total number of adverse events/total number of patients	Summary adverse event rate ^a (95% confidence interval) (%)	<i>P</i> difference (subgroups)
Graft erosion				
All grafts	110	982/11,785	10.3 (9.7, 10.9)	
Non-absorbable synthetic	91	897/10,440	10.3 (9.7, 11.0)	NS
Biologic	19	85/1,345	10.1 (8.3, 12.3)	
Wound granulation tissue formation				
All grafts	16	92/1,762	7.8 (6.4, 9.5)	
Non-absorbable synthetic	9	49/1,113	6.8 (5.2, 8.9)	NS
Biologic	7	43/649	9.1 (6.8, 12.1)	
Dyspareunia				
All grafts	70	350/5,638	9.1 (8.2, 10.0)	
Non-absorbable synthetic	54	284/4,566	8.9 (8.0, 10.0)	NS
Biologic	16	66/1,072	9.6 (7.6, 12.1)	

NS statistically non-significant ($p > 0.05$)

^a Calculated by meta-analysis

Updated review



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Review

Graft and Mesh Use in Transvaginal Prolapse Repair

A Systematic Review

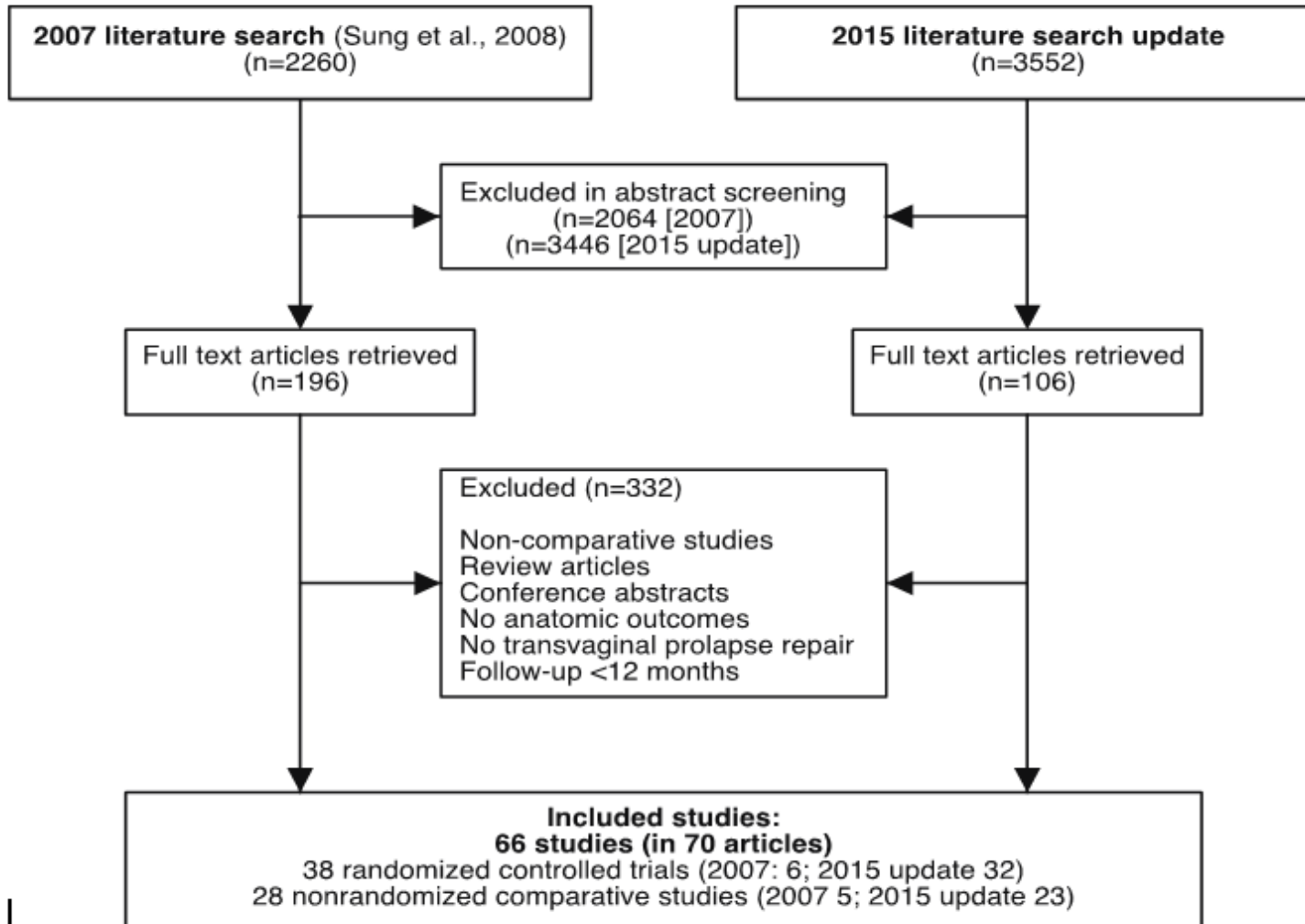
Megan O. Schimpf, MD, Husam Abed, MD, Tatiana Sances, MD, Amanda B. White, MD, Lior Lowenstein, MD, MS, Renée M. Ward, MD, Vivian W. Sung, MD, MPH, Ethan M. Balk, MD, MPH, and Miles Murphy, MD, MSPH, for the Society of Gynecologic Surgeons Systematic Review Group

Systematic Review PICO

- Population: Women undergoing transvaginal repair of prolapse
- Intervention: Mesh/graft surgery
- Comparator:
 - Native tissue repair
 - Other mesh/graft used
- Outcomes
 - Anatomic
 - Subjective/symptomatic
 - Mesh erosion*, return to OR

** For these reviews, mesh erosion may include extrusion, exposure or erosion, depending on what was reported in papers included*

Literature flow



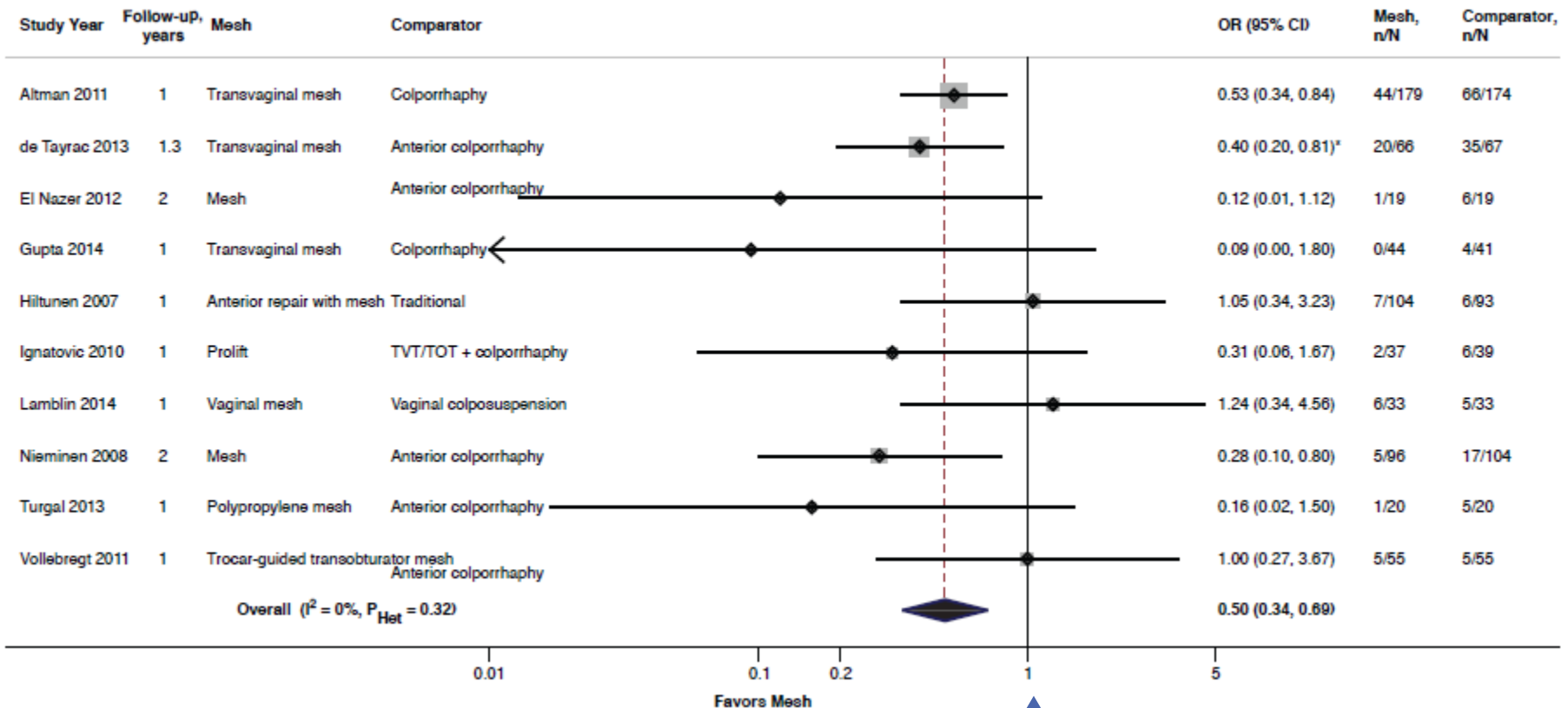
Anterior vaginal compartment

- 42 comparative studies
 - 26 RCTs
 - 16 cohort studies
 - 2008 review: 11 studies
 - Length of follow-up: Majority were about 12 mos, longest ~5yrs
- Synthetic non-absorbable mesh vs. native tissue repair
 - 20 studies: 13 RCTs, 7 cohort studies
 - High-quality evidence
 - Mesh use consistently resulted in improved anatomic outcomes vs native-tissue repair
 - No difference for subjective outcomes including quality of life, urinary and sexual function
 - Low-weight, macroporous monofilament polypropylene mesh used in all but one study
 - About half used a trocar-based, packaged kit
 - Kits: Perigee, Prolift, Nazca TC, Avaulta
 - Rest were self-tailored products
 - Erosion rates 1.4-19%
 - Operative mesh revision rates 3-8%

Outcomes used

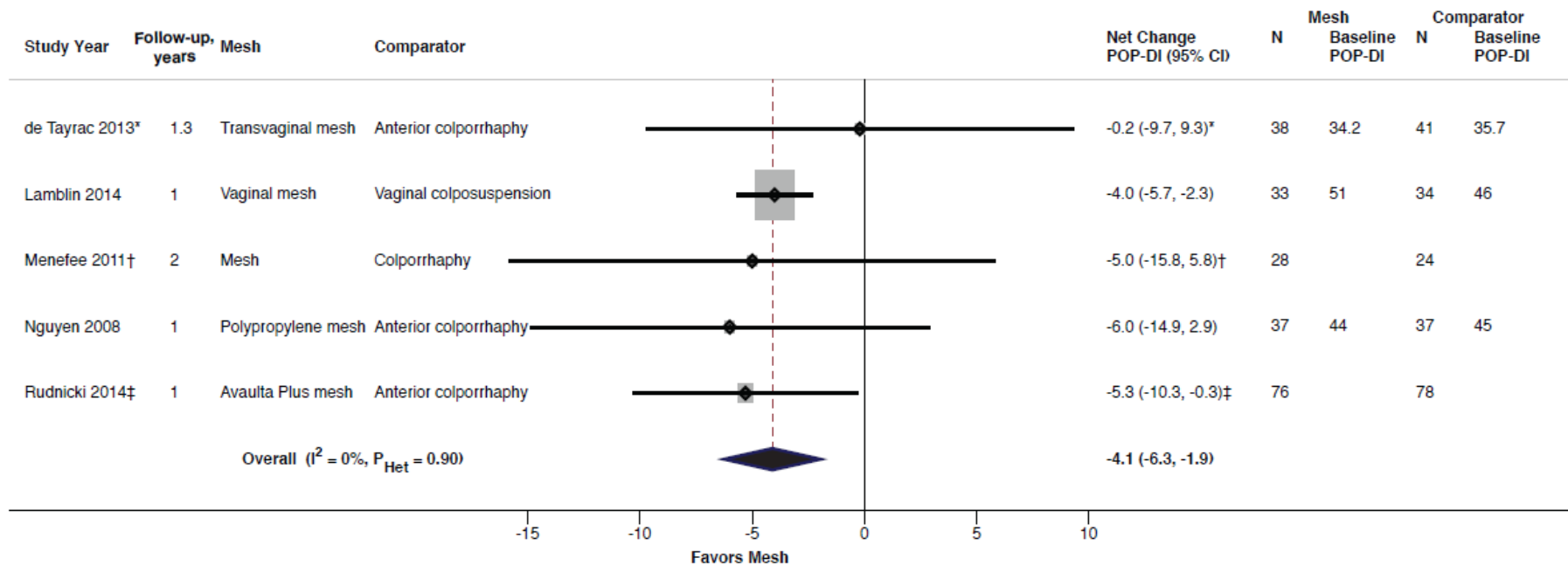
- Anatomic outcomes
 - POP-Q
 - Grade of cystocele (Baden Walker)
 - PFDI question 3: symptoms of bulge
 - Composite outcomes of bulge symptoms + anatomic exam findings
- Symptomatic outcomes
 - Symptoms of bulge, pain, slow urine stream, incontinence, urinary frequency, bladder emptying, constipation, functional status, postop pain, improvement (non-validated measures)
 - P-QOL
 - UDI/POP-DI/CRADI/PFDI
 - IIQ/PFIQ
 - APFQ
 - ICIQ
 - SEAPI
 - OAB-V8
 - POP-SS
 - ICI-UI
 - Kings Health Questionnaire
 - Satisfaction (VAS)
 - Quality of Life (VAS)
- Sexual function
 - PISQ-12
 - FSFI
 - APFQ
 - Dyspareunia (pre, postop, de novo)
 - Sexual activity rate (pre, postop)
- Erosion/extrusion/exposure of mesh
- Return to OR
 - SUI
 - Bleeding
 - Prolapse (vaginal or rectal)
 - Mesh exposure/extrusion/erosion

Meta-analysis for "bulge symptoms"



0.50 (0.34,0.69)
Favors use of mesh

Meta-analysis of POP-DI “bulge”



4.1 (6.3, 1.9)
Favors use of mesh

Comparing use of different grafts

- Graft/mesh vs other graft/mesh in anterior compartment
 - 11 studies: 4 RCTs and 7 cohort studies
 - Mesh consistently had superior anatomic outcomes vs graft
 - Pelvicol® was biologic graft of choice, no longer available in U.S.
 - Still heterogeneous, limited for mesh vs mesh

Anterior, apical or both?

- Comparing traditional anterior repair surgery to a mesh kit that incorporates higher anatomic support (eg, apical support) may not be 'fair' to this native-tissue surgery

We question whether comparing native tissue anterior colporrhaphy and mesh-augmented repair is truly a similar comparison. Many mesh-based anterior compartment repairs attach the mesh to either the proximal arcus tendineus fascia pelvis or the sacrospinous ligament, whereas a traditional anterior colporrhaphy does not take advantage of this element of apical support. It remains unclear whether the mesh augmentation or the additional apical support differentiates later success. Although many of these RCTs strictly enrolled patients with anterior wall prolapse, it is an unresolved question whether stage 3 anterior wall prolapse is truly isolated from apical support defects.

Multiple vaginal compartments

- 16 trials: 9 RCTs, 7 cohort
 - All but one published since 2008 review
- Synthetic non-absorbable mesh vs no graft (10 studies)
 - All used lightweight, macroporous polypropylene
 - Eight used a prepackaged kit (5 of those were Gynecare Prolift®)
- Anatomic outcomes favor mesh placement in most studies when the outcome of interest is overall prolapse staging using POP-Q
 - When reported by separate compartments, anterior compartment drives overall outcomes
- Mesh vs mesh (3 – all cohort)
 - No differences
 - Dyspareunia rates as high as 25%
 - Erosion rates up to 17%

Multiple vaginal compartments

- Erosion rates 3-36%
 - Highest rate of reoperation for mesh 8%
- Dyspareunia and urinary incontinence rates after surgery do not significantly differ between arms in any study
- High-quality evidence showing:
 - Synthetic non-absorbable mesh in multiple vaginal compartments improves anatomic outcomes compared to native-tissue repair
 - No difference for subjective outcomes including quality of life, urinary and sexual function at one-year follow-up

Systematic Review conclusions

- Best anatomic outcomes:
 - Anterior wall: synthetic non-absorbable mesh
 - Multiple compartments: synthetic non-absorbable mesh
- Best subjective outcomes:
 - No significant differences overall

In summary, there is high-quality evidence that the use of synthetic nonabsorbable mesh improves anatomic outcomes compared with native tissue anterior colporrhaphy. Data from meta-analyses confirm that mesh repairs also provided superior relief of subjective bulge symptoms. However, there is also high-quality evidence to suggest no difference for subjective outcomes including quality of life and urinary and sexual function.

SGS SRG Clinical Practice Guidelines

ANTERIOR WALL ONLY

- When performing isolated anterior vaginal wall repair, we recommend that native tissue repair remains appropriate compared with biologic graft (Strong).
- When performing isolated anterior vaginal wall repair, we suggest that native tissue repair remains appropriate compared with synthetic absorbable mesh (Weak).
- When performing isolated anterior vaginal wall repair, we recommend use of synthetic nonabsorbable mesh, specifically polypropylene, for anatomic objective cure of prolapse and bulge symptoms compared to native tissue repair, although there is not enough evidence to find a difference for urinary incontinence, pain, dyspareunia, or reoperation rate. (Strong).
- We are not able to provide practice recommendations regarding specific graft or mesh use due to the heterogeneity of the studies in which different graft/mesh products are compared at the anterior vaginal wall.

Cochrane Review Group

- 37 RCTs comparing transvaginal mesh or grafts to native tissue repair (all compartments)
- Awareness of prolapse at one to three years was less likely after mesh repair (risk ratio (RR) 0.66, 95% confidence interval (CI) 0.54 to 0.81, 12 RCTs, n = 1614, moderate-quality evidence).
 - If 19% of women are aware of prolapse after native tissue repair, between 10% and 15% will be aware of prolapse after permanent mesh repair.
- Rates of repeat surgery:
 - For prolapse - lower in the mesh group (RR 0.53, 95% CI 0.31 to 0.88, 12 RCTs, n = 1675, moderate-quality evidence).
 - For incontinence – no difference (RR 1.07, 95% CI 0.62 to 1.83, 9 RCTs, n = 1284, low-quality evidence).
 - For combined outcome of prolapse, stress incontinence, or mesh exposure – higher in mesh group (RR 2.40, 95% CI 1.51 to 3.81, 7 RCTs, n = 867, moderate-quality evidence).
 - If 5% of women require repeat surgery after native tissue repair, between 7% and 18% in the permanent mesh group will do so.
 - 8% of women in the mesh group required repeat surgery for mesh exposure.
- Recurrent prolapse on examination was less likely after mesh repair (RR 0.40, 95% CI 0.30 to 0.53, 21 RCTs, n = 2494, low-quality evidence).
 - If 38% of women have recurrent prolapse after native tissue repair, between 11% and 20% will do so after mesh repair.
- Permanent mesh was associated with higher rates of:
 - de novo stress incontinence (RR 1.39, 95% CI 1.06 to 1.82, 12 RCTs, 1512 women, low-quality evidence)
 - Bladder injury (RR 3.92, 95% CI 1.62 to 9.50, 11 RCTs, n = 1514, moderate-quality evidence).
- No difference between the groups in de novo dyspareunia (RR 0.92, 95% CI 0.58 to 1.47, 11 RCTs, n = 764, low-quality evidence).
- Effects on quality of life were uncertain due to the very low-quality evidence.

From 2016 to 2019 ...

Extending search to today

2007 literature search (Sung et al., 2008)
(n=2260)

2015 literature search update
(n=3552)

- Running the original search from 4/15/2015 until 12/21/18 in PubMed only:
 - 2421 total articles
- Extrapolating from prior papers, we suspect:
 - 15 new RCTs
 - 11 new nonrandomized comparative studies



Points for thought

- Over time, a substantial increase in studies, quality, diversity of outcomes has been seen
 - Need studies of longer duration, higher enrollment numbers
 - Unclear what synthetic material/placement technique is best
- Complication rates in high-quality study conditions do not seem to represent general practice
 - Skilled surgeons have lower complication rates
- Mesh is heterogeneous
 - Little evidence now comparing available options
 - This review excluded abdominal/robotic/laparoscopic mesh placement
 - A 2014 paper by our group evaluated midurethral slings:

UROGYNECOLOGY

Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis

Megan O. Schimpf, MD; David D. Rahn, MD; Thomas L. Wheeler, MD, MSPH; Minita Patel, MD, MS;
Amanda B. White, MD; Francisco J. Orejuela, MD; Sherif A. El-Nashar, MBBCh, MS; Rebecca U. Margulies, MD;
Jonathan L. Gleason, MD; Sarit O. Aschkenazi, MD; Mamta M. Mamik, MD; Renée M. Ward, MD;
Ethan M. Balk, MD, MPH; Vivian W. Sung, MD, MPH; for the Society of Gynecologic Surgeons Systematic Review Group

Safety of mesh

- Autoimmune Disease

- No increased risk with vaginal mesh

- Chughtai B, et al, *Am J Obstet Gynecol* 2017: 2,100 patients, up to 6 yrs

- No increased risk with hernia mesh in men

- Chughtai B, et al, *Hernia* 2017: 29,712 male patients undergoing mesh-based hernia repair
 - Chughtai B, et al, *Am J Surg* 2018: 1,894 male patients undergoing mesh-based hernia repair

- Cancer

- No increased risk with polypropylene mesh slings for incontinence

- Altman D, et al, *Obstet Gynecol*, 2018: 20,905 women
 - Linder BJ, et al, *Int Urogynecol J*, 2016: 2,474 women
 - King AB, et al, *Urology*, 2014: 2,545 women, 122 months

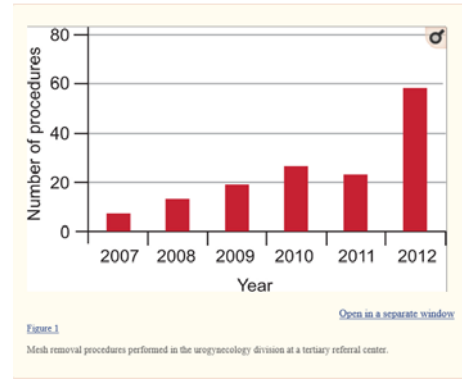
- No increased risk with transvaginal mesh or slings

- Chughtai B, et al, *J Urol*, 2017: ~12,200 patients, follow-up ~6yrs

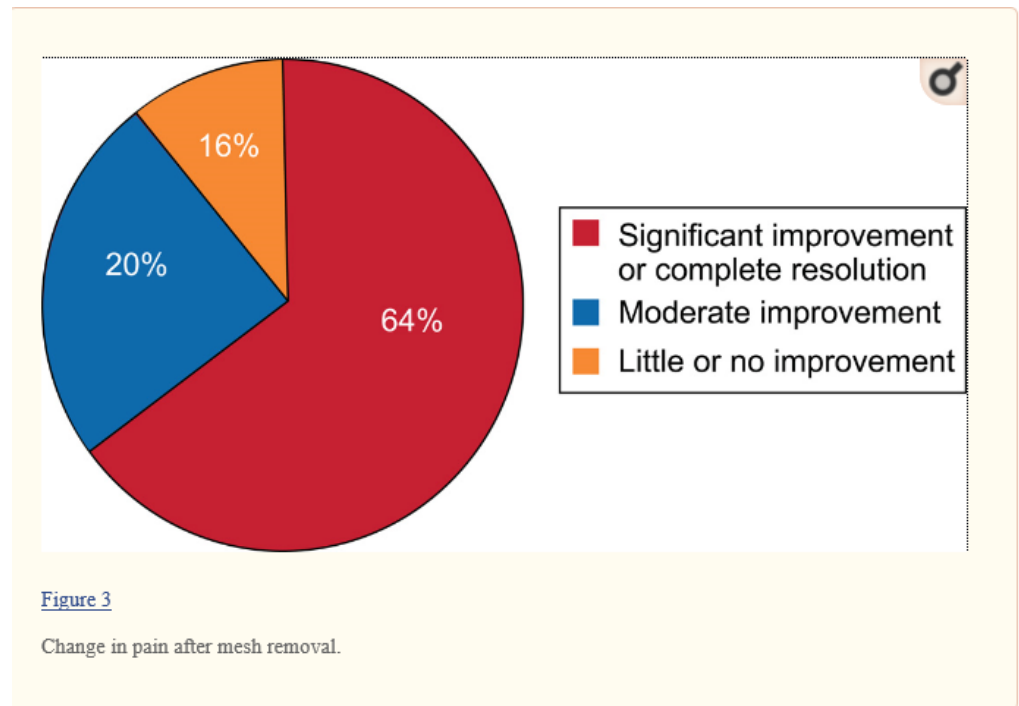
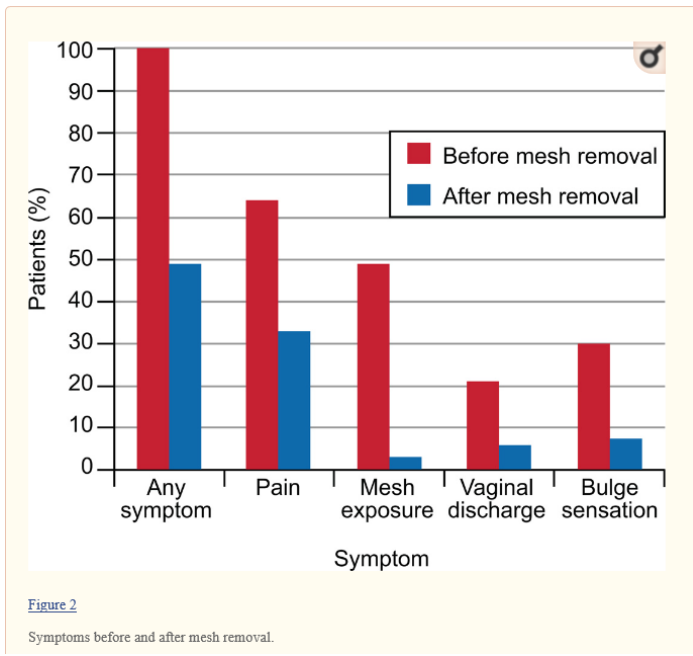
Surgeon Experience

- SGS Guidelines 2008
 - “need for practitioners to fully explain the relative merits of each alternative and carefully consider patients’ values and preferences to arrive at an appropriate decision”
- AUGS Guidelines
- Volume and complications
 - Hysterectomy and repairs for prolapse
 - 301 surgeons performed 4,238 hysterectomies
 - Rates of intraoperative complications:
 - High-volume: 4.4%
 - Intermediate: 11.6%
 - Low-volume: 6.3% (P = 0.011)
 - High-volume (OR, 0.42; 95% CI, 0.30-0.61) and low-volume (OR, 0.32; 95% CI, 0.15-0.66) surgeons were less likely than intermediate-volume surgeons to have intraoperative complications.
 - Difference between high- and low-volume surgeons was not statistically significant (OR, 0.77; 95% CI, 0.5-1.2).
 - Transvaginal mesh complications
 - 5,488 women had mesh implanted by 368 surgeons
 - Time to follow-up: 5.4 years
 - 218 women (4.0%) underwent mesh reoperation a median 1.17 years (0.58-2.90 IQR) after implant
 - Hazard of reoperation lower for patients of very high-volume surgeons
 - Risks for reoperation: younger age, concomitant hysterectomy, blood transfusion, medical comorbidities

Mesh removal



- Retrospective review of 90 women who had mesh removed by expert surgeons
- Presenting symptoms: mesh exposure (62%), pain (64%), dyspareunia (48%)
- Mesh exposure treated successfully in 95%
- Pain completely resolved in only 51%



Conclusions and Looking ahead

- Not all surgeons are the same
 - Fellowship/extensive years in practice
 - Ability to perform mesh and non-mesh options, offering patients a choice
 - Volume of FPMRS surgery
- Not all mesh is the same
 - Success and complications of polypropylene mesh cannot necessarily be extrapolated from one use to another (eg, vaginal vs abdominal mesh vs incontinence slings)
 - Biologic grafts, absorbable mesh have low success rates in current literature
 - Newer lighter-weight synthetic mesh is different than predecessors
 - 522 studies may help clarify or add new information for synthetic and biologic grafts
- Not all patients are the same
 - Prior failures, connective tissue disorders, prior extirpative surgery for cancer
 - Vaginal mesh surgery may still avoid risks of abdominal/laparoscopic surgery
 - Patient goals for surgery vary
- Native-tissue surgery is low risk and works for many patients
 - Value to having mesh augmentation available for those patients who have recurred following initial surgery, have advanced-stage prolapse or are at high risk
 - High-risk: levator muscle avulsion, family history, connective tissue disease, high-stage prolapse

Thank you

- For any questions:
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