GLOBAL CONGRESS ON MIGS

SYLLABUS

Debate 1 - Prolapse Surgery: Native Tissue Repair vs Mesh?
**Professional Education Information**

**Target Audience**
This educational activity is developed to meet the needs of surgical gynecologists in practice and in training, as well as other healthcare professionals in the field of gynecology.

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AAGL is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

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Debate 1 – Prolapse Surgery: Native Tissue Repair vs Mesh?

Chair: Andrew I. Sokol

Faculty: Peter Rosenblatt (MESH) vs Cheryl B. Iglesia (NATIVE TISSUE)

There has been much debate over the past several years about the outcomes of native tissue repairs versus mesh augmented repairs. FDA action, with the removal of vaginal mesh kits from the market, has re-focused attention on outcomes of native tissue repairs. However, graft augmentation is still in use, and recent studies have called into question the FDA’s actions prior to the completion of mandated surgical trials.

Learning Objectives: At the conclusion of this course, the participants will be able to: 1) Understand the most up-to-date evidence regarding the use of transvaginal mesh; 2) describe current FDA-approved uses of synthetic mesh in pelvic reconstructive surgery; and 3) discuss current medical society positions on the use of synthetic grafts in pelvic reconstructive surgery.
PLANNER DISCLOSURE
The following members of AAGL have been involved in the educational planning of this workshop (listed in alphabetical order by last name).
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Vadim Morozov, MD
Speaker: AbbVie
Consultant: Medtronic, Lumenis
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Other: Unrestricted educational grant to support NC FPMRS Fellow Cadaver Lab: Boston Scientific Corp. Inc.
Amy Park, MD
Speaker: Allergan
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Harold Y. Wu, MD*
Andrew I. Sokol, MD*

FACULTY DISCLOSURE
The following have agreed to provide verbal disclosure of their relationships prior to their presentations. They have also agreed to support their presentations and clinical recommendations with the “best available evidence” from medical literature (in alphabetical order by last name).
Cheryl B. Iglesia, MD*
Peter Rosenblatt, MD
Consultant: Boston Scientific, Medtronic, Solace, Coloplast
Legal Defense: Boston Scientific, Johnson & Johnson, Bard Medical
Stock Ownership: Origami, Solace

Content Reviewers have nothing to disclose.

Asterisk (*) denotes no financial relationships to disclose.

All relevant financial relationships noted have been mitigated.

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Debate 1
Prolapse Surgery: Native Tissue Repair vs Mesh?
Peter L. Rosenblatt, MD
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Mount Auburn Hospital, Cambridge
Assistant Professor, Harvard Medical School

Disclosure
- Consultant: Boston Scientific, Medtronic, Solace, Coloplast
- Legal defense: Boston Scientific, C.R. Bard, Johnson & Johnson
- Stock Ownership: Origami

Long-Term Outcomes of Robotic-Assisted Laparoscopic Sacrocolpopexy
- Prospective analysis of 253 patients who presented after > 5 years
- Success:
  • No retreatment for POP
  • No POP beyond hymen / no apical descent below -5
  • No POP symptoms
- Results
  • 89.3% success
  • Only 4.4% met both objective/subjective failure
  • 4% underwent subsequent POP repair
  • No mesh exposures or mesh-related complications.

MIS Sacrocolpopexy
- Salvage procedure
- Primary procedure

Culligan P. FPMRS 2020
OPTIMAL Randomized Trial

- Randomized trial of 374 women with prolapse at 9 centers
  - Sacrospinous ligament fixation (n=186)
  - Uterosacral ligament suspension (n=188)
- Primary composite outcome
- Subjective and objective prolapse
- Results at 2 years:
  - No significant difference in surgical success
    - SSLF (60.5%) v. ULS (59.2%).

Barber M. et al. JAMA 2014

July 2011

2011 FDA Safety Communication

2011 FDA Safety Communication: Serious Complications Associated with Transvaginal Placement of Surgical Mesh

- FDA has received over 1,500 additional reports on complications:
  - Erosion
    - Infection
    - Pain / dyspareunia
    - Urinary problems
    - Recurrent prolapse
    - Bowel, bladder, blood vessel perforation

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm

"Mesh used in transvaginal POP repair introduces risks not present in traditional non-mesh surgery for POP repair."
FDA 522 Studies
• On January 03, 2012, the FDA issued:
  • 88 post-market study orders to 33 manufacturers of urogynecologic surgical mesh for POP; and
  • 11 post-market study orders to seven manufacturers of single-incision mini-slings for SUI

April 16, 2019
• FDA orders BSC and Coloplast to stop selling transvaginal mesh or xenografts for POP in U.S.
• Mesh manufactures had not demonstrated reasonable assurance of safety and effectiveness
• Needed to work better than native tissue repair
• BSC and Coloplast required to continue follow-up on patients in 522 studies.

Sacrospinous hysteropexy with graft vs. vaginal hysterectomy with uterosacral ligament suspension
• 5-year results of RCT at 9 sites of PFDN
  • 183 women (93 hysteropexy, 90 hysterectomy)
  • Failure: POP retreatment, POP beyond hymen, POP symptoms
• Results through 5 years
  • 37% hysteropexy failure
  • 54% hysterectomy failure
• Adverse events (mesh vs. USLS)
  • Mesh exposure (8% vs. 0%)
  • Granulation tissue at 12 weeks (1% vs. 12%)
  • Suture exposure at 12 weeks (3% vs. 21%)
• "Our results suggest that this vaginal mesh hysteropexy procedure should be made available to patients."

Nager C, Visco A, Riach H. AJOG 2021

Where are we today?
• No transvaginal mesh (TVM) products or xenografts on the market
• Customized mesh at your own risk
• Sacrocolpopexy mesh still available
• Midurethral slings still available
• 522 studies on single-incision slings completed.

Device Procedure Penetration
What have we learned during this journey?

- We, as FPMRS surgeons, are frustrated with poor results.
- Midurethral slings and MIS sacrocolpopexy are gold standards.
- For the right patient, in the right surgeon’s hands, vaginal mesh can improve results.
- The surgery should fit the patient, and not the other way around…
- Reconstructive surgery should be done by surgeons who dedicate their practice to the field.

References

Prolapse Repair: Native Tissue
Cheryl B. Iglesia, MD FACOG
Director, Section of Female Pelvic Medicine and Reconstructive Surgery
MedStar Washington Hospital Center
Professor, Departments of Ob/Gyn and Urology
Georgetown University School of Medicine
Washington, DC

Disclosure
“I have no financial relationships to disclose”

Objectives
At the conclusion of this presentation, the participant should be able to:

✓ List advantages of native tissue repair and mechanisms of failure
✓ Highlight impact of prolapse surgery on sexual function
✓ Determine when mesh is indicated

Case: Patient MO
56 yo G2P2 female (IVF, SVD largest 7#) presents with worsening prolapse and mild SUI while exercising with trainer and Jimmy Fallon
No significant medical or surgical history

Her Goals for Surgery
• No more bulge
• No impact on sexual function
• Quick return to function (has a book tour)

PO-P-Q
BMI: 25
Stage 2
Aa +1 Ba +1 C 0
GH 4 PB 3 TVL 9
Ap -1 Bp -1 D -4

URODYNAMICS: No SUI
Options for treatment include all of the following:

A. Pessary
B. Laparoscopic /robotic hysterectomy and sacrocolpopexy
C. Vaginal mesh kit
D. Vaginal hysterectomy with native tissue
E. Hysteropexy with native tissue

Steps
1. Transvaginal Hysterectomy/bilateral salpingectomy
2. Placement of Uterosacral Sutures
3. Anterior Colorrhaphy
4. Tie Down Uterosacral Sutures to support apex
5. Cystoscopy
6. Close Cuff
7. Posterior colpoperineorrhaphy

Complications: USLS
- Ureteral obstruction rate:
  - 1 - 11% intraoperatively
  - 0.9% ureteral injury/ intervention
- Neural entrapment
- Suture erosion

USLS Anatomic Outcomes
- Anterior 81.2%
- Apical 98.3%
- Posterior 87.4%
- Stage 2 > Stage 3 prolapse (92.4% vs 66.8%; P = .06)
Risk of re-operation 7%
Primary Outcome

- Composite Outcome
  - No bulge beyond the hymen (apex not <1/3 TVL)
  - No bulge symptoms
  - No re-treatment (pessary or surgery)

2014: 2 Year Outcomes on 374 Patients

- No Difference Composite Primary Outcome
- Anatomic Failure ULS, 45% [76/172] vs SSLF, 52% [76/166]
- Retreatment 5.1% at 2 years
- Perioperative BPMT was not associated with greater QoL or anatomic success at 24 months

2018: 5 Year Outcomes 244 Patients

- No Difference
- Failure ULS 61.5% vs SSLF 70.3%
- Retreatment 10% at 5 years
- Prolapse symptoms scores POPDI unchanged

OPTIMAL 5 Year ULS vs SSLS

SF36 functional activity improves 2 years after USL

Pain is low and returns to baseline 4-6 weeks postop

• These techniques should not be abandoned for mesh procedures
• Native tissue repairs are still considered gold standard treatment

Patients are more willing to accept FAILURE over MESH Complications

(4% mesh exposure SCP; 8% TVM)

Genital hiatus > 3.5 cm associated with anatomic and surgical failure after native tissue repair at 2 years

Genital hiatus > 3.5 cm associated with anatomic and surgical failure after native tissue repair at 2 years
**SUPER Trial**

- 5 year data 156 patients
- Failure 37% VMH and 54% TVH ULS, p=.03
- 8% mesh exposure
- Granulation/suture exposure 12-21%


**Recurrence Following Apical Repair Based on MRI Imaging**

88 patients SUPER trial recurrent prolapse beyond the hymen @ 30-42 months
- 13/45 (29%) VM hysteropexy
- 23/43 (56%) TVH ULS


**Anatomic Failure with VM Hysteropexy or TVH ULS**

- Apical Descent in 85% VMH and 67% native tissue
- NOT Lengthening of the Anterior Vaginal Wall
- It’s All About that APEX!

**Risk factors for recurrence (SUPER trial)**

- Obesity
- Prolapse symptoms >5 years


**Considerations and Counseling**

- Consider Mesh Sacrocolpopexy:
  - Failed Native Tissue
  - Stage 3 or 4 Prolapse
  - Physically Fit, Active, <65 yo
  - GH >3.5 cm
  - D Point <4.25
- Counsel
  - Weight loss BMI <30
  - Pessary/early intervention

**Sexual Function after Native Tissue Prolapse Repairs**
Female Sexual Function (SF) and POP

- Women consider sexual dysfunction as a severe adverse event from surgery
- SF usually improves or remains unchanged after POP surgery

Sexual Function After Pelvic Organ Prolapse Surgery

Obstet Gynecol Oct 2020

Overall Sexual Function

- 44 (59%) Studies reporting SF validated questionnaires

<table>
<thead>
<tr>
<th>Surgery Type</th>
<th># Studies</th>
<th>Change PISQ-12</th>
<th>Mean of</th>
<th>WOMEN FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Native Tissue Repair</td>
<td>3</td>
<td>5.9 (5.8, 6)</td>
<td>IMPROVED</td>
<td>PISQ12=1413</td>
</tr>
<tr>
<td>Posterior Repair</td>
<td>2</td>
<td>5.1 (7.7, 16)</td>
<td>IMPROVED</td>
<td>PISQ12=1413</td>
</tr>
<tr>
<td>Uterosacral (USL)</td>
<td>4</td>
<td>5.2 (6.5, 7.9)</td>
<td>IMPROVED</td>
<td>PISQ12=1413</td>
</tr>
<tr>
<td>Sacropinous (SS)</td>
<td>4</td>
<td>3.7 (1.3, 5.8)</td>
<td>IMPROVED</td>
<td>PISQ12=1413</td>
</tr>
<tr>
<td>Transvaginal Repair</td>
<td>11</td>
<td>0.9 (3.1, 8.5)</td>
<td>IMPROVED</td>
<td>PISQ12=1413</td>
</tr>
<tr>
<td>Biologic Graft</td>
<td>2</td>
<td>12 (-3.6, 27.5)</td>
<td>UNCHANGED</td>
<td>PISQ12=1413</td>
</tr>
<tr>
<td>Sacrocolpopexy</td>
<td>8</td>
<td>5.7 (3.1, 8.4)</td>
<td>IMPROVED</td>
<td>PISQ12=1413</td>
</tr>
</tbody>
</table>

Conclusions

- Overall Sexual Function
  - IMPROVED: Native Tissue repairs, Posterior Repairs, Uterosacral Suspensions, Sacrospinous suspensions, and Sacrocolpopexy
  - UNCHANGED: Anterior Repairs, TV Mesh and Biologic Graft Repairs
- Postoperative Persistent Dyspareunia: 9-24%
- De Novo Dyspareunia: (excluding PR) 0-9%
- Although most studies are high quality, there is poor reporting of Sexual Function outcomes

Transvaginal Mesh (TVM) vs. Native Tissue (NT)

- 30 Papers on 24 studies (22 RCTs; 2 nRCS); N=7,543

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Mean (SD)</th>
<th>95% CI</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall SF (PISQ-12)</td>
<td>28.5 (2.6)</td>
<td>28.3 to 28.8</td>
<td>High</td>
</tr>
<tr>
<td>Overall SF (PISQ 12)</td>
<td>29.0 (2.6)</td>
<td>28.8 to 29.2</td>
<td>High</td>
</tr>
</tbody>
</table>

Sexual Function After Pelvic Organ Prolapse Surgery: A Systematic Review Comparing Different Approaches to Pelvic Floor Repair

Am J Obstet Gynecol June 2021
Sacrocolpopexy (SCP) vs. Native Tissue (NT)

- 5 studies (3 RCTs; 2 nRCS); N=472
- Quality of Outcomes: low to moderate

<table>
<thead>
<tr>
<th></th>
<th>SCP</th>
<th>NT</th>
<th>OR (95% CI)</th>
<th>Consistency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sexual Activity Pre</td>
<td>2 (n=213)</td>
<td>40.7%</td>
<td>45.5%</td>
<td>OR 0.80</td>
</tr>
<tr>
<td>Sexual Activity Post 1 (n=79)</td>
<td>45.2%</td>
<td>45.9%</td>
<td>OR 0.97</td>
<td>95% CI 0.40 to 2.36</td>
</tr>
<tr>
<td>Sexual Activity De Novo 1 (n=37)</td>
<td>27.8%</td>
<td>21.1%</td>
<td>OR 1.44</td>
<td>95% CI 0.32 to 6.53</td>
</tr>
<tr>
<td>Baseline Dyspareunia 1 (n=60)</td>
<td>31%</td>
<td>29%</td>
<td>OR 1.10</td>
<td>95% CI 0.36 to 3.32</td>
</tr>
<tr>
<td>Total Dyspareunia Post 3 (n=170)</td>
<td>6.7%</td>
<td>11.6%</td>
<td>OR 0.56</td>
<td>95% CI 0.12 to 2.51</td>
</tr>
<tr>
<td>De Novo Dyspareunia 1 (n=79)</td>
<td>4.8%</td>
<td>8.1%</td>
<td>OR 0.57</td>
<td>95% CI 0.09 to 3.59</td>
</tr>
<tr>
<td>Persistent Dyspareunia 1 (n=16)</td>
<td>44.4%</td>
<td>57.1%</td>
<td>OR 0.60</td>
<td>95% CI 0.08 to 4.40</td>
</tr>
<tr>
<td>Overall SF (PISQ-12) Preop</td>
<td>28</td>
<td>25</td>
<td>Mean difference -0.7</td>
<td>95% CI -1.8 to 0.4</td>
</tr>
</tbody>
</table>

Conclusion

For patient MO

1. TVH USLS APR achieves goals:
   - relief of bulge symptoms
   - return to activity
   - improvement sexual function
2. If fails then Laparoscopic Sacrocolpopexy (10% @ 5yrs)

References

References

Assembly Bill 1195 was signed into law on July 1, 2006 requiring local CME providers, such as the AAGL, to assist in enhancing the cultural and linguistic competency of California’s physicians (researchers and doctors without patient contact are exempt). This mandate follows the federal Civil Rights Act of 1964, Executive Order 13166 (2000) and the Dymally-Alatorre Bilingual Services Act (1973), all of which recognize, as confirmed by the US Census Bureau, that substantial numbers of patients possess limited English proficiency (LEP). It is the intent of the Legislature to encourage physicians and surgeons, continuing medical education providers located in California, and the Accreditation Council for Continuing Medical Education to meet the cultural and linguistic concerns of a diverse patient population through appropriate professional development.

**Cultural and Linguistic Competency**

**Linguistic Competence**: Providing readily available, culturally appropriate oral and written language services to limited English proficiency (LEP) members through such means as bilingual/bicultural staff, trained medical interpreters, and qualified translators.

**Cultural Competence**: A set of congruent behaviors, attitudes, and policies that come together in a system or agency or among professionals that enables effective interactions in a cross-cultural framework.

**Cultural and Linguistic Competence**: The ability of health care providers and health care organizations to understand and respond effectively to the cultural and linguistic needs brought by the patient to the health care encounter.

**Cultural competence** requires organizations and their personnel to:

- Value diversity.
- Assess themselves.
- Manage the dynamics of difference.
- Acquire and institutionalize cultural knowledge.
- Adapt to diversity and the cultural contexts of individuals and communities served.

**California Business & Professions Code §2190.1(c)(3)** states that associations that accredit continuing medical education courses shall develop standards before July 1, 2006, for compliance with the cultural competency requirements. The associations may update these standards, as needed, in conjunction with an advisory group that has expertise in cultural and linguistic competency issues. Cultural competency means a set of integrated attitudes, knowledge, and skills that enables a health care professional or organization to care effectively for patients from diverse cultures, groups, and communities. At a minimum, cultural competency is recommended to include the following: (A) Applying linguistic skills to communicate effectively with the target population. (B) Utilizing cultural information to establish therapeutic relationships. (C) Eliciting and incorporating pertinent cultural data in diagnosis and treatment. (D) Understanding and applying cultural and ethnic data to the process of clinical care, including, as appropriate, information pertinent to the appropriate treatment of, and provision of care to, the lesbian, gay, bisexual, transgender, and intersex communities.

**Title VI of the Civil Rights Act of 1964** prohibits recipients of federal financial assistance from discriminating against or otherwise excluding individuals on the basis of race, color, or national origin in any of their activities. In 1974, the US Supreme Court recognized LEP individuals as potential victims of national origin discrimination. In all situations, federal agencies are required to assess the number or proportion of LEP individuals in the eligible service population, the frequency with which they come into contact with the program, the importance of the services, and the resources available to the recipient, including the mix of oral and written language services. Additional details may be found in the Department of Justice Policy Guidance Document: Enforcement of Title VI of the Civil Rights Act of 1964 [http://www.usdoj.gov/crt/cor/pubs.htm](http://www.usdoj.gov/crt/cor/pubs.htm).

**Executive Order 13166, “Improving Access to Services for Persons with Limited English Proficiency”**, signed by the President on August 11, 2000 [http://www.usdoj.gov/crt/cor/13166.htm](http://www.usdoj.gov/crt/cor/13166.htm) was thegenesis of the Guidance Document mentioned above. The Executive Order requires all federal agencies, including those which provide federal financial assistance, to examine the services they provide, identify any need for services to LEP individuals, and develop and implement a system to provide those services so LEP persons can have meaningful access.

**Dymally-Alatorre Bilingual Services Act (Assembly Bill 305)** requires that state agencies that serve a substantial number of non-English-speaking people employ a sufficient amount of bilingual persons in order to provide certain information and render certain services in a language other than English.