Mesh Repair for High Grade Anterior-Apical POP: Which route should we choose?

Transvaginal Route: Lora A. Plaskon, MD, MS, FPMRS

Abdominal Route: Jennifer T. Anger, MD, MPH, FPMRS
Surgery for Ant-Apical POP

• High recurrence rates for anterior compartment when related to apex, but no real effective NTR to suspend the apex/uterus (Eilber 2012).

• Mesh for cystocele repair associated with higher anatomic cure and lower recurrence (Julieto 2016; Lamblin 2014)

• ASCP = “Gold Standard” for apical repair, although longevity for anterior compartment is lacking.
Surgery for Ant-Apical POP

- TVM initiated to:
  - Address the anterior compartment more effectively
  - Provide less-invasive surgical option (TV vs ABD)

- Apical attachments differ:
  - TVM: Bilateral SSL
  - ASCP: Sacral Promontory

- But … Mesh rests in the same plane between the vaginal epithelium and the bladder:
Surgery for Ant-Apical POP

• So …. Why such an unbalanced concern about the use of mesh placed TV versus ABD?

• Is the ASCP truly superior to TVM with respect to anatomical longevity and surgical morbidity?
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Mesh Sacrocolpopexy is the Gold Standard for Anterior/Apical Repair

Jennifer T. Anger MD, MPH

Associate Professor of Urology
Associate Director of Urological Research
Greetings from Los Angeles!
Disclosures:

Investigator Boston Scientific
Expert Witness Boston Scientific
Investigator Astellas
Introduction

• 25% of women report at least one pelvic floor disorder (Wu J, 2014)

• Approximately one in ten women undergoes surgery for prolapse or incontinence in her lifetime (Olsen A, 1997).

• Of these, up to thirty percent require a re-operation for recurrence of their prolapse or incontinence symptoms.

• One in nine women will undergo a hysterectomy in her lifetime, and up to 10% of these women will require surgery for symptomatic vaginal vault prolapse (Marchionni M, 1999).

• The search for the ideal repair for vaginal vault prolapse has led to the invention of several approaches to this problem (Elliott D, 2006).
Classic Cystocele Repair: Doomed to Fail When Apical Descent Present

Note location of Cervix!

Cervix is still at introitus, you just can’t see it here!
Cystocele vs. Apical Prolapse

Isolated Cystocele: a rare entity

Isolated Vault Prolapse: a rare entity

Advanced anterior vaginal wall prolapse is highly correlated with apical prolapse (Rooney K, 2006).
“When a curtain falls off the rod, we don’t cut off the bottom of the curtain”

- Beth Mueller

10 year reoperation rate
20% after anterior repair vs. 11% anterior/apical repair

Eilber, 2013
Several mesh kits have been designed to address vaginal prolapse with the following goals:

- Vaginal approach
- Prevent cystocele recurrence by mesh augmentation
- Address apical descent through sacrospinous ligament fixation
- Address apical descent through a user-friendly extraperitoneal approach
- Potential uterine preservation
Ligaments used for Vaginal Approaches to Prolapse Repair
As numbers of mesh-related complications rose to over 3,874, an updated warning by FDA on July 13, 2011 stated the following:

“The FDA is issuing this update to inform you that serious complications associated with surgical mesh for transvaginal repair of POP are not rare. This is a change from what the FDA previously reported on Oct. 20, 2008. Furthermore, it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk……”
KEEP THIS AWAY

FROM MY VA-J-J!!!
WHY NOT TRANSVAGINAL MESH

• Transvaginal mesh is good when the vaginal incision overlying it is small (sling) or nonexistent (ASC)

• Transvaginal mesh is good when in the hands of experts who have specialized training in its use.

• Experts are a small proportion of mesh users. Hence, outcomes not easily reproduced.

• Even in the hands of experts complications of TV mesh are higher than those of ASC.
Why is sacrocolpopexy better than a vaginal repair?

- Sacrocolpopexy does not rely on inherently weak ligaments
- Mesh restores tissue strength in women who lack it
- ASC preserves vaginal length (De la Cruz, 2014)
- ASC associated with less dyspareunia (Maher, 2011)
- Mesh-related complication rates from sacrocolpopexy mesh are low and acceptable.
Why is sacrocolpopexy better than a non-mesh vaginal repair?

• Siddiqui et al. conducted a systematic review of outcomes of native tissue vaginal repairs to mesh sacrocolpopexy

• Systematic Review Group of the Society of Gynecologic Surgeons

• 12 studies (5 RCTs) comparing durability

• 79 studies measuring adverse events
Why is sacrocolpopexy better than a non-mesh vaginal repair?
Why is sacrocolpopexy better than a non-mesh vaginal repair?

• Adverse events from 79 studies:
  – Ileus/SBO 2.7% vs. 0.2% (p < 0.01)
  – Mesh or suture complications 4.2% vs. 0.4% (p < 0.01)
  – Thromboembolic phenomena 0.6% vs. 0.1% (p = 0.03)

• No difference in reoperation

CONCLUSIONS:
“When anatomic durability is a priority, we suggest that mesh sacrocolpopexy may be the preferred surgical option. When minimizing adverse events or reoperation, there is no strong evidence supporting one approach over the other.”
Long-Term Outcomes also Better

• Analysis of Public Use Files from CMS:
  - Apical repairs (1999) with ten years follow-up

<table>
<thead>
<tr>
<th>Outcome</th>
<th>10 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Abdominal</td>
</tr>
<tr>
<td>N = 300</td>
<td>126</td>
</tr>
<tr>
<td>Non-surgical</td>
<td>1.6%</td>
</tr>
<tr>
<td>Any prolapse surgery</td>
<td>7.9%</td>
</tr>
</tbody>
</table>

• Higher rate of dyspareunia in vaginal group (52.3% vs. 38.1%, \( p = 0.02 \))  
  Khan, unpublished
A Return to Sacrocolpopexy

• The high complication rate of vaginally placed mesh has led many pelvic surgeons to return to the gold standard technique for vaginal vault prolapse - the abdominal sacrocolpopexy.

• A systematic review by Diwadkar et al. compared complication and reoperation rates after apical vaginal prolapse surgical repair:
  – Traditional vaginal surgery: Highest reoperation rate
  – Vaginal mesh kits: Highest complication rate

Obstet Gynecol 113: 367-73, 2009
SACROCOLPOPEXY MESH 0.5%

POSTERIOR PROLAPSE MESH 3.70%

UNKNOWN/MISC MESH PRODUCT 3.00%

SINGLE INCISION TOT 8.80%

ANTERIOR PROLAPSE MESH 8.90%

GENERAL PROLAPSE MESH 17.70%

RETROPUBIC SLINGS 30.20%

TOT 27.10%

PRODUCT LIABILITY CLAIMS FILED

Wood, et al.
SUFU 2016
Is it a fad or will it become the new gold standard?

Slide courtesy of Dr. Courtenay Moore
A Return to the Abdominal Sacrocolpopexy

• In operations where a pure laparoscopic approach is feasible, such as in appendectomy and cholecystectomy, the use of robotic assistance may not be justifiable.

• However, the use of robotic technology has made laparoscopic sacrocolpopexy a more feasible procedure for many pelvic surgeons.

• The dexterity of the robot and precision of instruments allow suturing of mesh to the vagina to be accomplished with ease.

• Further, the three-dimensional imaging of the robotic camera provides close visualization of the vessels overlying the sacral promontory.
Who is the ideal candidate for a robotic sacrocolpopexy?

- Not just for young athletes with isolated apical prolapse anymore!
- Good candidates are women with:
  - *Symptomatic* prolapse AND
  - Stage II or greater prolapse (that extends within 1 cm of introitus with strain) AND
  - A significant apical component (apex that descends to approximately 1/2 of total vaginal length with strain) AND
  - A negative cardiac stress test (patient is a candidate for laparoscopy and can tolerate steep Trendelenberg)
Who is the ideal candidate for a robotic sacrocolpopexy?

- Patients who desire vaginal depth & sexual function
  - Maher et al. 2011
  - TVL was significantly reduced in the vaginal group (p<0.001)

- Rule of Thumb: If a patient laughs at you when you ask about sexual activity, THINK COLPOCLEISIS!

Photos courtesy of Courtenay Moore, MD
Sacrocolpopexy: What trainees see
Vaginal Vault Suspension: What trainees see
Thank you
Data from the ACCESS trial revealed that, beyond the purchase price, robotic and laparoscopic costs were comparable.

- *Day of surgery costs 11.5K (lap) vs. 12.6K (robotic), p= 0.161*

One year outcomes:

- 100% robotic arm (97% lap) considered pOP symptoms improved
- Sexual function improved in both cohorts
- No woman had a sacrocolpopexy mesh complication or reoperation for mesh exposure

Kenton, 2016
You get what you pay for.
This *Never* Happens in Abdominal Surgery

TEXAS JURY AWARDS
$73 MILLION IN TRANSVAGINAL MESH LAWSUIT

TransVaginal Mesh Lawsuit

Do you or a loved one have complications from a surgery where TransVaginal Mesh Implants were used?

Thousands of women have undergone surgery to repair Pelvic Organ Prolapse or Stress Urinary Incontinence with surgical mesh implants.

The FDA has issued a safety notice that these products should be classified as posing a high risk to patients.
COME TO SUFU

SUFU 2017 Winter Meeting
February 28 - March 4, 2017
Hyatt Regency Scottsdale Resort & Spa
Scottsdale, Arizona,

AND
COME TO

7:00am
TOMORROW
Women in Urology Rock!
Transvaginal Mesh: Keep it Effective
Keep it Affordable
Keep it Safe

Society for Women in Urology, January 20, 2017

Lora Plaskon MD MS FPMRS

EvergreenHealth, Kirkland, Washington
Disclosures - None
One size does not fit all, but once it’s out... native tissue alone will not do

Photos credit Bernard Haylen MD 2017
Patient Wants POP Surgery, Things for Surgeon to Consider

• Is this her first POP repair?
• Why repeat a failed native tissue repair (NTR)?
• What are her risk factors for intra-op complications?
• Are their other medical conditions to consider?
• What are her risk factors for postop complications?
Offer Her Choice-Empower with Information, Things for Patient to Consider

- What are her goals from a surgical repair? Bulge? Incontinence? LUTS? UTIs?
- Does she also have vaginal work to be done? Sling? Perineoplasty?
- Surgeons – are you a one-trick pony? Or a triple threat? Be honest!

She can, Act, Sing, and Dance!

Go see LaLaLand!

She can, Manage conservative care, Operate in abdomen, and Operate transvaginally!

Mia Swartz MD MS FPMRS
TVM – The Details REALLY Matter!

- **Lonestar retractor**, solo surgeon
- Local injection, *max Marcaine*
- **Thick flaps**
- Small *tunnel* incision
- **Reduce POP** before onlay graft
- Isolate SSL, *control bleeding*
- **Trim mesh** to fit defect
- **No tension** on mesh or incision
- **Cystoscopy and rectal exam**
- Interrupted absorbable closure
- Vaginal **pack** and Foley <24 hours
Transvaginal Mesh Prolapse Repair
It’s Natural Orifice Surgery

Advantages:
- No external incisions
- No risk intra-abdominal complications
- No risk internal or ab wall hernia
- Less operative expense/time
- Shorter recovery
- Better objective level 2 anterior support
- Equivalent subjective patient outcomes

Disadvantages:
- Worse objective apical POP outcomes (who cares? surgeon? patient?)

Similarities to abdominal mesh placement:
- Mesh is mesh – the vagina doesn’t know how it got there
- Mesh extrusion/erosion
- Scar/contraction/change in vaginal wall compliance
- Litigation risk - counsel&consent!
TVM – Let’s Look at the Evidence

- Hard to compare apples to apples in TVM studies
- Most big TVM studies with long follow up were done with Prolift
- Focus on “pure” RCTs, high level studies, skeptical of meta-studies data washout
Efficacy
SCP Efficacy Over Time – Not So Great
Apex Up, But Hammock Sags!


- SCP+Burch with 7 year follow-up
  - Half patients had symptomatic POP failure
  - Defined Ba or Bp at stage 3 (it’s out again!)
  - 10% mesh erosion rate at 7 years

SCP misses a/p level 2 support half the time!
TVM is Better Than Native Tissue
Anterior Colporrhaphy for Level 2 Support


Anatomic success (\leq Stage I): Mesh – 87% AC – 55%

Dyspareunia:
Mesh – 9% AC – 16%

Subjective Sx Scores Improved in All; More so in the Mesh group
But not statistically significant between the groups at 1 year

12 RCTs Objective cure greater with anterior mesh (OR=1,28 [1,07-1,53]

RCT TVM vs cystorrhaphy POP < stage 1, TVM 60%, cystorrhaphy 30%
TVM Benefit – Better Level 2 Support
SCP Level 2 – Depends How Low Do You Go?

- Laparoscopic sacrocolpopexy: how low does the mesh go? Ultrasound Obstet Gynecol. 2016 Feb 15
  Wong V etal
  - 97 patients SCPs, follow-up of 3.01 years, 61.8% recurrent anterior POP
  - Mesh position, mobility associated with recurrent cystocele on exam and ultrasound (p < 0.01).
  - For every millimeter the mesh is located further from the bladder neck on Valsalva, the likelihood of cystocele recurrence is increased by 6-7%.
TVM – Long Term Efficacy

- We need data – there’s not much out there – and nothing for the current products on the market
- The French got really good at implanting Prolift though
- Let’s go to France (and Belgium)
What’s the Surgical Reintervention Rate for TVM?

Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years’ median follow-up

Laurent de Landsheere, MD; Sharif Ismail, MD; Jean-Philippe Lucot, MD; Valérie Deken, ScD; Jean-Michel Foidart, MD, PhD; Michel Cosson, MD, PhD

AJOG, 2012

- N = 600 consecutive patients with TVM
  - 524 (88%) included -- 68 lost to fu, 8 died
  - Mean f/u duration: 38 mo (range 15-63 mo)

<table>
<thead>
<tr>
<th>Type of Prolift</th>
<th>Count (Percentage)</th>
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<tbody>
<tr>
<td>Anterior only</td>
<td>48 (9.15)</td>
</tr>
<tr>
<td>Posterior only</td>
<td>103 (19.65)</td>
</tr>
<tr>
<td>Anterior and posterior</td>
<td>373 (71.2)</td>
</tr>
<tr>
<td>Anterior and posterior with uterine preservation</td>
<td>286 (54.6)</td>
</tr>
<tr>
<td>Anterior and posterior with concomitant hysterectomy</td>
<td>22 (4.2)</td>
</tr>
<tr>
<td>Total (previous hysterectomy)</td>
<td>65 (12.4)</td>
</tr>
<tr>
<td>Mesh-related complication</td>
<td>19 (3.6)</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Mesh exposure</td>
<td>13/524 (2.5)</td>
</tr>
<tr>
<td>Anterior</td>
<td>5/421 (1.2)</td>
</tr>
<tr>
<td>Posterior</td>
<td>8/476 (1.7)</td>
</tr>
<tr>
<td>Mesh infection</td>
<td>1/524 (0.2)</td>
</tr>
<tr>
<td>Severe symptomatic mesh retraction</td>
<td>2/524 (0.4)</td>
</tr>
<tr>
<td>Rectal compression</td>
<td>2/476 (0.4)</td>
</tr>
<tr>
<td>Symptomatic synechia</td>
<td>2/524 (0.4)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prolapse recurrence</th>
<th>16 (3)</th>
<th>23 (3.2–61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>After anterior Prolift</td>
<td>1/18 (1.3)</td>
<td>21 (12–43)</td>
</tr>
<tr>
<td>Rectocele</td>
<td>3/48 (6.2)</td>
<td>23 (12–43)</td>
</tr>
<tr>
<td>Uterine prolapse</td>
<td>1/48 (2.1)</td>
<td>14</td>
</tr>
<tr>
<td>After posterior Prolift</td>
<td>4/103 (3.9)</td>
<td>23 (3–41)</td>
</tr>
<tr>
<td>Cystocele</td>
<td>2/103 (1.95)</td>
<td>31 (21–41)</td>
</tr>
<tr>
<td>Uterine prolapse</td>
<td>2/103 (1.95)</td>
<td>15 (3–26)</td>
</tr>
<tr>
<td>After anterior and posterior Prolift</td>
<td>8/373 (2.1)</td>
<td>25 (5–61)</td>
</tr>
<tr>
<td>Uterine prolapse</td>
<td>7/373 (1.9)</td>
<td>28 (5–61)</td>
</tr>
<tr>
<td>Enterocele&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1/373 (0.2)</td>
<td>7</td>
</tr>
</tbody>
</table>
In Best Hands 5-year POP Recurs: TVM 3%, SCP 20%

Figure
Time to reoperation after transvaginal Prolift mesh repair

CARE Trial – SCP POP recurrence 7 years

Long-term Outcomes Following Abdominal Sacrocolpopexy for Pelvic Organ Prolapse


Ingrid Nygaard, MD
Efficacy of SCP depends on who’s doing it, and how it’s done…
In Experienced Hands – Very Little Difference in Lap-Ab vs Vag Mesh


- Laparoscopic sacral hysteropexy (74) and vaginal mesh hysteropexy (76) had similar 1-year objective cure rates and high satisfaction.

- Laparoscopic procedure was longer OR time (174 vs 64 minutes, P < .0001) and total operating time (239 vs 112 minutes, P < .0001)

- There were no differences in blood loss, complications, and hospital stay. Mesh exposure 2.7% laparoscopic vs 6.6% vaginal hysteropexy (P = .44).

- QOL improved for both groups with no difference between groups.
SCP vs TVM efficacy— it’s a wash!


**Conclusions:**
- Mesh (ab or vag) indicated for recurrent advanced POP
- Need high volume, expertise in technique, handle complications
- Controversy in how to teach techniques, track outcomes
- Cost considerations more expensive lap/robotic and longer length of stay
- TVM lacks long term outcomes
TVM - In My Experience
Over 1000 TVM Implants, 2005-present

- Preop:
  - Average age 65
  - Nonsmoker
  - Most are re-do’s, post-hysterectomy, +/- HRT or topical estradiol

- Intraoperative:
  - Blood loss average <50cc
  - Operative time a/p mesh, average 90 minutes
  - Half patients go home, other half <24 hour stay

- Postop:
  - UTI/BV/vaginitis in first 6 weeks 3-5%
  - Voiding dysfunction – high in first month, normalizes in 3-4 months, PT rehab 75%

- Longterm followup (2-10 years):
  - Extrusion rate <2% all have been delayed by years, no erosions
  - Objective failure increases with time, only operate if subjective bother – very few
  - Majority of patients not sexually active, overall high satisfaction, would do it again
Cost
TVM is Less Expensive Than SCP

- Robotic compared with laparoscopic sacrocolpopexy: a randomized controlled trial. Obstet Gynecol. 2014 Jan;123(1):5-12 Anger JT et al

- Robotic compared with laparoscopic ($12,586 compared with $11,573; P=.160) or hospital costs over 6 weeks ($13,867 compared with $12,170; P=.060). The robotic group had longer operating room times (202.8 minutes compared with 178.4 minutes, P=.030)


- Overall mean robotic operative time was longer with and without hysterectomy compared to TVM (279 minutes vs 174 minutes, P < .001 and 201 minutes vs 91 minutes, P < .001). Mean total costs were higher with robotic technique ($9675 vs $6718, P < .001), primarily driven by anesthesia ($1141 vs $675, P < .001), and operative ($6883 vs $4487, P < .001) costs.
### What’s Your Time Worth?

<table>
<thead>
<tr>
<th>Surgery</th>
<th>CPT</th>
<th>Total RVU</th>
<th>CMS MD Reimbursement*</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCP (lap or robot)</td>
<td>57425</td>
<td>27.63</td>
<td>27.63x$35.89=$991.64</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>SCP TOTAL = $991.64</td>
</tr>
<tr>
<td>Vaginal a/p repair</td>
<td>57260</td>
<td>23.67</td>
<td>23.67x$35.89 = $849.52</td>
</tr>
<tr>
<td>Vaginal colpopexy</td>
<td>57282</td>
<td>14.24</td>
<td>14.24x$35.89/2 = $255.54</td>
</tr>
<tr>
<td>Anterior mesh</td>
<td>57267</td>
<td>7.31</td>
<td>7.31x$35.89 = $262.36</td>
</tr>
<tr>
<td>Posterior mesh</td>
<td>57267</td>
<td>7.31</td>
<td>7.31x$25.89 = $262.36</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TVM TOTAL = $1629.78</td>
</tr>
</tbody>
</table>

Anger takes 178min to do lap SCP makes $991.64, or $333.89/hour  
Ehlert takes 91min to do TVM makes $1629.78, or $1,072.22/hour

* augscodingtoday.com, using national values, participating facility
Feeling Uncomfortable?

• Something isn’t right here…

• Physician reimbursement long overdue for an overhaul – volume to value – it’s coming
What About The Value of Women’s Care? RVUs, Time, and Gender-Worth


- Evaluation of work RVU's for the paired procedures revealed that in 36 cases (72%), male vs female procedures had a higher wRVU and tRVU.

- For total fee/reimbursement, 42 (84%) male based procedures were compensated at a higher rate (27.67%) than the paired female procedures.

- Female procedure based work RVU's have increased minimally from 1997 to 2015
Now are You Uncomfortable **and** Angry?
Put your pussy hats on!
We have a lot of work to do!
Safety
SCP Safety – Beware, Tiger Country!

- *Von Theobold 2004: 8 years F/U of LSCP:*

  - 8 years f/u, n=100
    Success rate (anatomical)=96%
  
  Complications
  - Intra-op – 11% (bladder, ureteric, vaginal, bowel and vascular injuries)
  - **Conversion rate – 4%**

- Early post-op – 9%

- Late post-op – 25% (erosions, bowel Cx (volvulus), USI, de novo, constipation, chronic pelvic pain)
  - Mesh erosion – 12%
  - Stress urinary inocontinence – 20%
  - De novo constipation – 56%.
This Never Happens in Vaginal Surgery
Bowel Injury, Perforation, Hernia
This Rarely Happens in Vaginal Surgery
Vessel Injury, Thermal Burn, Ureter Injury
Robot Risk Includes Death and Death Rate is Constant Over Time

- **Adverse Events in Robotic Surgery: A Retrospective Study of 14 Years of FDA Data** (Submitted on 13 Jul 2015 (v1), Homa Alemzadeh, Ravishankar K. Iyer, Zbigniew Kalbarczyk, Nancy Leveson, Jaishankar Raman

- FDA MAUDE database review 2000-2013

- 144 deaths (1.4% of the 10,624 reports), 1,391 patient injuries (13.1%), and 8,061 device malfunctions (75.9%) were reported.

- **Numbers of injury and death events per procedure have stayed RELATIVELY CONSTANT since 2007** (mean = 83.4, 95% CI, 74.2-92.7)

Presented as the J. Maxwell Chamberlain Memorial Paper for adult cardiac surgery at the 50th Annual Meeting of the Society of Thoracic Surgeons in January.
Do you see the light between the trees?
Concluding Rebuttal Thoughts

- TVM better level 2 support, maybe worse at apex, but patients are asymptomatic, subjectively they are “cured” and happy with their outcome

- So who cares?

  - SCP worse at level 2 support – in 7 years 2/3 end up back at stage 3, symptomatic, and now you got a harder re-do case with mesh revision

- Who cares? Patient! Surgeon! Maybe some lawyers too…
If subjective outcomes similar, then…

• Why take the extra time and expense to do SCP?

• Why expose patient to additional risk of morbidity and mortality from abdominal approach?

• Why expose patient to a both SCP ab incisions if she also needs vaginal work too? Pick one approach!
We Operate in a World of Risk Happening Outside the OR
My current approach to POP repairs

- Put patient’s needs first, empower her with information and choice!
Thank You!