# Native Tissue Vaginal Repairs: The Apex as the Keystone of Surgery for Pelvic Organ Prolapse

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## Disclosures

- Pelvalon-consultant; research funding, device study, non-surgical treatment FI
- Renovia-consultant, non-surgical treatment UI
- UpToDate
- NIA-research funding
- NICHD-research funding

No Conflict of Interest

## Objectives

After hearing this presentation, the participant should:

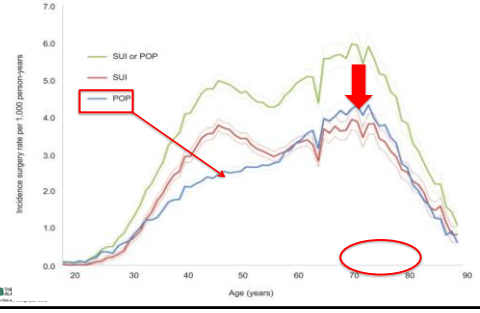
- Be aware of the prevalence of Pelvic Organ Prolapse (POP) in the USA, risk factors, grading system and goals for reparative surgery
- Understand the importance of restoration/maintenance of apical support in POP surgery
- Be cognizant of the various apical vaginal vault suspension surgical techniques
- Appreciate the technique of the high USVVS and Michigan technique, reported results and potential complications

## Surgery for Pelvic Organ Prolapse

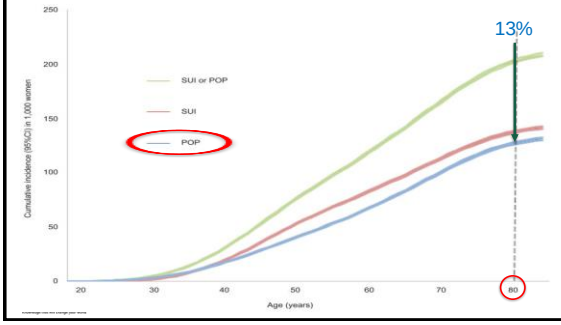
- 300,000 surgical procedures per year in the US [1,2]
- Up to 19% undergo surgery for POP or incontinence by age 85 [3,4]
- POP surgery - the most common inpatient procedure performed in women older than 70 years [5,6]

- 1. Jones et el, 2012; 2. USFDA, CDRH, July, 2011; 3.Boyles et al, 2003; 4. Olsen et al, 1997; 5. Kurkijarvi et al, 2017; 6. Oliphant et al, 2010

## Age-specific annual risk of POP surgery increases with age and peaks at 73 years



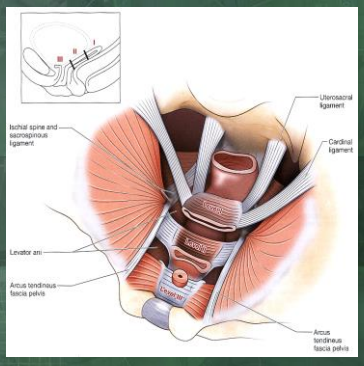

## Cumulative incidence, or lifetime risk, of surgery: up to 13% women undergo POP surgery by age 80



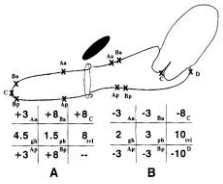
## Risk Factors for Development of Prolapse

- Smoking
- Obesity
- Menopause
- Age
- Race
- Childbirth
- Genetics
- Chronic straining
- Constipation
- COPD
- Occupational

## Levels of Support




## Pelvic Organ Prolapse Quantification System (POP-Q)




- Stage O – Points Aa/Ba, and Ap/Bp are at -3 cm and either Point C or D at ≤ - (TVL-2)
- Stage I – Criteria for Stage O not met and leading edge of prolapse is < -1 cm
- Stage II – Leading edge of prolapse is ≥ -1 cm but ≤ + 1 cm
- Stage III – Leading edge of prolapse is > +1 cm but <(+TVL-2)
- Stage IV – Leading edge of prolapse is ≥ (+TVL-2) cm

Bump, R.C. et al, Am J Obstet Gynecol, 1996

## Defining Success for Prolapse Surgery

- Stage O, Stage I, i.e. "perfect anatomic support"?
- Symptomatic cure is often more clinically relevant than anatomic cure
- Definitions of anatomic success commonly used are too strict and often not clinically relevant

## What Defines Failure after POP Surgery?

- Reoperation or retreatment?
- Recurrence of Symptoms, i.e. "a bulge"?
- Complications requiring treatment?
- Anatomic recurrence
  - Stage II + ?
  - Beyond hymen?
  - Stage III + ?

## Defining Success After Surgery for Pelvic Organ Prolapse

322 women who completed 2-year follow-up in the CARE trial

| Definition of Treatment Success Requiring: | Range of Success |
|---|---|
| • All anatomic support proximal to hymen | 19.2 – 57.6% |
| • Absence of prolapse beyond hymen | 94% |
| • Absence of bulge symptoms | 92.2% |
| • Absence of retreatment | 97.2% |

Absence of bulge, lack of retreatment, no visible prolapse has a significant relationship with patients' assessment of improvement, while anatomic success alone does not

Barber, M.D. et al, Obstet Gynecol, 2009

## Goals of Surgery for Pelvic Organ Prolapse

- Restore vaginal and/or visceral function
- Restore anatomy: correction versus over-correction
- Restore or improve symptom-specific and general QOL

## Vaginal vs. Abdominal

- Vaginal Procedure:
  - Most commonly performed approach
  - Vaginal: 80-90% vs. Abdominal: 10-20%[1-4]
- Preferred especially in older women
  - Shorter operation (i.e. *Laparoscopic SCP 107 ± 34 min by "high volume L/s surgery practice", Robotic – longer)
  - Easier to perform concomitant a/p and incontinence procedure
  - Fewer adverse events (vs. laparotomy)
  - Lower Cost

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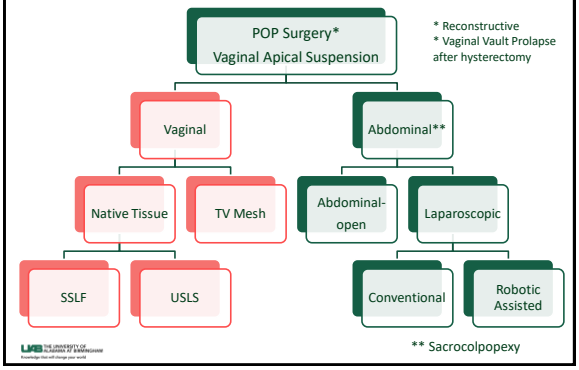
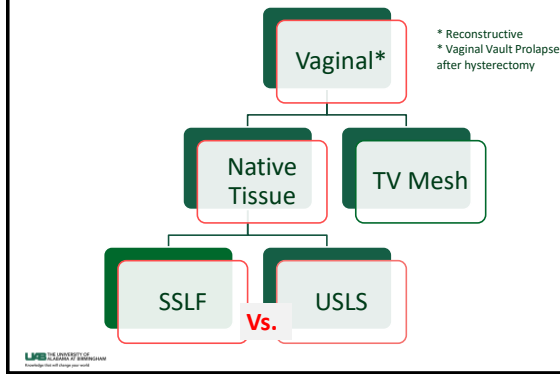
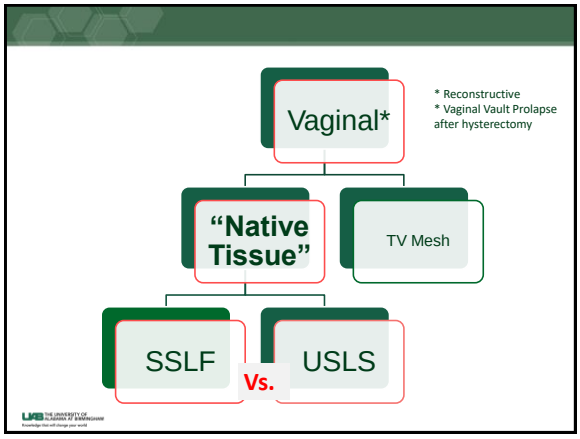
1.US FDA, 2014; 2.Brown et al, 2002; 3.Olsen et al, 1997; 4.Boyles et al, 2003

## Types of Native Tissue Vaginal Apical Repairs

- Uterosacral Ligament Suspension
  - High
  - Low (McCall and modifications)
- Sacrospinous Ligament Suspension approaches
  - Posterior
  - Apical-Michigan 4-corner
- Iliococcygeus Vaginal Suspension
- Obliterative procedures






## USLS vs SSLS

1) Efficacy: Success Rate?
2) Potential Disadvantages?
3) Procedure Unique Complications?

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## Evidence Reflecting Critical Importance of Vaginal Apical Support

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## The Impact of Apical Vaginal Repairs on Prolapse Recurrence

Data from Centers for Medicare and Medicaid Services

In 1999: 21,245 women had a diagnosis of POP (CPT)

2756 underwent ant±post colporrhaphy with or without apical repairs

10 year follow-up

| Anterior repair only 20.2% | P <0.01 | Anterior plus apical 11.6% |
|---|---|---|

Cumulative reoperation rates

Eilber, K.S., et al, Obstet Gynecol, 2013

## The Role of Apical Vaginal Support in the Appearance of Anterior and Posterior Vaginal Prolapse

197 women, mean age 62 ± 14 years
By POP-Q: - 36% Stage II prolapse
- 54% Stage III prolapse
- 10% Stage IV prolapse

Posterior blade of Graves speculum used to support anteriorly and posteriorly while re-measuring points Aa, Ba and Ap, Bp

With simulated apical support:
- Ba changed to Stage O or I in 55% of cases
- Bp changed to Stage O or I in 30% (P <.001)
- Mean change for point Ba was 3.5 ± 2.6 cm and point Bp 1.9 ± 2.9 cm (P <.001)

Lowder, J.L., et al, Obstet Gynecol, 2008

## Advanced Anterior Vaginal Wall Prolapse is Highly Correlated with Apical Prolapse

325 women, mean age 60 with POP-Q Stage O-IV

Vaginal Apex (POP-Q point C) strongly correlated with most prolapsed portion of anterior wall, point Ba
(Spearmans rho = 0.835, P < .0005)
Moderately correlated with most prolapsed portion of posterior wall, point Bp
(Spearmans rho = 0.55, P < .0005)

- A strong linear relationship was found between C and Ba
- Anterior vaginal wall prolapse is associated strongly with apical prolapse

Rooney, K., et al, Am J Obstet Gynecol, 2006

## The Predictive Value of a Cystocele for Concomitant Vaginal Apical Prolapse

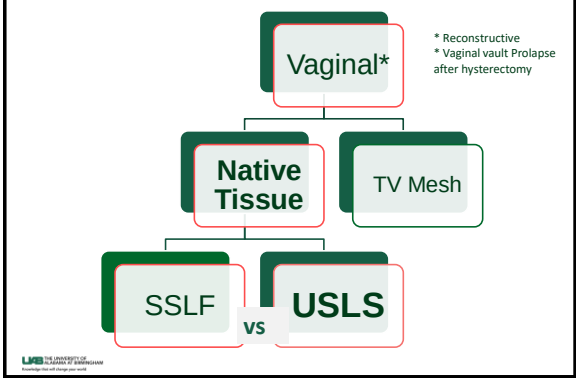
Retrospective review of 385 women with Ba ≥ −1 (Stage II cystocele and greater)

Point Ba leading edge of prolapse in 83.9%
Position of Ba strongly correlated with apex
Spearmans rho = 0.769, P <.001

Clinically significant apical prolapse increased significantly with increasing Ba values.
Of patients with Stage II, III, and IV cystocele, point C was ≥ −3 in 42%, 85% and 100%, respectively

Conclusion: As cystocele stage increases, predictive value of apical prolapse increases

Elliott, C.S., et al, J Urol, 2013




## Uterosacral Ligament Suspension (USLS)

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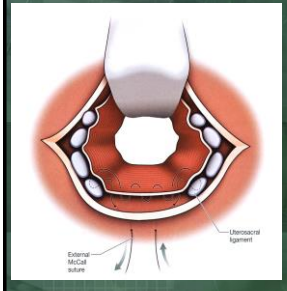
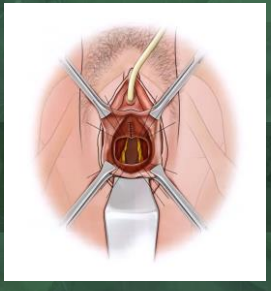
## McCall (Low Uterosacral Suspension)




## High Uterosacral Suspension

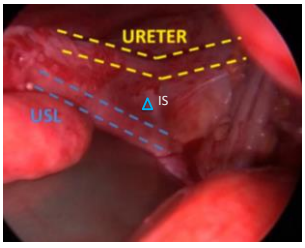


## Studies on Uterosacral Ligament Suspension, ICI, 2016

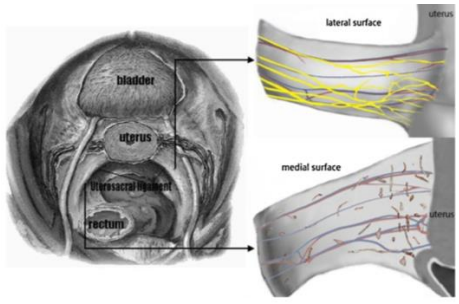
| Study | N | Mean Follow-up Months (Range) | Complications | No. Cured (Rate) |
|---|---|---|---|---|
| Amundsen, et al. J Urol, 2003 | 33 | 28 (6-43) | 1 transfusion | 27/33 (82%) |
| Karram, et al. Am J Obstet Gynecol, 2001 | 168 | 22 (6-36) | 5 ureter injury<br>1 small bowel injury | 158/168 (94%) |
| Shull, et al. Am J Obstet Gynecol, 2000 | 289 | 48 | 1% ureteral injury<br>1% tranfusion | 251/289 (87%) |
| Barber, et al. Am J Obstet Gynecol, 2000 | 46 | 15.5 (3.5-41) | 11% ureteral occlusion | 90% |
| Jenkins, et al. Am J Obstet Gynecol, 1997 | 50 | 33 (6-48) | 3 (6%) vaginal apex suture eroded | 48/50 (96%) |
| Miklos, et al. Laparoscopic and vaginal. Am J Obstet Gynecol, 1998 | 17 | 6.3 (1-17) | 1 post-op pneumonia | 88% |
| Silva, et al. Obstet Gynecol, 2006 | 72 | 5.1 (3.5-7.5) | 0 ureteral injuries | 61/72 (85%) |

## Complications

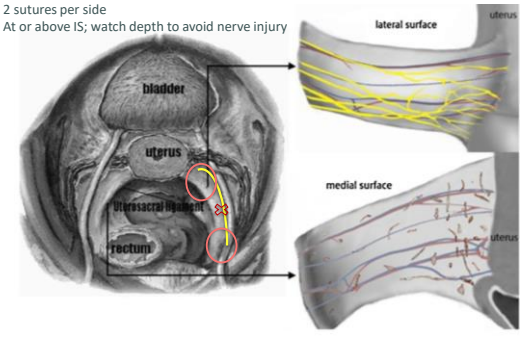
- Ureteral kinking, 1-11%
- Nerve entrapment, 0-2%
- Sensory nerve injury, 0-5%
- Bowel Injury (4%)




Nerve Injuries: USL is a condensation of visceral endopelvic fascia containing nerves and vessels




2 sutures per side
At or above IS; watch depth to avoid nerve injury



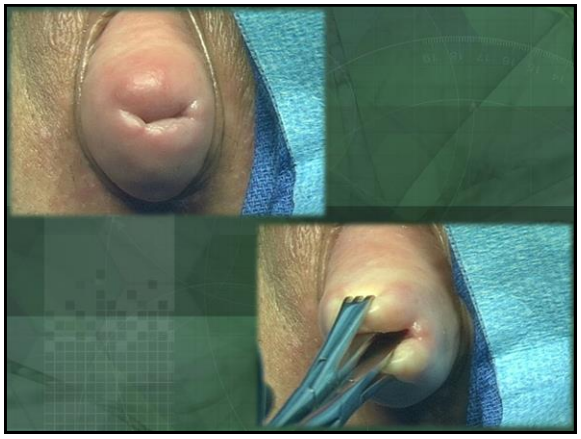

Case

68 year-old healthy female with vaginal pressure and protrusion affecting her ability to be on her feet for any period of time

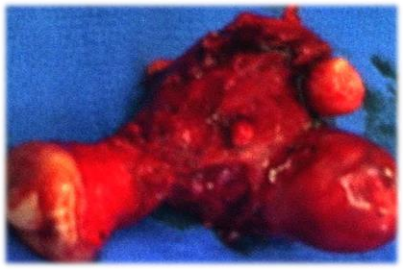
She has had no previous GYN surgery

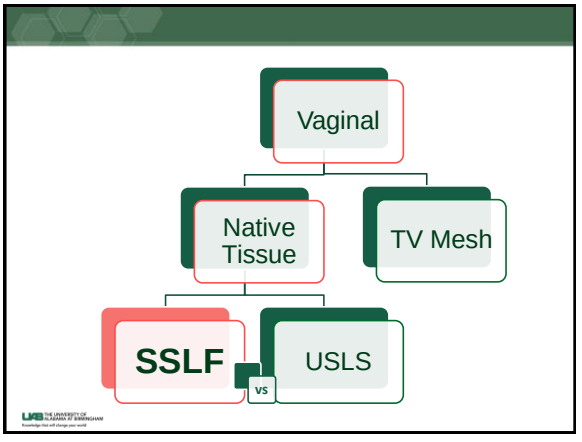
No lower urinary or rectal complaints

History of fibroids



## Uterus with fibroids removed






## Sacrospinous Ligament Suspension (SSLS)

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**Sacrospinous Ligament Suspension (SSLS) procedures, ICI 2016**

| First Author, Year (year) | Study Design | N | Mean Follow-up Mo. (range) | Definition of Anatomic Success | Anatomic Success-all segments | Anatomic recurrence by segment | Reoperation for prolapse |
|---|---|---|---|---|---|---|---|
| Morley, (1998) 11 | Retrospective | 92 | 51.6 (1-132) | Not defined | 90% | Apex 4% Anterior 6% | 4 (5%) |
| Shull, (1992) 241 | Retrospective | 81 | (24-60) | Grade 0-1 | 82% | Apex 4% Anterior 12% Posterior 1% | 4 (5%) |
| Benson, (1996) 77 | RCT SSLS vs ASC | 42 | 30 (12-66) | Vaginal walls above hymen or apical descent less than 50% length | 67% | Apex 12% Anterior 28.5% Posterior 2.3% | 14 (37%) |
| Paraiso, (1998) 61 | Retrospective | 243 | 76. (1-190) | Grade 0 or asymptomatic grade 1 | 79.7% at 5 years | Apex 4.9% Anterior 15.9% Posterior 4.9% | 11 (4.5%) |
| Lovatsis, (2001) 252 | Retrospective | 293 | (12-30) | At or beyond the introitus | 97% | Apex 3% Anterior NR Posterior NR | 3% |
| Cruikshank, (2003) 253 | Prospective cohort | 695 | 43 (6-60) | Reoperation for recurrence | 89.4% | Apex 5.1% | 105 (15)% |
| Hefni (2006) 181 | Prospective | 305 | 57 (24-84) | Vaginal Vault at least 6cm distal to hymen | 96% | Apex 4% Anterior 13% Posterior 0% | NR |
| Larsen, (2013) 258 | Retrospective | 242 | 96 +/- 20 | At or above hymen | 86% | Apex 0.6% Anterior 13.6% Posterior 1.2% | NR |
| Mothes, (2015) 261 | Retrospective | 110 | 14 +/- 7 | Apex Stage 0 or 1 | 94.5% | Apex 5.5% Anterior 8.3% | NR |

## "Criticism" of SSLF

First described in 1958*

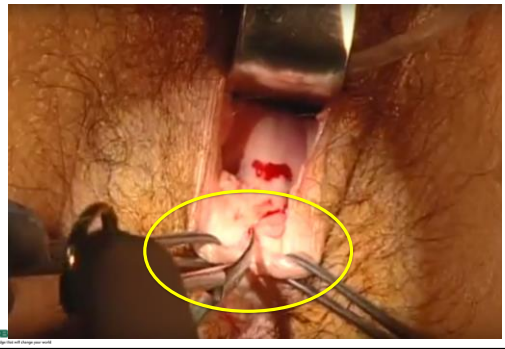
↑ Surgical failure rate, esp. anterior compartment

- Potential disadvantage for SSLF

Data are based on level 2 evidence, using the traditional approach

Sederl J, 1958

## Traditional Entry for the Access to SSL



- Posterior deviation of the vaginal axis ⟹ anterior prolapse recurrence

## SSLF

- "Michigan Modification" technique-perirectal space entered at the apex
- All four vaginal walls are directly approximated to the sacrospinous ligament (instead of only the posterior vaginal wall)
- The sutures are placed through the sacrospinous ligament, then incorporated to both anterior and posterior apex, and tied to the ligament

Morley and DeLancey, 1988

## CASE

68 year-old healthy female with vaginal pressure and protrusion affecting her ability to be on her feet for any period of time

She is s/p TVH for menorrhagia at 47 years of age

No lower urinary or rectal complaints

## Sacrospinous Ligament Fixation

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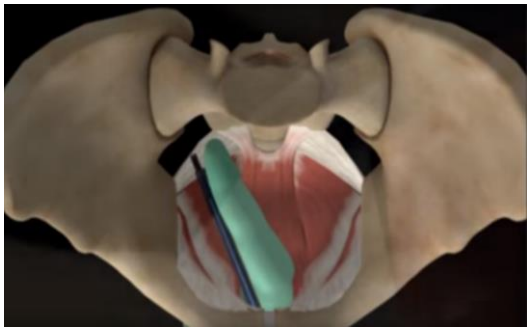
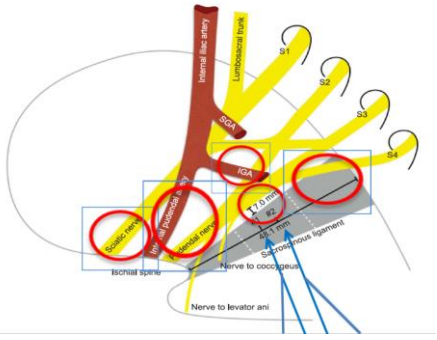
## Unilateral (Right-sided) Fixation- bilateral suspension not superior



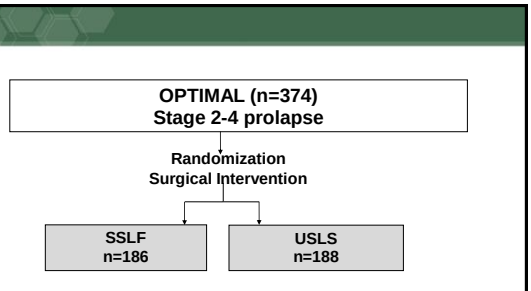



Original Investigation

## Comparison of 2 Transvaginal Surgical Approaches and Perioperative Behavioral Therapy for Apical Vaginal Prolapse
The OPTIMAL Randomized Trial

Matthew D. Barber, MD, MHS; Linda Brubaker, MD; Kathryn L. Burgio, PhD; Holly E. Richter, PhD, MD; Ingrid Nygaard, MD; Alison C. Weidner, MD; Shawn A. Menefee, MD; Emily S. Lukacz, MD; Peggy Norton, MD; Joseph Schaffer, MD; John N. Nguyen, MD; Diane Borello-France, PhD; Patricia S. Goode, MD; Sharon Jakus-Waldman, MD; Cathie Spino, ScD; Lauren Klein Warren, MS; Marie G. Gantz, PhD; Susan F. Meikle, MD; for the Eunice Kennedy Shriver National Institute of Child Health and Human Development Pelvic Floor Disorders Network

Journal of the American Medical Association (2014)




- 2 year success rate
  (Composite outcome: anatomy + symptoms + retreatment)
- SSLF: 63.1% vs. USLS: 64.5% , aOR 1.1 (95%CI: 0.7-1.7)

## Adverse Events

- Serious adverse events:

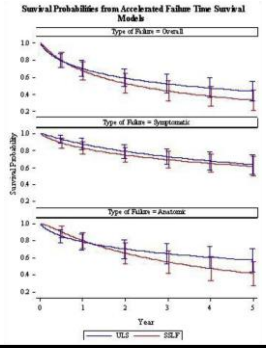
→ not significantly different
USLS 17%, vs SSLF 17%

- Neurologic pain higher in SSLF
  USLS 7%, vs SSLF 12%

→ most resolved by 6-weeks

- Ureteral obstruction (kinking)
  USLS 3%* vs SSLS 0%
  *recognized and successfully managed intraoperatively

## 5 year outcome of OPTIMAL trial




## Summary

- The prevalence of symptomatic pelvic organ prolapse in the USA is expected to increase significantly over the next 20-30 years
- Definitions of success for POP surgery are highly variable-PRO outcomes most important
- Restoration/maintenance of apical vaginal function is a critical aspect of prolapse surgery
- There is no difference in short-term or longer-term outcomes between the USVVS and SSLS

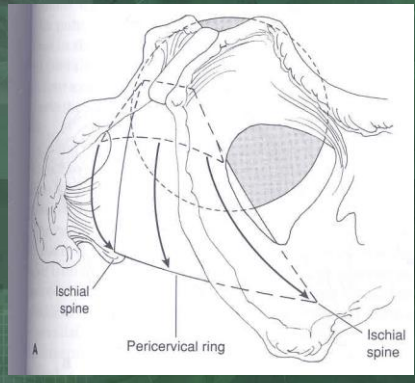
## Summary

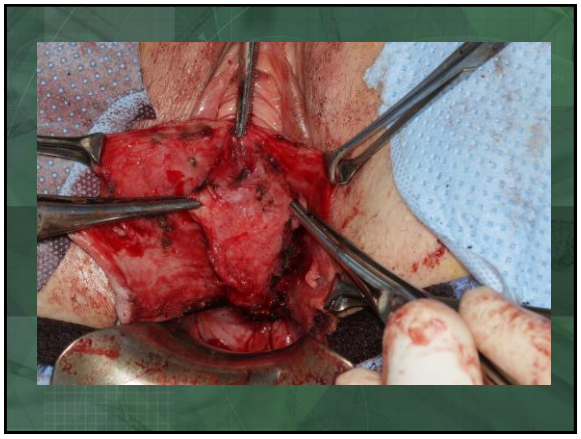
- Overall rate of adverse events are similar – understanding relevant anatomy is important
  - Ureteral injury higher in USLS -> ureteral kinking corrected in OR
  - Neurologic pain higher in SSLF -> short-lived, conservative management
- *Most minimally invasive approach
- *Shorter operating time
- Always assess ureteral patency!

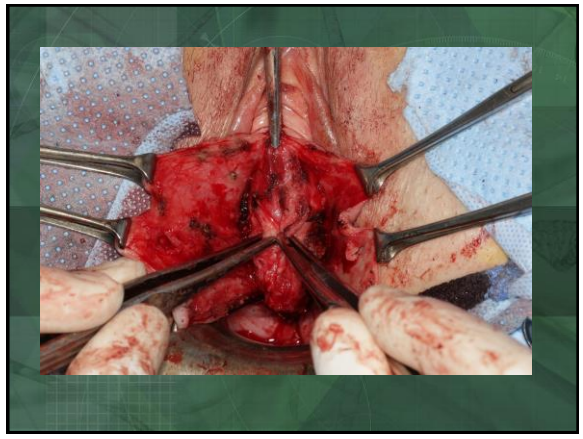
## Documentation of Ureteral Patency

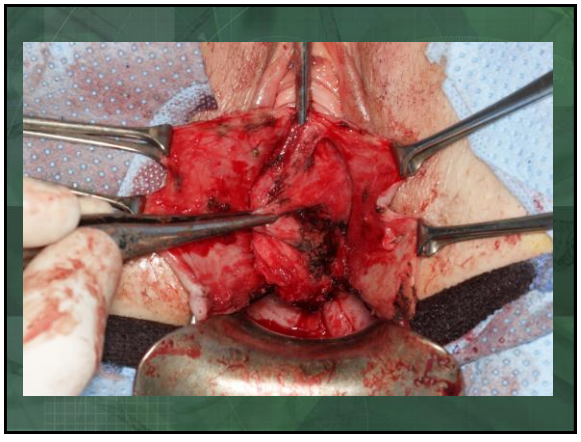
## Anterior Repair

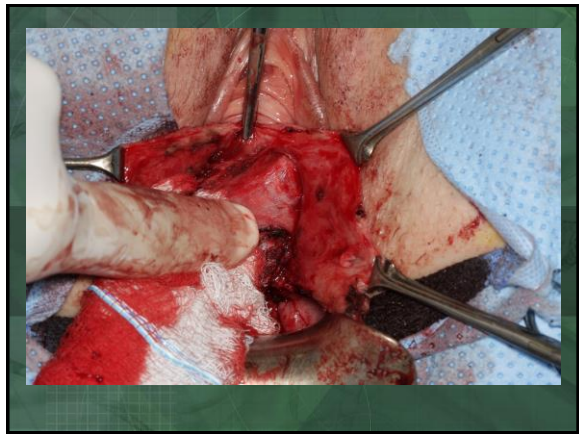
- Success rates 45-100% in primarily retrospective series (ICI, 2016, pp1865-1866)
- Usually a transverse apical defect
- Rare paravaginal defect
- Must re-secure pubocervical musculo-connective tissue at the vaginal apex……..

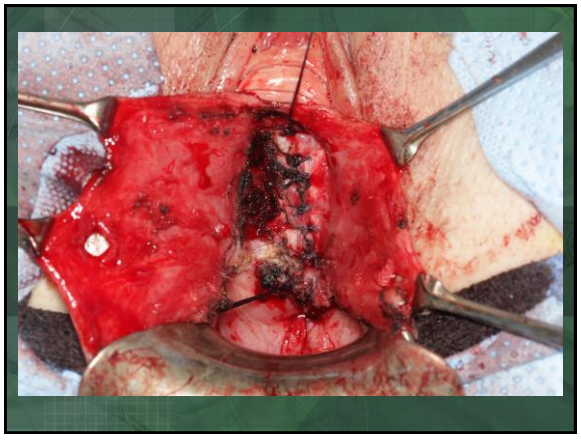






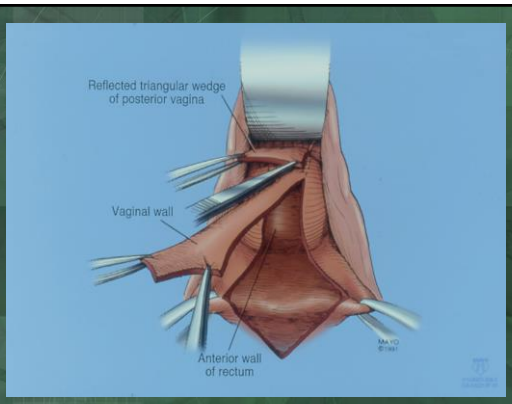


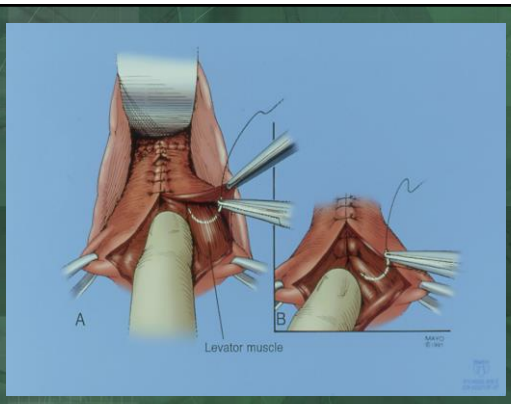


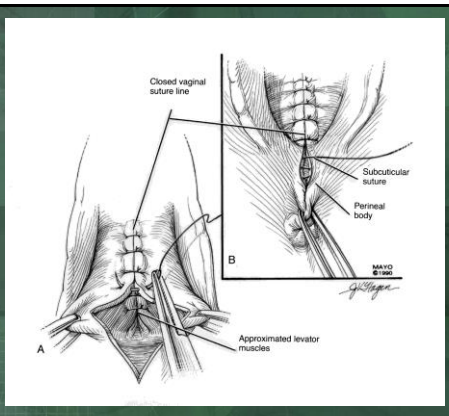


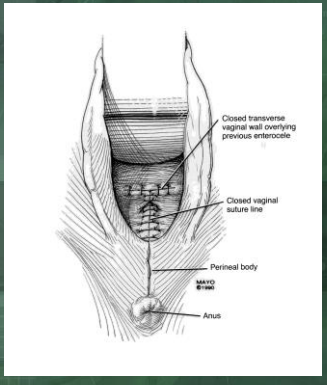
## Posterior Compartment

- 1/3 to 1/2 of prolapse surgeries include a posterior repair
- Anatomic cure rates, 76-96% (ICI, 2016, pp 1908-1909)
- Vaginal approach
  - midline with fascia plication
  - careful for over-correction
  - perineorraphy


Reflected triangular wedge of posterior vagina
Vaginal wall
Anterior wall of rectum


A
B
Levator muscle


Closed vaginal suture line
Subcuticular suture
Perineal body
B
A
Approximated levator muscles


Closed transverse vaginal wall overlying previous enterocele
Closed vaginal suture line
Perineal body
Anus

Thank you!