



## Approaches to Pelvic Organ Prolapse Workshop 7 Monday 23 August 2010, 09:00 – 12:00

Time	Time	Topic	Speaker
9:00	9:10	Goals of Pelvic Organ Prolapse	Sandip Vasavada, MD
9:10	9:25	Pelvic Floor Prolapse: Anatomic, Functional and Surgical Principles	J. Christian Winters, MD
9:25	09:55	Vaginal Repairs of Pelvic Organ Prolapse	Sandip Vasavada, MD
09:55	10:05	Robotic Sacrocolpopexy	Kimberly Kenton, MD
10:05	10:30	Management of recurrence and mesh complications	Philippe E. Zimmern, MD
10:30	10:50	Break	
10:50	11:20	Graft Materials in Lower Urinary Tract Reconstruction	J. Christian Winters, MD
11:20	11:40	Assessment of outcomes after reconstructive pelvic surgery	Kimberly Kenton, MD
11:40	12:00	Case discussion and Q&A	Philippe E. Zimmern, MD

### **Aims of course/workshop**

Our attendance at the recent ICS meeting was very international. The comments were overall very favorable. The main criticisms were insufficient information in the syllabus (but this cannot be changed easily since we were only given one page for each lecture) and more surgical videos to see how the procedures are being performed. The latter point will be integrated in our planning for this course at the next ICS in Toronto

### **Educational Objectives**

Key learning points:

- discussion of anatomical landmarks and indications for each described procedure
- detailed review of surgical techniques for all compartment prolapse, including robotic and meshes
- use of video clips to illustrate current techniques
- discussion on current outcome measures and how it can impact published results
- presentation of cases involving complications to discuss different approaches and their outcomes

Take home messages:

- Prolapse repair surgery entails a solid knowledge of pelvic anatomy
- Traditional techniques are being challenged by vaginal repair using mesh, but the safety of these procedures, even with elaborate kits, is not certain.
- As pointed out by the FDA (October 2008), serious complications can occur and some are difficult to correct, especially pain and dyspareunia.
- Mesh sacrocolpopexy (open, laparoscopic, or robotic) has level I evidence for its safety and long-term effectiveness.



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- Complications such as erosion can occur and failures, although rare, can occur.
- Literature reviews, including Cochrane database, are helpful to discern the best procedures.

Nonetheless, outcome measures are varied and there is no consensus in the field.

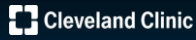
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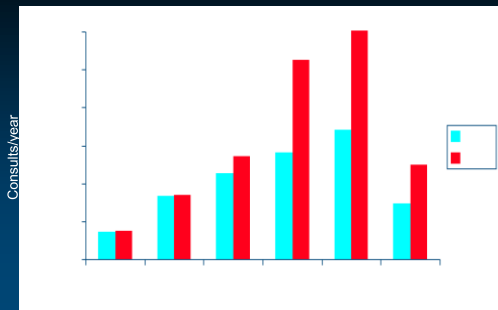


## Goals of Pelvic Organ Prolapse Repair

Sandip P. Vasavada, MD  
 Center for Female Pelvic Medicine and  
 Reconstructive Surgery  
 Glickman Urological and Kidney Institute

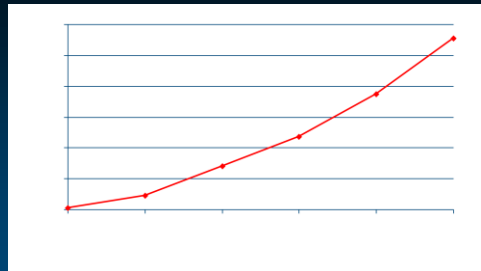


### Pelvic Floor Disorders – U.S.

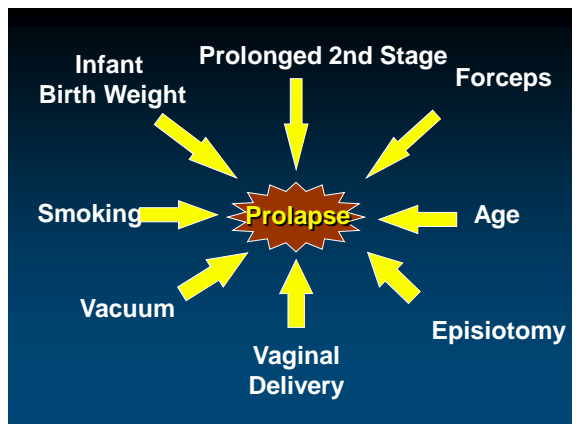
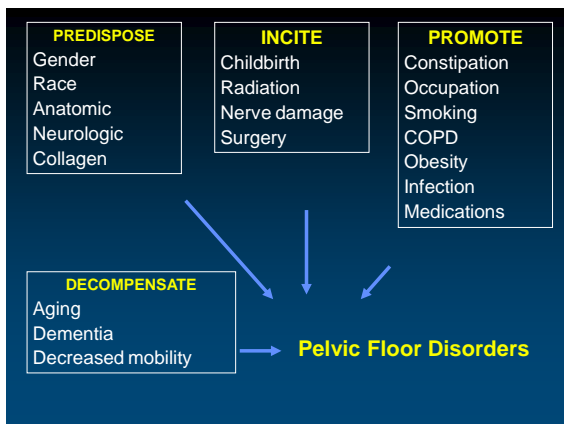


Luber et al, 2001

### Surgery for UI and POP



Olson et al, Obstet Gynecol 1997;89:501



## WHAT IS THE GOAL OF OUR REPAIR?

## Goals of Repair

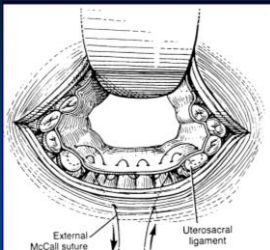
- Presenting complaints?
- Primary or secondary
  - Incontinence
  - Prolapse/bulge
  - Pressure
  - Pain
  - UTI
  - Constipation/ defecatory dysfunction
  - Retention

## Tailor Goals of Surgery to Patient Needs

- Reconstructive or Obliterative
- Vaginal or abdominal (can include lap or robotic too)
- Sexual activity
- Physical activity
- Bowel issues
- *Patient expectations*

## A WORD ABOUT PREVENTION.....

## POP prophylaxis at time of hysterectomy – McCall's Culdoplasty



Follow-up	Moscowitz-type	McCall-type	Peritoneum only
At 1 y			
Stage 0	30	33	26
Stage 1	3	0	4
Stage 2	0	0	4
At 2 y			
Stage 0	28	30	24
Stage 1	3	2	5
Stage 2	2	0	4
At 3 y			
Stage 0	23	30	20
Stage 1	4	2*	8
Stage 2	6	0*	5

\*At 3 years patients who underwent McCall-type procedures had a significantly lower incidence of prolapse ( $P = .004$ ).

## When is the optimal time to assess treatment goals?

- After consultation and information
- *How much information is enough.... mesh debates etc.. and informed consent*
- Lowenstein et al. (Am J Obstet Gynecol 2007; Dec 197(6): 640 e1-3
  - Patients were more likely to focus goals from “symptoms” and “information-seeking” to “treatment” after consultations: **reassess goals after visit**

## Patient Centered Surgical Outcomes

### What can affect this?

- Mahajan, S et al: Am J Obstet Gynecol 2006 Mar; 194(3): 722-8
  - 70% of patients reported a change in satisfaction ratings between 3 mo and 1 year
  - This was strongly associated with decreased goal achievement
  - 56% reported urge incontinence (44% de novo and 12% persistent) and represented the most common reason for dissatisfaction after surgery ( $p=0.04$ )

## Other Thoughts on Patient Expectations when Undergoing Prolapse Repair

- Srikrishna et al (BJOG 2008: Oct 115(11): 1362-8
  - Disease specific QOL questionnaires help but not sensitive enough to address individual symptom bother
- Hullfish et al (Am J Obstet Gynecol, 2004 Jul; 191 (1): 201-5
  - Self achievement of patient centered goals should be considered in addition to clinical and subjective data


## Conclusions

- Identify patient goals at time of visit/operative planning
- Write them down (EMR etc..)
- **Mutual** understanding of what patient and physician want/need from repair
- Active re-assessment of goals in follow up period
- **Consideration of additional therapies to help achieve goal (potential road map of future therapies needed)**

## Pelvic Floor Prolapse: Anatomic, Functional and Surgical Principles


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**J. Christian Winters, M.D.**  
Professor and Chairman, Department of Urology  
Louisiana State University Health Sciences Center  
New Orleans, Louisiana




### Pelvic Organ Support

- Both static and dynamic forces important
- Pelvic organ stability dependent on:
  - Bony structures
  - Pelvic floor musculature
  - Fascial condensations
  - Intact innervation
- Understanding of normal anatomy aids in restoring pelvic organ function & position



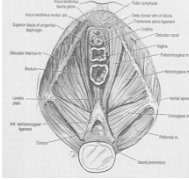
### Pelvic Floor Musculature

- Striated musculature providing 2 main functions:
  1. Support of visceropelvic organs
  2. Maintenance of urinary and fecal continence.
- Not “bowl”, but horizontal or flat.
- Pelvic diaphragm - levator ani and coccygeus muscles.
  - Levator ani = pubococcygeus, iliococcygeus.




### Anterior Levator Ani group “Pubovisceral”

- Pubococcygeus (puborectalis)
- Directly attached to the bladder, urethra, vagina, rectum.
- Actively contribute to visceral control
- Crucial during increased abdominal pressure.

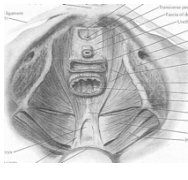


Anderson J and Gendry E. Anatomy and Embryology in Novak's Text of Gynecology




### Posterior Levator Ani Group “Diaphragmatic”

- Iliococcygeus and coccygeus.
- Originate from more posterior portions of tendinous arc and ischial spines.
- The two sides fuse in midline posterior to the rectum and attach to the coccyx.
- This horizontal plate extends from the rectal hiatus to the coccyx, and the upper vagina and cervix are situated in this horizontal plane created by levator plate.




Source: Netter's Atlas of Anatomy




### Levator Ani – Muscle Composition

- Type I muscle fibers – slow twitch and provide a sustained tone of pelvic floor.
  - Support pelvis in normal activity.
- Type II fibers – fast twitch fibers reflexively contract during sudden increases in intraabdominal pressure (ie cough etc).




### Levator Ani - Function

- Tonic contraction of pubococcygeus muscle closes the genital hiatus.
- Pelvic muscle contraction leads to elevation of the visceral organs and vaginal closure.
  - The vagina and rectum are supported over the levator plate, which elevates these organs and narrows the genital hiatus by traction from the levator ani.




From: Wall L, Menefee S. Novak's Text of Gynecology



### Pelvic Floor Support


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Combination of:  
Pelvic Floor Musculature  
Connective Tissue Attachments



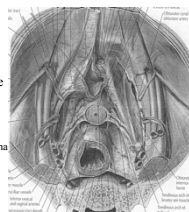
### Endopelvic Fascia

- Sheet of fibroareolar tissue following blood supply to visceral organs. “*Retropelvic Mesentery*”
- Attaches the cervix and vagina to the lateral pelvic sidewall.
- Composed of 2 parts:
  1. Parametrium (connected to uterus) which are the uterosacral and cardinal ligaments.
  2. Paracolpium (connected to vagina). The parametrium fuses to the paracolpium and this extends all the way to perineal body.



### Uterosacral and Cardinal Ligaments

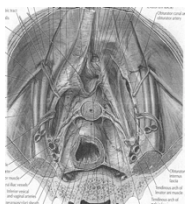
- Two different parts of a single mass of tissue.
- Uterosacral ligaments are the visible and palpable medial margin of this tissue complex.
  - Stabilize cervix and upper vagina posteriorly to sacrum.



Source: Netter's Atlas of Anatomy

### Uterosacral and Cardinal Ligaments

- Cardinal ligaments - are thick condensations of fascia originating from the greater sciatic foramen inserting into the lateral aspect of the cervix and upper vagina.
  - Important in support of bladder base as it is contiguous with perivesical fascia.
- Support cervix (uterus) and upper vagina to maintain a posterior position over the levator plate, which pulls them away from genital hiatus.




Source: Netter's Atlas of Anatomy

### Lateral pelvic support

- Linear condensations of obturator and levator ani fascia:
  - Arcus tendineus fascia pelvis- fibrous band extending from pubic bone to ischial spine. Supporting structure of pubocervical and rectovaginal fascia.
  - Arcus tendineus levator ani - fibrous band overlying obturator internus muscle from which iliooccygeus inserts and travels behind the rectum to insert on levator plate.

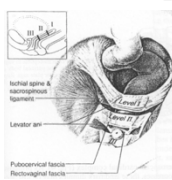
### Perineal Membrane

- Dense, triangular sheet of fascia.
- Extends from ischial pubic rami laterally and anterior to the pubic symphysis.
- The perineal body represents the central tendon between the 2 halves of perineal membrane.
- The fibers of the perineal membrane tighten and resist against increased abdominal pressure and gravity as well as supporting the rectum.



Delancey JO. Am J Obstet Gynecol 180:815-823, 1999

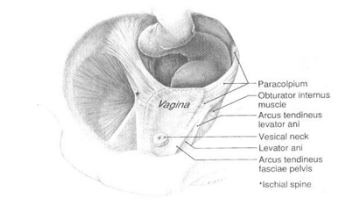
### Levels of Vaginal Support



- Level I:** Uterosacral and Cardinal Ligaments
- Level II:** Arcus Tendineus Fascia Pelvis, Pubocervical and Rectovaginal Fascia (Proximal)
- Level III:** Pubocervical and Rectovaginal Fascia (Distal), Pubourethral Ligament and Perineal Body

Delancey JOE. Am J Obstet Gynecol 166:1717, 1992

### Continuous layers of support



- Paracolpium
- Obturator internus muscle
- Arcus tendineus levator ani
- Vesical neck
- Levator ani
- Arcus tendineus fasciae pelvis
- \*ischial spine

Delancey JOL. Am J Obstet Gynecol 166:1717, 1992

### Delivery Induced Neural Dysfunction

- Pelvic floor function may be altered by neuropathy in the pudendal or sacral nerves.
- Nerve injury may occur via pressure necrosis or stretching of terminal nerve endings.
  - Altered pudendal nerve terminal motor latencies (16%)
  - Evidence of partial denervation via EMG with later recovery.

Wall et al. J Bone Joint Surg Br, 1992  
Sultran et al. Br J Obstet Gynecol, 1994  
Smith A et al. Br J Obstet Gynecol, 1989

### Connective Tissue Defects

Collagen provides tensile strength  
Elastin provides flexibility.

- Women with prolapse had higher proportion of Type III collagen than those without prolapse.
- Higher activity of elastase which breaks down elastin.
- Decreased estrogen receptors in menopausal women.

Norton et al. Neuroanal Urodynam, 1992  
Aybeck et al. J Urol, 1998  
Smith et al. Gynecol Obstet Invest, 1990

### POP – Multifactorial Nature

- Childbirth trauma
  - Direct muscle and connective tissue injury
  - Neuropathic induced pelvic floor dysfunction
  - Widened levator hiatus
- Connective tissue disorder / Menopause
- Genetics?
- Lifestyle / Weight

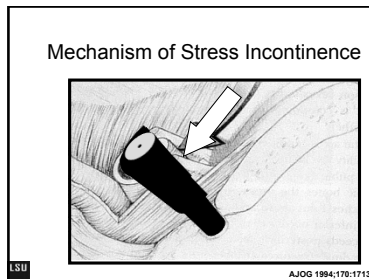
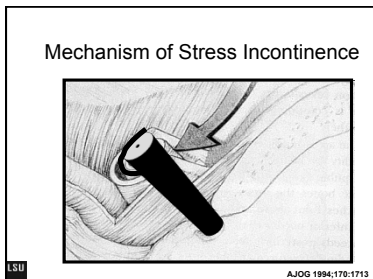
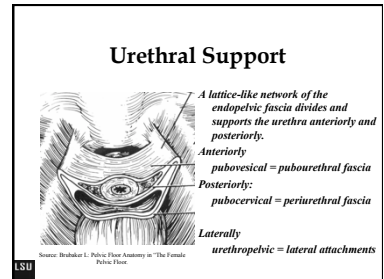


- Pelvic Floor Defects**
- Urethrocele “Urethral Hypermobility”
  - Cystocele
  - Uterine Prolapse
  - Vaginal vault or “cuff” Prolapse
  - Enterocele
  - Rectocele
  - Perineal Body Defects
- LSU

- Pelvic Floor Defects, think compartments
- Anterior**
- Urethrocele “Urethral Hypermobility”
  - Cystocele
- LSU

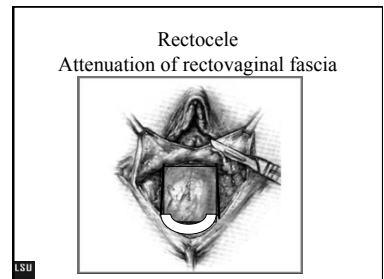
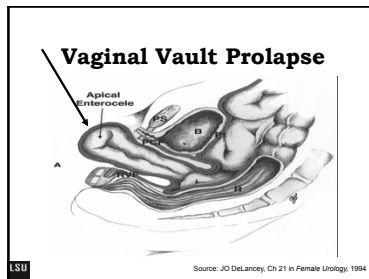
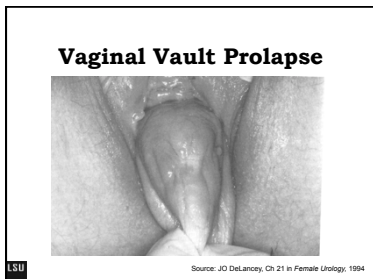
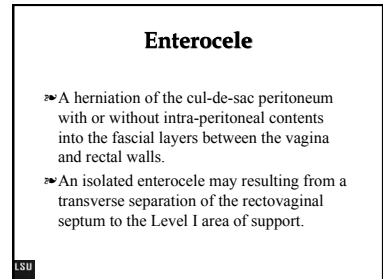
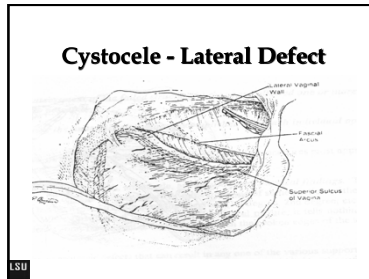
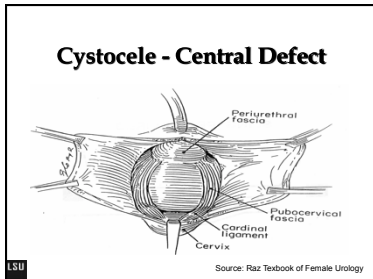
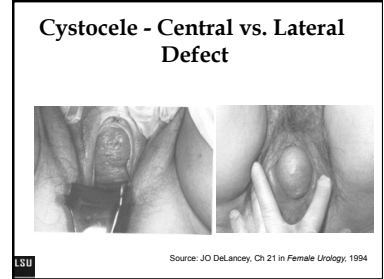
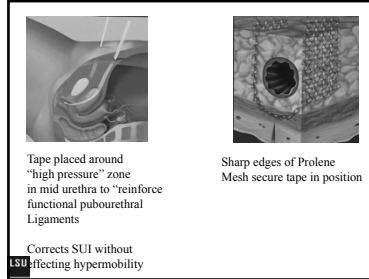
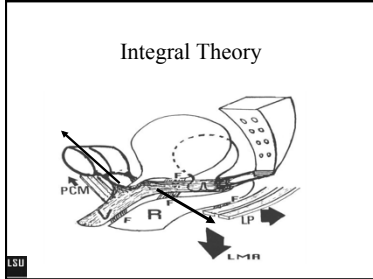
- Pelvic Floor Defects, think compartments!!
- Middle or Apical Compartment**
- Uterine Prolapse
  - Vaginal vault or “cuff” Prolapse
  - Enterocele
- LSU

- Pelvic Floor Defects, think compartments!!
- Posterior Compartment**
- Enterocele
  - Rectocele
  - Perineal body defects
- LSU



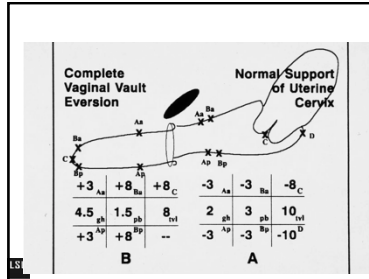
- Integral Theory**
- Pubourethral Ligament
  - Suburethral Vaginal Hammock
  - Pubococcygeus muscle
- All three structures work together by drawing the urethra forward against the pubourethral ligament and closing the urethra.
- The PCM muscle can only contract so much, if there is excessive vaginal laxity, it can't draw urethra against the PUL to achieve closure.*
- LSU





### Management of Pelvic Organ Prolapse Defect Assessment: POP-Q

Aa Distal portion of anterior vaginal wall  
 Ba Proximal portion of anterior vaginal wall  
 C Cervix or Cuff  
 D Cul desac (Douglas)  
 Ap Distal portion of posterior vaginal wall  
 Bp Proximal portion of posterior vaginal wall



### Surgical Approach

POP-Q	DEFECT	STRATEGY
1st degree	Cervix	Observe/Support
2nd degree	Cervix	Support
3rd degree	Cervix	Support
4th degree	Cervix	Support
5th degree	Cervix	Support
6th degree	Cervix	Support
7th degree	Cervix	Support
8th degree	Cervix	Support
9th degree	Cervix	Support
10th degree	Cervix	Support

### Summary

- Pelvic floor anatomy is complex, often challenging to master.
- Proper support is achieved by a contiguous connective tissue network enhanced by properly functioning levator ani function.
- It is important for the pelvic surgeon to understand these concepts and incorporate these principles into anatomic repair of site-specific defects.

## Vaginal Repairs of Pelvic Organ Prolapse

Sandip Vasavada, MD

Center for Female Pelvic Medicine and  
Reconstructive Surgery  
The Glickman Urological and Kidney Institute  
The Cleveland Clinic

## “Traditional repairs vs Augmented repairs”

- Should we abandon “traditional repairs”?
- If no, then what situations to use
  - First time occurrence of prolapse
  - Thin tissues/ atrophic
  - Sexually active patients?
- Constant need to “innovate” or “keep up”

## Challenges in Vaginal Prolapse Surgery

- Anterior Vaginal Wall Prolapse
- Apical Prolapse
  - At time of hysterectomy
  - Post-hysterectomy
- Posterior Vaginal Wall Prolapse

## Anterior Vaginal Wall Prolapse

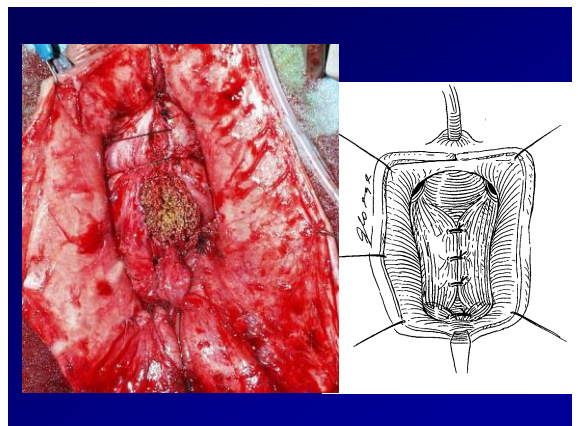
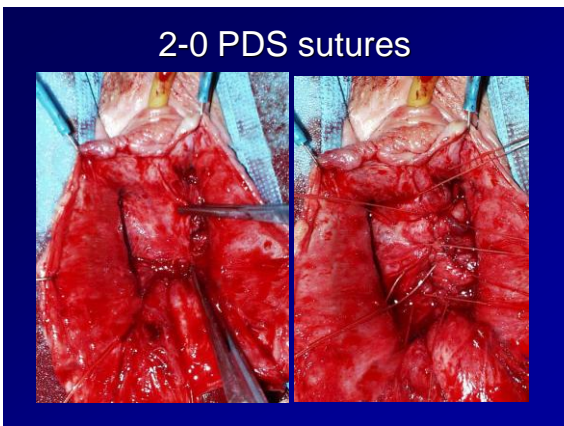
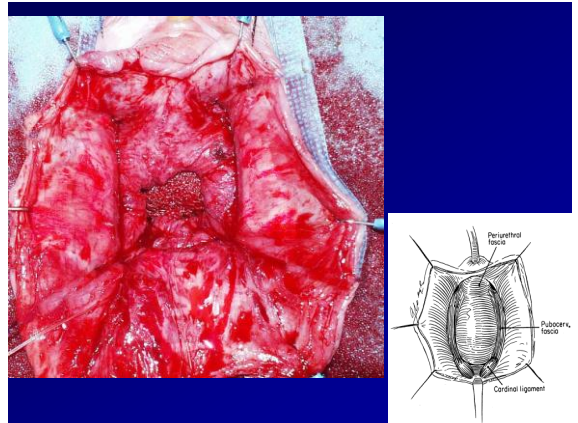
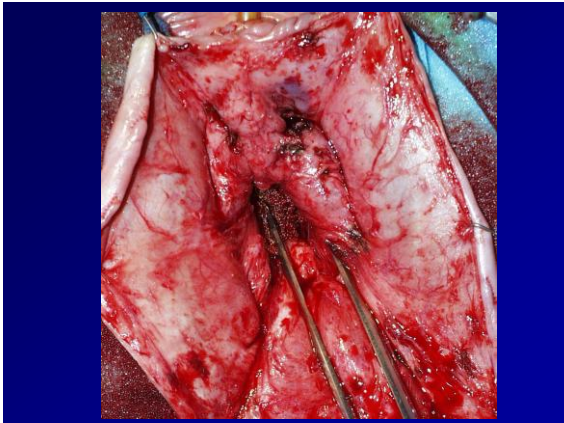
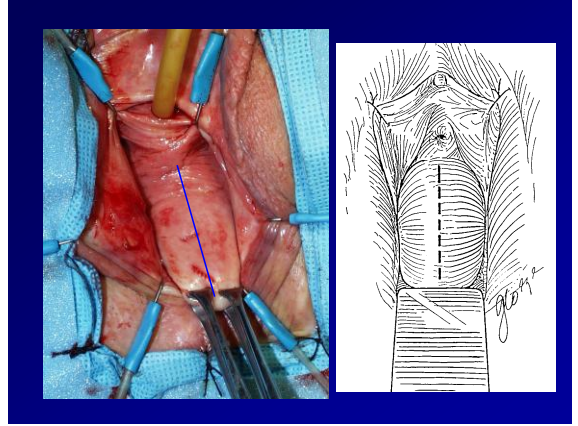
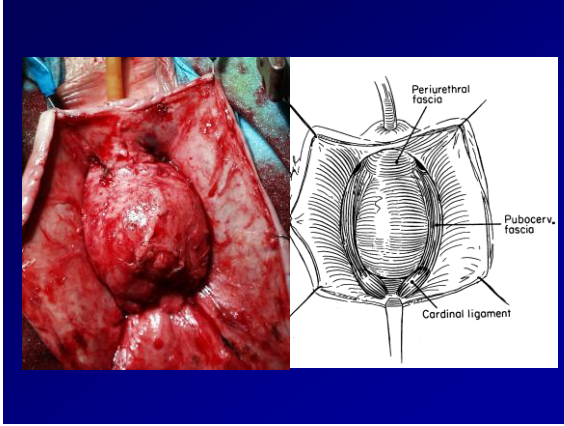


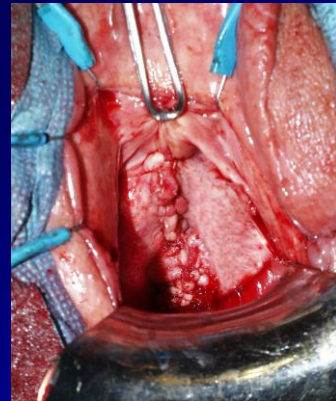
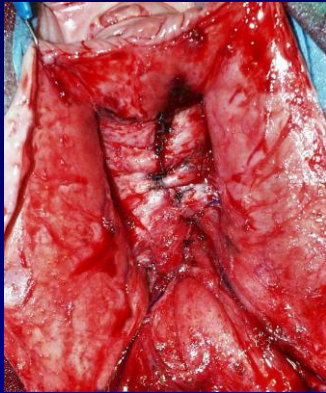
## Four Defects of Anterior Vaginal Wall Prolapse

- **Repair of central defect**
  - re-approximation of widened pubocervical fascia
- **Repair of lateral defect**
  - Suspension/support of bladder base and apex
- **Urethra and BN support**
  - vaginal sling (if necessary), same or **separate** incision
- **Cardinal ligament repair/ Bladder base/ Apex**
  - dissection and approximation to midline

## Anterior Vaginal Wall Prolapse

- Identify and correct all defects
- Evaluate potential other coexistent defects of pelvic organ support (e.g enterocele, rectocele, vault mobility)
- Assess and address potential urethral incompetence
- ? Patch augmentation of repairs





## Anterior Colporrhaphy +/- Absorbable Mesh

- Weber, AM, Walters, MD, Piedmonte, MR, Ballard, LA (Am J Obstet Gyn 2001)
  - 109/114 patients underwent ant colporrhaphy 3 techniques
    - Standard
    - Standard + mesh (polyglactin)
    - Ultralateral colporrhaphy
  - Evaluated by POP-Q
  - Median follow up was 23.3 months
  - 7% stage I preop, 37% stage II preop, 54% stage III preop, 2% stage IV
  - 30% satisfactory outcomes after standard colporrhaphy alone, 42% standard + mesh, and 46% ultralateral colporrhaphy
  - VAS: symptom severity improved overall (6.0 +/- 2.7 → 1.1 +/- 0.8)
  - **Addition of mesh did not seem to make a difference**

## Anterior Colporrhaphy

- Sand, PK et al. (Am J Obstet Gyn, June 2001)
  - Prospective randomized trial of stage 2 < cystocele with and without vicryl mesh
  - Follow up at 2,6,12,52 weeks postop
  - 80 with mesh, 80 none
  - Technique: mesh reduction of prolapse only
  - **After 1 yr, 43% patients without mesh and 25% with mesh had recurrence to mid vaginal plane (p = 0.2), concurrent slings may be protective as well**
  - **Mesh does make a difference**

## Lateral or Paravaginal Defect

## Paravaginal Defects

- Lateral support of pubocervical fascia to condensation of obturator internus and levator fascia's (White line of arcus tendineus)
- Widespread belief that AVW prolapse patients have co-existent lateral and central defects (up to 80%)
- *If so many patients have lateral defects that are not routinely corrected, why do our central defect only repairs work most of the time*

## Paravaginal Defect

### Retropubic repair

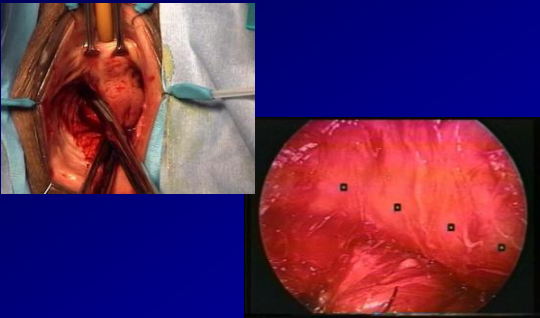
- Can be done open or laparoscopically
- Four to six non absorbable sutures
- Success rates good for retropubic and laparoscopic
- Minimal morbidity (aside from access route)

## Paravaginal Defect Correction

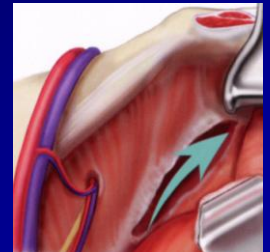
### Vaginal

- Identify lateral defect
- Enter paravaginal space
- Re-approximate pubocervical fascia with ATPF (interrupted non absorbable sutures)

## Vaginal Correction of Lateral Defect



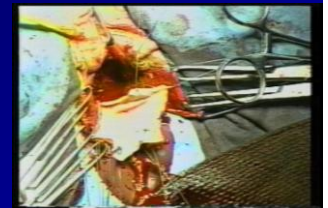
## Vaginal Correction of Lateral Defect



## Vaginal Correction of Lateral Defect



## Vaginal Correction of Lateral Defect



## Paravaginal Defect Repairs Vaginal corrective repairs

Study (year)	No. of pts	Study design	Follow-up		Cure * (%)	Failed (%)
			Mean	range		
White (1909) <sup>4</sup>	19	Retrospect ive cohort	NR	Up to 3 years	100	0
Shull et al (1994) <sup>32</sup>	62	Retrospect ive cohort	1.6 yrs	0.1 – 5.6 yrs	76	24
Farrell & Ling (1997) <sup>31</sup>	27	Retrospect ive cohort	8 mo.	NR	80	20
Nguyen & Bhatia (1999) <sup>33</sup>	10	Retrospect ive cohort	1 yr.	NR	100	0
Elkins et al (2000) <sup>24</sup>	25	Retrospect ive cohort	NR	0.5 – 3 yrs	76	24
Mallipeddi et al (2001) <sup>32</sup>	35	Retrospect ive cohort	20 mo.	8 – 35 mo	97	3
Young (2001) <sup>32</sup>	100	Retrospect ive cohort	11 mo.	1 – 36 mo.	78	22

NR = not reported

Barber, M and Vasavada, S

## Patch Augmentation for AVW Prolapse

- Poor quality tissues used for durable repair
- High recurrent prolapse rates (29-42%)
- What to do for patients with 2-3 previous failed repairs ?
- Younger patient population: what will happen to results over time?
- What happens to sexual function with patch?
- “Bladder Cripples”

## Rationale for Patch Augmentation for AVW Prolapse

- Simultaneous Central and Lateral Defect Support
- Reinforce weak tissues
- Materials for augmentation
  - Autologous ?
  - Allograft (fascia, dermis): falling out of favor ?
  - Xenograft (porcine, bovine): Cross linked vs not
    - Incisional dehiscence
    - Granulation
    - encapsulation
- Synthetic (prolene, soft prolene mesh, marlex, gortex, etc.)

} ?dyspareunia

## Cystocele Conclusions

- Key to success is recognition and correction of all defects
- Address central and lateral defects
- Good apical support cannot be overemphasized
- Patch augmentation evidence is evolving (level I-II), but lack of long term data and limited prospective randomized and controlled studies
- Wide pore polypropylene mesh with anterior repair data is encouraging
- Standardized techniques of support will allow better comparisons

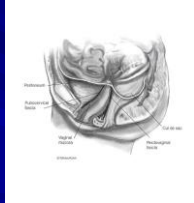
## Apical Prolapse



**Solid Support of the Vaginal  
Apex is the Cornerstone of a  
Good Vaginal Prolapse Repair**

## Vaginal Vault Suspension

- Vault is key to a good prolapse repair !
- Many failures because of lack of vault suspension
- Many don't repair vault
  - Advanced procedures
  - Difficult dissection
  - Were not trained
  - Not recognized
  - Time consuming



## Options for Vault Support

- Sacrospinous Ligament Fixation
  - Risks and benefits?
- Uterosacral Ligament fixation
  - Stretched out ligaments already
  - Data is good, long term ?
  - Risks of ureteric injury are not insignificant
- Sacrocolpopexy
  - Approach lap or open
  - Data is the best ..... Gold standard
  - Material options ??
- Transvaginal replication of best of above approaches??

## Objectives of Vaginal Vault Surgery

- Preserve normal vaginal axis
- Minimize complication rates, blood loss, postoperative discomfort, and cost
- Repair all coexistent pelvic floor defects
- Attempt to restore
  - Vaginal anatomy
  - Visceral function
  - Sexual function
  - Quality of life

## Transvaginal Procedures for Vaginal Vault Prolapse

- Modified McCall's Culdoplasty
- Iliococcygeus Vaginal Vault Suspension
- Levator Myorrhaphy
- Sacrospinous fixation
- High Uterosacral Vaginal Vault Suspension (USVVS)
- Total Vaginal Mesh Apical Suspension
- Colpocleisis

## Mayo/McCall culdoplasty

- Elevation of vaginal apex to high uterosacral ligament
- Proven efficacy in enterocele repair
- Wide experience in specific centers
- Reported high success rates
- Usefulness in complete prolapse in question

## Iliococcygeus suspension

- Transmucosal sutures placed to coccygeus fascia, bilaterally
  - inferior to white line, anterior to ischial spine
- Reported success rates similar to sacrospinous fixation
- Simplicity and decreased morbidity
- May allow for only 6-7 cm depth

Shull, et al. Am J Obstet Gynecol 1993;168:1669-77.  
 Meeks, et al. Am J Obstet Gynecol 1994;171:1444-54.  
 Peters, et al. Am J Obstet Gynecol 1995;172:1894-902.  
 Maher, Dwyer, et al. Obstet Gynecol 2001;98:40-4.



## SSF technique

- Posterior or Anterior approach
- Penetrate right rectal pillar into pararectal space
- Placement of two permanent sutures 1 ½ fingerbreadths medial to ischial spine
- One end of each suture is secured to undersurface of posterior vaginal apex with “pulley stitch”
- Upper ½ of posterior colporrhaphy closed, then SSF sutures tied elevating the apex. No intervening bridge of suture

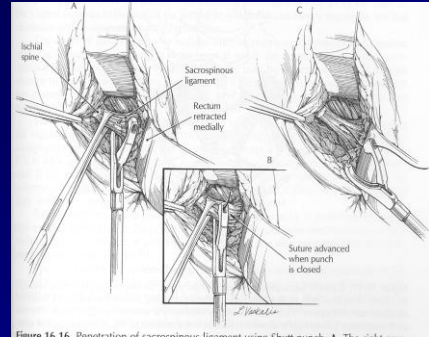


Figure 16-16 Illustration of sacrospinous fixation. (Courtesy of J. J. Nichols)

Adapted from Nichols DH. Vaginal Surgery

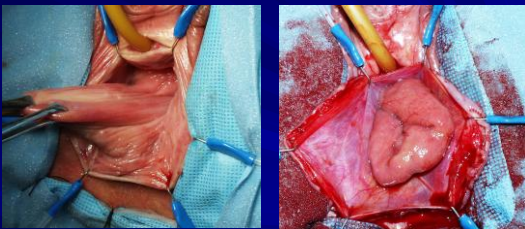
## Sacrospinous Fixation vs. ASC

- ASC better than SSF with lower recurrence rates (RR: 0.23, 95% CI 0.07-0.77)
- ASC less dyspareunia
- Trend towards lower reoperation rates in ASC pts
- SSF quicker and cheaper to perform
- Return to daily activities longer with ASC
- Maher, C et al: NUJ 27: 3-12, 2008 Cochrane Review

## Levator Myorrhaphy

- Transvaginal placement of sutures through levator complex and shelf towards midline to anchor upper vagina
- Similar in concept to Mayo Culdoplasty
- Uses #1 absorbable sutures thru neovaginal apex and into levator muscles bringing them towards the midline to contralateral side. Then, 2 purse string sutures to close enterocele sac

## Apical Prolapse



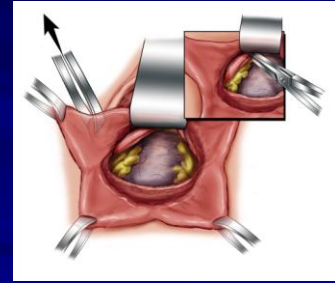
## Levator Myorrhaphy Results

- Lemack, GE et al (Eur Urol Dec 2001)
  - 35 patients (mean age 71, f/u 27.0 months)
  - 5 recurrent prolapse (3 ant enterocele, 1 vault)
  - 7/35 recurrent cystoceles (5 grade 1, 2 grade 2)
  - Satisfaction > 90% in 17/35
  - One ureteral injury

## Uterosacral Vaginal Vault Suspension

- Placement of sutures through “normal” vaginal apical suspension points
- Ideal at time of hysterectomy for prolapse
- Thought to be more physiologic suspension of apex
- Addresses level I and II support continuity
- Low, but not insignificant complication of ureteral injuries as the ligament is close to the ureters especially distally

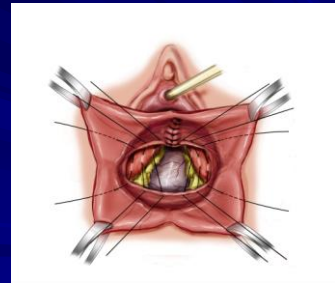
## Uterosacral Vaginal Vault Suspension



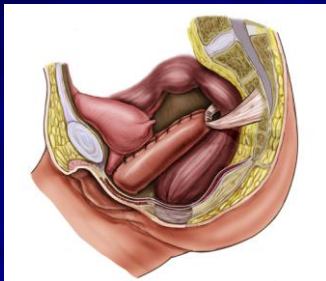
## Uterosacral Vaginal Vault Suspension



## Uterosacral VVS



## Uterosacral VVS



## Uterosacral VVS Results

First Author	Year	No.	Follow-up Months (range)	Definition of anatomic success	Anatomic success - all segments	Anatomic recurrence by segment	Reoperation for POP
Jenkins	1997	50	(6-48)	Not defined	96%	Anterior 4%	None reported
Comiter	1999	100	17 (6.5-35)	Grade 0-1	96%	Apex/enterocele 4%	4 (4%)
Barber	2001	46	15.5 (3.5-40)	Stage 0/1 or asymptomatic Stage 2	90%	Apex 5% Anterior 5% Posterior 5%	3 (6.5%)
Kurram	2001	168	21.6 (6-36)	Grade 0-1	88%	Apex 1% Anterior or posterior 11%	11 (5.5%)
Shull	2001	289	Not stated	Grade 0-1	95%	Apex 1% Anterior 3.5% Posterior 1.4%	None reported
Amundsen	2003	33	28 (6-45)	Stage 0 or 1	82%	Apex 6% Posterior 12%	None reported

## Challenges of Vault Suspension Procedures

- No standardized procedure<sup>1,2</sup>
  - More than 40 different operations for the treatment of vaginal vault prolapse have been described<sup>1</sup>
  - Wide variation in suture materials<sup>3</sup>
- Data on comparative efficacy and safety of different procedures are inconsistent<sup>1,2</sup>
  - No standardized outcome measures in trials<sup>1</sup>
  - Few randomized prospective trials<sup>1,4</sup>
- No routine application of tools to assess postoperative anatomical and functional outcomes<sup>2</sup>
- Variable impact on vaginal axis: change in axis may cause new prolapse to occur<sup>2</sup>

1. Beer M, et al. *Eur J Obstet Gynecol Reprod Biol*. 2005;119:144-155.  
 2. Arbel R, et al. *Best Pract Res Clin Obstet Gynaecol*. 2005;19:1-19.  
 3. Levatis D, et al. *Comp Opin Obstet Gynecol*. 2003;15:435-447.  
 4. Davila GW, et al. *Int Urogynecol J*. 2002;13:319-323.

## Total Vaginal Mesh Kit Repairs

- Idea to replace components of normal anatomic structure and support of posterior vaginal wall and apex (may also include anterior vaginal wall)
- Typically done with wide pore polypropelene mesh (may use other substitutes)
- May offer more solid and reproducible points of fixation

## If so many kits are available why is everyone not using them?

- Cost
- Is it that much better than traditional repairs ?
- FDA statement?
- Risks of erosion and dyspareunia/pain is too much for comfort?
- Relies on mesh for support as opposed to any sutures

## Conclusions

- Many procedures for vaginal vault suspension
- Current movement is towards use of mesh and "kits" that may reproduce native support in a minimally invasive fashion
- Cost is an issue, but hospitalization may be shorter
- Complications profile being noted with more experience
- Role for a registry for mesh use?
- Ideally suited for development of a randomized prospective trial
  - Issues of control arm: SSF, USVVS ?

## Posterior Repair

## Posterior Repair



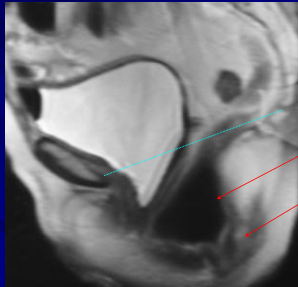
- Anatomical restoration
- Visceral function
- Sexual function

Rectocele repair

Narrow levator hiatus

Perineal repair

## Rectocele



Rectum

Anal sphincter

## Site Specific Defect Repair Literature Review

Study	N	Follow up (months)	Cure Rate (%)
Cundiff et al. (1998)	43	12	81 (35/43)
Karram et al. (1999)	89	6	82 (73/89)
Brubaker et al. (1999)	44	12	77 (34/44)
Monga et al. (2000)	46	13	82 (38/46)

## Graft Augmented Posterior Repairs

- Rationale ? Recurrences to decrease?
- Maher et al, NUU Cochrane Review
  - Vaginal approach had lower recurrence rates than transanal
  - Higher EBL and pain
  - Data on bowel sx insufficient
  - Use of SIS and absorbable mesh insufficient but trended to not be of benefit

## Conclusions

- Vaginal approach to prolapse still easiest and often most effective (esp isolated cystoceles and rectoceles)
- Use of “traditional” vs “non traditional” methods must be weighed with pros and cons of approaches with appropriate informed consent i.e “ risk vs reward”

## **Robotic Sacrocolpopexy**

### **Overview:**

The role of robotic surgery in reconstructive pelvic surgery will be reviewed. Specifically, course participants will (1) be able list the advantages of robotic surgery when compared to other routes of access; (2) be able to discuss outcomes of robotic prolapse repair; and (3) become familiar with technique of robotic sacrocolpopexy.

Sacrocolpopexy with or without concomitant hysterectomy is the most commonly performed robotic procedure in Female Pelvic Medicine & Reconstructive Surgery. Although randomized trials demonstrate that sacrocolpopexy has more durable anatomical outcomes than vaginal approaches to apical vault suspension without mesh, open abdominal surgery has increased short-term morbidity. In a retrospective cohort analysis of laparoscopic and open sacrocolpopexy, operating room times were longer for the laparoscopic cases when compared to open cases; however, hospital stay and estimated blood loss for the laparoscopic cases was significantly less. Both cohorts had similar complication and re-operation rates.

The utilization of laparoscopy for surgeries traditionally performed via laparotomy is limited by a steep learning curve and ergonomic difficulties. Initial reports of short and long-term outcomes of robot sacrocolpopexy report comparable anatomic success, decreased hospital stay, and lower complication rates when compared with open sacrocolpopexy. A recent retrospective cohort study of robotic versus open sacrocolpopexy, the robotic group had slightly better 6 week postoperative POP-Q apical support, as noted by point "C" [-9 (-10 to -8) vs -8 (-9 to -8);  $p=.008$ ], shorter hospitalization ( $1.3\pm 0.8$  vs.  $2.7\pm 1.4$  days;  $p<.001$ ) and less intraoperative blood loss ( $103\pm 96$  vs.  $255\pm 155$  ml;  $p<.001$ ) when compared with the open group. Operative times were shorter for the open sacrocolpopexy group ( $225\pm 61$  vs.  $328\pm 55$  minutes;  $p<.001$ ). With the exception of 3 patients with postoperative fevers in the robotic group, no other significant difference in perioperative complications was seen between the groups. Concurrent hysterectomy (35 vs. 31 patients;  $p=.02$ ) and anti-incontinence surgery, either synthetic midurethral sling or Burch urethropexy, (37 vs. 42;  $p=.17$ ) were similar in both groups. Further studies assessing short and long-term anatomic and subjective outcomes using standardized, validated methods are imperative to determine efficacy and complications as well as identify optimal patients for robotic sacrocolpopexy.

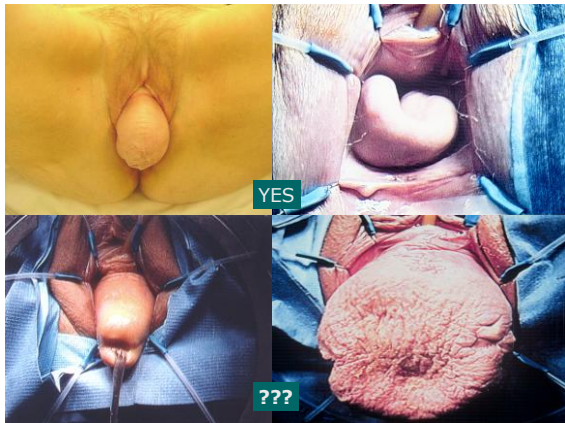
There seem to be advantages to robotic surgery over conventional laparoscopy that may improve the generalizability and applicability of minimally invasive surgery to female pelvic surgeons who have not embraced complex laparoscopic procedures. However, with new technology comes new responsibility and only well-designed clinical trials will determine if robot surgery is the best option for patients and surgeons, who wish to offer their patients minimally invasive surgical alternatives.

## Management of recurrence and mesh complications

Philippe E. ZIMMERN

### My Indications for open mesh sacrocolpopexy

- ✓ Primary repair: NO!
- ✓ Secondary repair : YES (but limited data)
- ✓ Issues:
  - Young patient
  - Steroids; Diabetes
  - Vaginal wall ulcerations



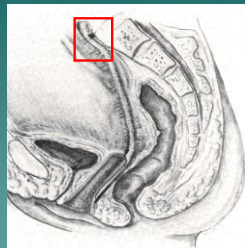
### Mesh sacrocolpopexy Background

- ◆ First described in 1962 by Lane
- ◆ Until then, treatment options were:
  - Pessary
  - Colpocleisis
  - Vaginal repair

- ✓ Support upper vagina toward S3 and S4
- ✓ Sutton et al. (1981): Life-threatening bleeding from pre-sacral vessels

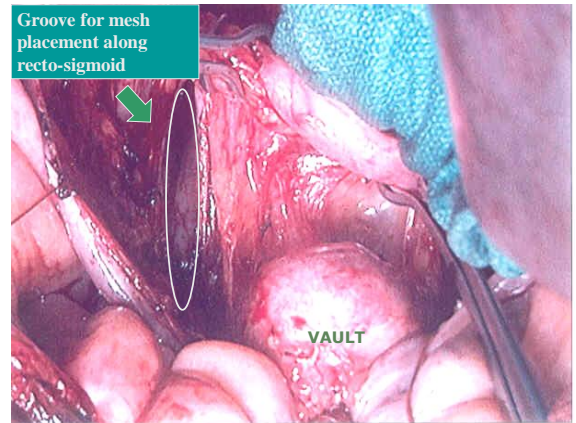
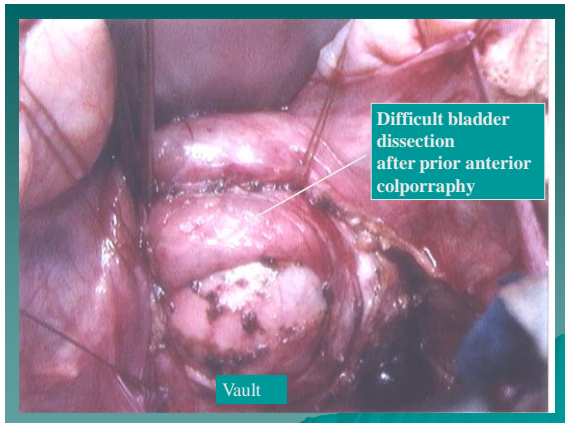
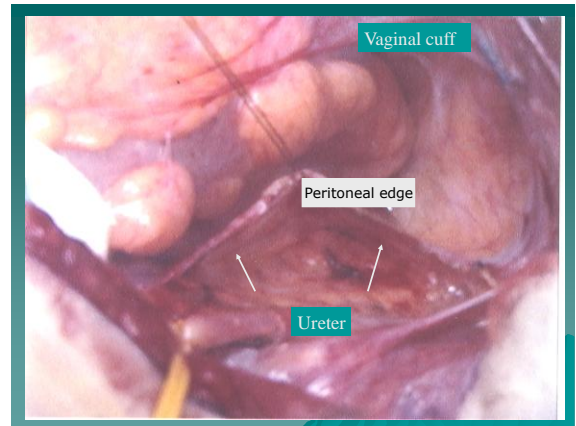
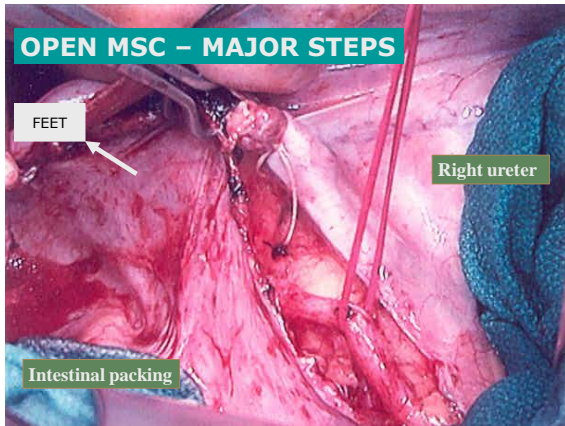
=> Suspension of the vagina to upper third of sacrum, near sacral **promontory**

### GOAL



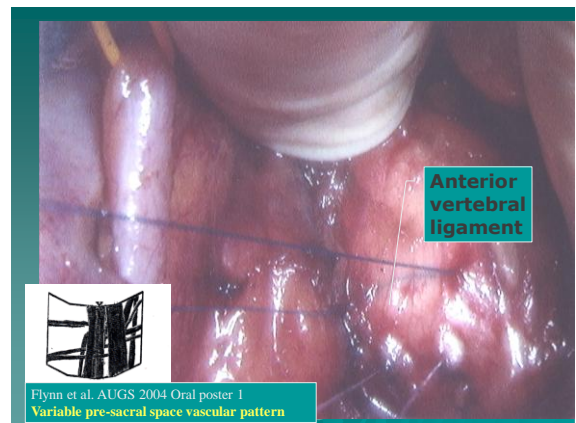
### Types of Synthetic meshes

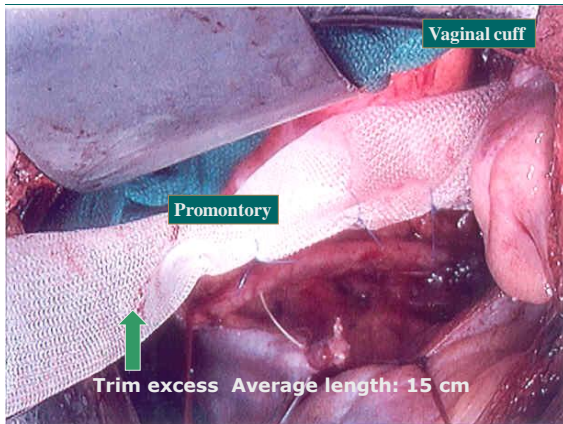
- Pore > 75 micron (**Marlex, Polypropylene-Prolene, Trelex**)
- Pore < 10 micron/Multifilament (Gore-Tex)
- Multifilament (Teflon, Mersilene, Surgipro)



**Sutures to anchor the mesh to the vagina**

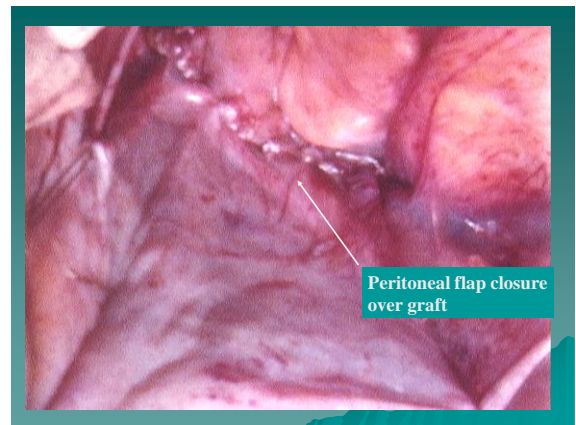
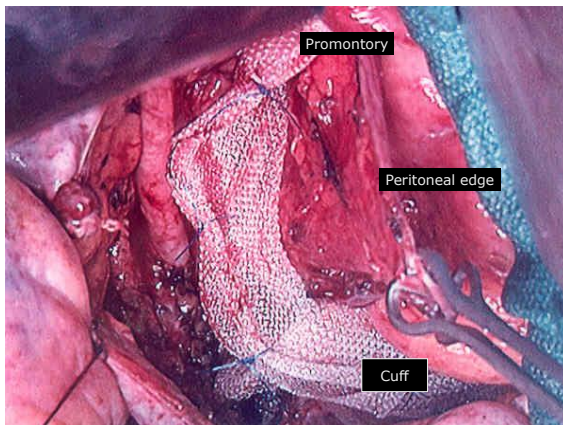
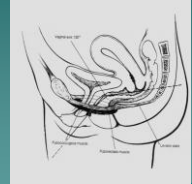
- Non-absorbable/Absorbable?
- 1-2 cm apart, transversely
- ± Avoid vaginal epithelium
- Knots tied over mesh





## Final checkpoints

- Check vagina to ensure no transfixing sutures
- Cystoscopy
- Vaginal pack (molding)
- Lay graft along sigmoid
- No mesh tension



### Results of abdominal sacrocolpopexy

Authors	Ref.	Year	Patients (n)	Follow-up (months)	Success rate (%)
Angulo	[10]	1989	18	36	100
Baker	[8]	1990	95	—	100
Maloney	[7]	1990	10	—	90
Creighton	[20]	1991	23	17	91
Snyder	[9]	1991	147	60	93
Timmons	[6]	1992	163	33	—
van Lindert	[27]	1993	61	32	95
Iosif	[28]	1993	40	6	97
Valaitis	[15]	1994	43	21	88
Virtanen	[19]	1994	30	36	85
De Vries	[13]	1995	101	168	32
Drutz	[14]	1995	15	28	93
Hardiman	—	1996	130	12	99
Cundiff	[12]	1997	19	3	100
Constantini	[11]	1998	21	39	90
Pilsgaard	[16]	1999	35	6	97
Geomini	—	2000	40	42	93

## Cochrane Review 2007

- ◆ **22 RCT with 2368 patients**
- ◆ **PROS:** Lower rates of recurrence and dyspareunia compared to vaginal approach
- ◆ **CONS:** Longer procedure & recovery, and higher costs



### Geomini et al

*Eur J Obs and Gynecology* 94:234-238 2001

- **40 patients Median F/U: 38 months**
- **"Success" rate: 93% (37/40)**
  - If vaginal protrusion was the only pre-operative complaint, surgery produced symptom-free results in 13/14 patients
  - If combination of complaints (protrusion plus incontinence, defecatory symptoms, or sexual dysfunction), surgery produced symptom-free results in only 10/27 (37%)

### Given et al

*Am J Obstet Gynecol* 169:284 1993

- Effect on **vaginal length and sexual function**
- 59 patients
- MSC or Sacrospinous fixation (SSF)
- Measurements taken with a marked plastic cylinder from introitus to the posterior fourchette

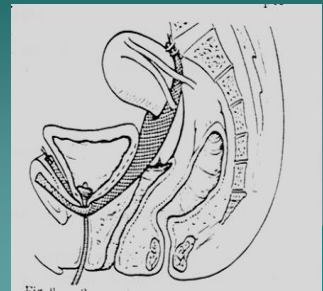
### Given et al

- **Average vaginal length:**
  - 8.2 cm after SSF
  - 11.3 cm after MSC
- **A sexual function survey also revealed MSC to be superior**

### Uterine preservation

Huguier, J. et al.  
*J.Chir.* 94:285, 1967

Repair of large cystocele with sub-urethro vesical prosthesis



### Recurrent triple compartment POP

- ✓ 29 pts 2000-2006
- ✓ Median f/up: 23 mths
- ✓ Improved UDI and QoL
- ✓ 2 pts: ≥gr.2 Cystocele (standing VCUG at 6 months)
- ✓ No change in sexual or defecatory functions

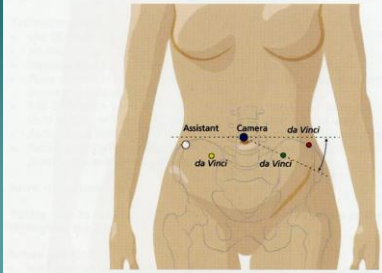
Gilleran JP, Zimmern, P: *BJUI* 103:1090, 2009

### ROBOTIC: Indications

- ◆ BMI < 30
- ◆ Few prior abdominal surgeries
- ◆ No significant respiratory disease
- ◆ <75-80 y-old patients
- ◆ Vault prolapse alone, or with one additional compartment defect
- ◆ Consent : possible open repair (+)

## ROBOTIC EQUIPMENT

Port Placement for 4-Arm da Vinci Sacrocolpopexy

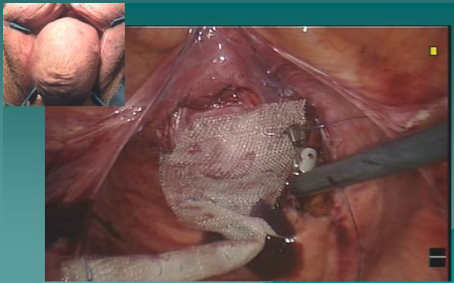


Approved by FDA April 2005

## Technical Pointers

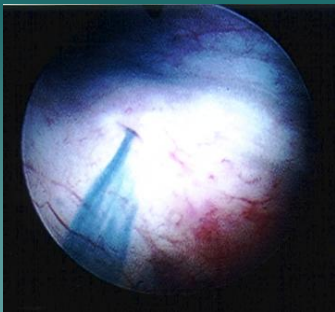
- ◆ ? Side docking for vaginal access
- ◆ Difficult: vaginal cuff & promontory
- ◆ Mesh and suture choices
- ◆ Transfixing sutures
- ◆ Tensioning the mesh

Case 3: 62 y old – S/P vag.hyst.  
Wanting to resume sexual activity



Movie

Check efflux of blue



## Robotic MSC- Literature review

- ◆ Several techniques described
- ◆ Few short series
- ◆ Short follow-up
- ◆ No comparative series

### Elliott, DS et al. J.Urol 2006

- ◆ N=30 mean age:67
- ◆ 21 with at least 1 y follow-up
- ◆ Mean duration: 3.1 hours
- ◆ One conversion to open
- ◆ Mean hospital stay: 1,5 day
- ◆ 2 recurrences at 7 and 9 months
- ◆ 2 vaginal mesh extrusion at 6 months

### Daneshgari, F et al. BJU 2007

- N=15 mean age: 64
- 3 conversion to open
- Mean duration: 317' (> 5 hours)
- Mean blood loss: 80 ml
- Mean hospital stay:2,4 days
- Mean follow-up: 3 months
- Mean POPQ stage: 3.1 decreased to 0

### Geller et al. Obstet Gynecol.2008

- ◆ Retrospective series
- ◆ Open (105) versus robotic MSC (78)
- ◆ More POP and supracervical hysterectomy in the robotic group
- ◆ Also less blood loss and shorter stay
- ◆ Longer operating time (mean>5h)
- ◆ Same 6 wks short term outcome (POP-Q)

### Akl et al. Surg Endosc.2009

- ◆ N=80
- ◆ Learning curve (3hrs down to 1h30')
- ◆ C:cystostomy (2), enterotomy (1),ureteric injury (1)
- ◆ Erosion: 5 (6%) (mean 5 months!)
- ◆ Conversion rate: 4/80 (5%)

## Conclusions

- ◆ 3 D vision
- ◆ Enhanced instrument maneuverability
- ◆ Attractive to patients
- ◆ Major cost compared to open

=> **New application** - unproven long-term outcome and no RCT yet

## Future

- ◆ **Single incision**
- ◆ **Decrease cost**
- ◆ **Technological improvements**
  - Tactile feedback
  - Smaller units

## Mesh Complications

- ◆ Bleeding (promontory ++)
- ◆ Infection
- ◆ Vaginal erosion
- ◆ Bladder erosion (stone, fistula)
- ◆ Dyspareunia
- ◆ Recurrence (< 10%)

## Snyder et al

*Obstet Gynecol* 77(6): 944 1991

- **One of the largest series:** 147 pts
- Mean F/U: 43 months
- 78 GORE-TEX, 65 Dacron, 4 others
- Hospital stay: 2-13 days

## Snyder et al

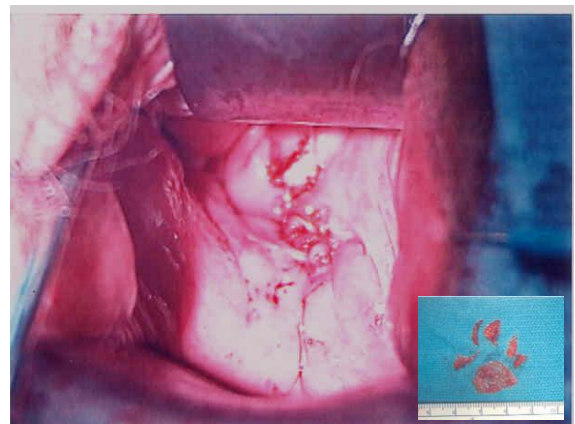
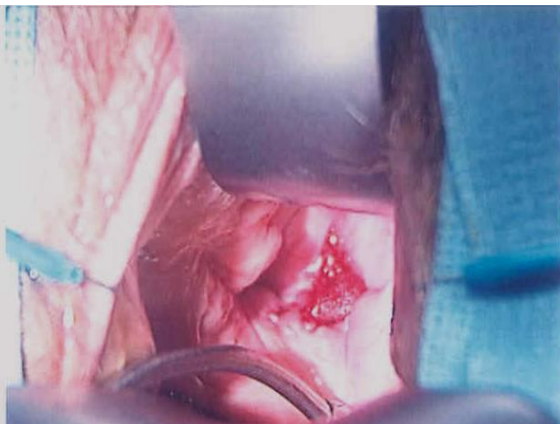
- 108/116 (93%) who had at least 6 months F/U had a successful outcome
- No recurrent prolapse
- **Complications:**
  - Bleeding (>500cc EBL) in 23
  - Graft erosion (4) → Removal of graft, with 1 having recurrent prolapse

## Iglesia et al

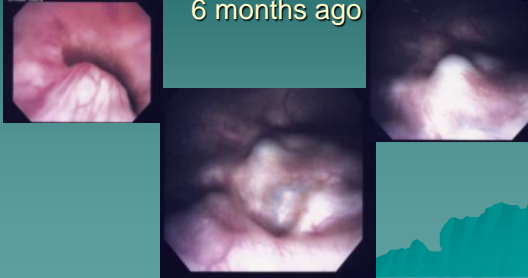
*Int Urogynecol* 8: 105-115, 1997

### Review incidence of mesh erosion

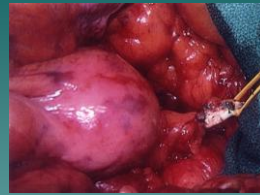
- Procedures used Marlex, Prolene, Mersilene, and Gore Tex
- Overall incidence of erosion: 9%
  - Highest for Gore Tex



Case Discussion: 72 y old Totally incontinent after prophylactic TVT placed at time of laparoscopic mesh repair (prolene) 6 months ago



### Case Discussion - Recurrence



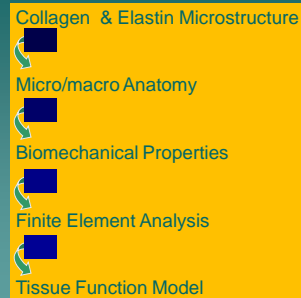
Failed GoreTex mesh



### Conclusions on MSC

- ✓ High success rate (>90%), which appears durable
- ✓ Concomitant anterior or posterior defects should be treated
- ✓ Best option for sexually active pts
- ✓ Major complications include bleeding and mesh erosion or infection

### Biomechanics Analysis Methodology: Adapted from mitral valve experience



2002-2007

In process

### Cutometer: Potential for Office Exam Procedure

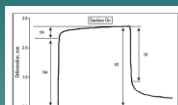


Figure 4. Graph depicting in-office deformation (D), absolute deformation (Δ), the deformation (Δ), and resistance variation (Δ) of the normal skin.

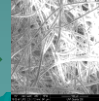
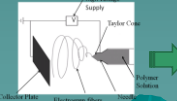
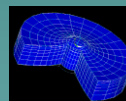
Table 2. Red Skin Elasticity Before and After Pulsed Carbon Dioxide Laser Treatment (n = 32)<sup>a</sup>

Site	Mean (SD) (n=32) Before		Change in Elasticity, %
	Elasticity	After Treatment	
Forehead	0.20 (0.02)	0.23 (0.03)	12
Forearm	0.08 (0.01)	0.12 (0.02)	22
Midline chest	0.10 (0.01)	0.14 (0.02)	20
Upper arm	0.05 (0.01)	0.08 (0.01)	16
Lower arm	0.05 (0.01)	0.08 (0.01)	12
Hand	0.10 (0.02)	0.12 (0.02)	12

<sup>a</sup>SD indicates standard deviation; n, skin elasticity; (P < .001).

### Glimpse into the Future

- ✦ Office testing (tissue signature /Cutometer)
- ✦ Finite element modeling
- ✦ Biomaterials for tissue enhancement/ replacement unique to each patient



### Graft Materials in Lower Urinary Tract Reconstruction

**J. Christian Winters, M.D.**  
 H. Eustis Reilly Professor of Urology and Gynecology  
 Chairman, Department of Urology  
 Louisiana State University Health Sciences Center  
 New Orleans, Louisiana, USA  
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*Too often we enjoy the comfort of opinion without the discomfort of facts...*

John F. Kennedy

### Ideal Implant

- Readily available and affordable
- Biocompatible and chemically inert
- Noncarcinogenic
- Strong, sterile
- Minimal risk of infection or rejection
- No detrimental effect on pelvic function
- More durable than autologous tissue

3

### Classification of graft materials

Togami J, Kfir R, Winters JC. AUA Update Series XXX, 2008

4

### Biologic Materials

Chen C. Clin Obstet Gynecol 2007; 50: 383-411

### Tissue Ingrowth

- An orderly arrangement of collagen fibers and connective tissue facilitates an ingrowth of host tissue.
- If an integration of host tissue occurs, the implant retains its strength.
- Does irradiation or freezing effect this arrangement?

Photo: Kim H, et al: Urology 58: 800-804, 2001

6

### Host Tissue Ingrowth

- Neovascularization and fibroblasts infiltrate at periphery and superficial surfaces of the graft.
- Central portion of graft acellular for years.
- Once entire graft infiltrated, transformation process is completed.

Photo: Nikolaeu P, Am J Sports Med 14: 349-360, 1986

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### Host Tissue Incorporation

- It appears that for long-term graft survival, host tissue incorporation must occur to facilitate a process of graft remodeling, "transformation" into host.
- Even for permanent materials!!!
- "Graft remodeling"

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### Biologic Grafts: Lessons learned

- Cadaveric materials:
  - harvesting technique is standardized
  - varying processing techniques
    - variance in the tensile strength and tissue quality of these graft materials (and degree of incorporation)
- Xenografts:
  - Fenestrations
    - Used to facilitate tissue ingrowth
    - Has not been definitely proven to work
  - Cross linking decreases degradation
    - May not allow adequate tissue integration

### Synthetic Graft Materials

#### Case for Synthetics:

1. Readily available
2. Inexpensive
3. Favorable tensile strength
4. Permanent, durable material
5. No potential disease transmission

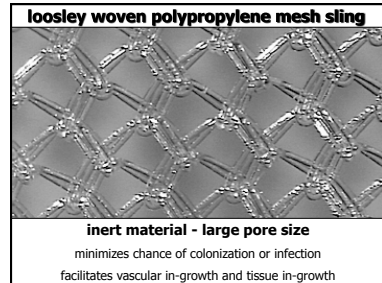
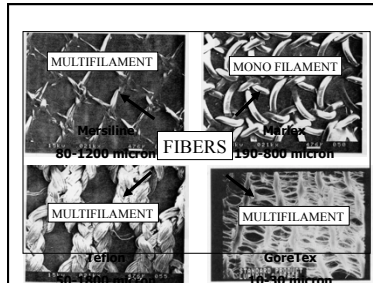
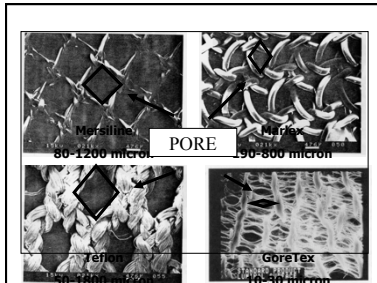
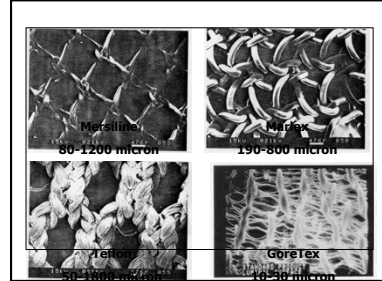
*Must be accepted by host "remodeling"* <sup>10</sup>

### Mesh Characteristics

#### • Amid Classification:

- Type 1: Macroporous and Monofilament
  - Desirable for vaginal surgery: large pores promote tissue ingrowth and host defenses against bacteria.
  - Flexible, easier to implant.
- Type 2: Microporous with small pore size
- Type 3: Macroporous, multifilament mesh – small interstices
- Type 4: "Coated" biomaterials with extremely small pore size

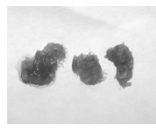
11



### Sling Graft Histopathology: A Comparison Time Controlled



Porcine Dermis



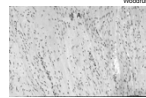
Polypropylene mesh

Woodruff A, et al Urology 2008

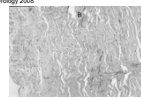
### Microscopic Assessment:

#### Time Controlled

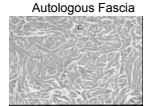
Woodruff A, et al Urology 2008



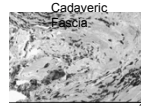
Autologous Fascia



Cadaveric Fascia



Porcine



PPM

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### Principles for the practicing physician

- Mesh material safe for implantation.
  - Volume of material and technique of implantation intimately related to incorporation
- Encapsulation of grafts not beneficial (contrary to prosthetic devices)
  - Mesh does not encapsulate
  - Coated and microporous meshes or synthetics likely to elicit adverse host reaction and / or encapsulation

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**Outcomes: Comparison Difficult**

- Apples vs Oranges
- Procedures differ:
  - Mesh procedures tend to be multi-compartmental repair
  - Colporrhaphy doesn't address the apex
  - Mesh procedures are free graft or "kit" procedures
- Definition of success not uniform

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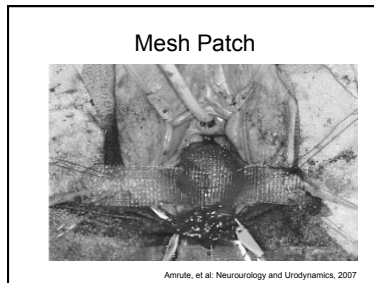
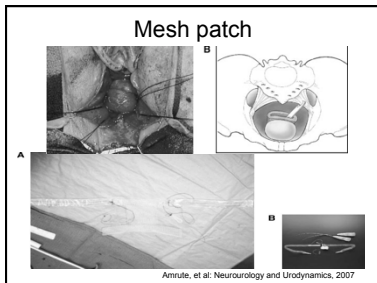
**Use of Mesh in ASC**

- Reports verifying benefits of synthetic mesh material during ASC
  - patients undergoing ASC using either absorbable cadaveric fascia lata graft (Tutoplast) or nonabsorbable monofilament polypropylene were randomized.
  - The objective failure rate for recurrence was 14 out of 44 in the fascial group and 4 out of 45 in the mesh group (RR 3.58, 95%CI 1.28 to 10.03)

• Maher et al. Surgical management of pelvic organ prolapse in women. Cochrane database of systematic reviews (Online) (2007) (3) pp. CD004014  
• Culligan et al. Long-term success of abdominal sacral colpopexy using synthetic mesh. Am J Obstet Gynecol (2002) vol. 187 (6) pp. 1473-80; discussion 1481-2

**Use of mesh in vaginal surgery**

- Mesh patch augmentation:
  - Free graft
  - Variable fixation: SSLF, iliococcygeus, arcus tendineus, (Sling)
  - Transvaginal kits
- Variable methodology makes comparison quite difficult.



**Mesh patch repair**

Compliments of Victor Nitti

**Synthetic Mesh: Prolapse Repair**

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Winters, et al: BJU Int, 2006

**Proposed Advantages of Kits**

- Standard technique
- Standard mesh
- Standard size – can be cut
- Addresses all compartments of interest?
- Straight out of the box
- Easier to compare results?

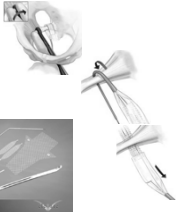
**Currently Available Kits**

- AMS
  - Apogee/Perigee
    - Integro – synthetic
    - InteXen LP – biologic
- Bard
  - Avaulta
    - "Biosynthetic"
- Gynecare/Ethicon Women's Health & Urology
  - Prolift
    - synthetic

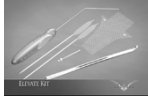


**New Generation:  
No Trochar**

Pinnacle: Boston Scientific



Elevate: AMS



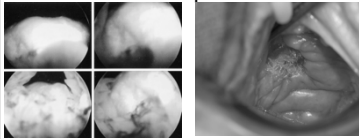
**Cost**

- AMS
  - Apogee – synthetic - \$1295
  - Perigee – synthetic - \$1595
  - Biologic - \$400 more each
- Bard - Avaulta
  - Anterior ~ \$1300
  - Posterior ~ \$1300
- Gynecare/Ethicon - Prolift
  - Anterior - \$1200
  - Posterior - \$1200
  - Total - \$1500

**Principles of TransVaginal Mesh (TVM) Technique**

- **Tension Free Placement**
- **Broad coverage of the implants**
- **Fixation™ – of straps**
- **No trimming of the vagina**
- **Mesh options: Anterior, Posterior, and Total (with & without hysterectomy)**

**Mesh Complications**



EROSION

EXTRUSION

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**U.S. Food and Drug Administration**

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**

**FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence**

Issued: October 20, 2008

Dear Healthcare Practitioner:

This is to alert you to complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI). Although rare, these complications can have serious consequences. Following is information regarding the adverse events that have been reported to the FDA and recommendations to reduce the risks.

**Recommendations for Physicians**

- Obtain specialized training for each mesh placement technique, and be aware of its risks.
- Be vigilant for potential adverse events from the mesh, especially erosion and infection.
- Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.
- Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
- Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall (in POP repair).
- Provide patients with a written copy of the patient labeling from the surgical mesh manufacturer, if available.

<http://www.fda.gov/cdrh/afm/102008-surgicemesh.html>

**Synthetic Mesh Prolapse Repair: Complications**

- Extrusion "**Vaginal Erosion**" rate – 8.3-11%  
Hardman P, et al: BJOG, 2000
- Dyspareunia:
  - Up to 20% using anterior mesh (6.3% extrusion)
  - Higher incidence expected in posterior compartment.Milani, et al: BJOG, 2005
- Initial Erosion rate of 17.5% using "kit"  
Debodiance, et al: J Obstet Gynecol Biol Reprod, 2004.

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**Conclusions: My take home thoughts**

- Prolapse outcomes appear to be better after synthetic interposition. (No controlled data!!)
- Biologic materials are at risk of failure, and should be used sparingly.
- With higher volumes of implanted mesh, complications more likely.
- Unique complications related to synthetic materials can be significant, and disasters can (and will) occur...

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**Pelvic Organ Prolapse**

- Surgical treatment of prolapse depends upon:
  - Severity of prolapse
  - Severity of symptoms
  - General health of the patient
  - Surgeons preferences and skill level
- Aims of surgical therapy
  - Restoration of normal anatomy
  - Restore or preserve bladder, bowel and sexual function

### Surgical Procedures: POP

- Vaginal approach
  - Vaginal hysterectomy
  - McCallis culdoplasty
  - Anterior colporrhaphy
  - Posterior colporrhaphy
  - Enterocele closure
  - Sacrospinous colpopexy
  - Colpoceleisis
  - Vaginal mesh kits
- Abdominal approach
  - Abdominal hysterectomy
  - Uterosacral suspension
  - Sacrocolpopexy
  - Paravaginal repair

### Laparoscopic Prolapse Surgery

- Total laparoscopic hysterectomy
- Laparoscopic supracervical hysterectomy
- Uterosacral ligament suspension
- Sacrocolpopexy
- Sacrocolpoperineopexy
- Enterocele closure
- Paravaginal repair

### Re-operation rate for prolapse

**Recurrence Rates**

- Transvaginal Procedures
  - 3.9% (range 0-29.1)
  - (32.6 ± 19.8 months)
  - Mean complication rate was 15.3%
- Colpopexy Procedures
  - 2.3% (range 0-31.3)
  - (26.5 ± 20.1 months)
  - Mean complication rate was 17.1%
- Mesh Kits
  - 1.3% (range 0-16.0)
  - 17.1 ± 13.8 months
  - Mean complication rate was 14.5%

### Cochrane Review

Authors' Conclusion: The benefits of the Abdominal sacral colpopexy procedure must be balanced against:

- longer operating time
- longer time to return to activities of daily living
- increased cost of the abdominal approach.

Summary: The trials show that abdominal sacral colpopexy may be better than vaginal sacrospinous colpopexy for uterine or vault prolapse.

### Lap vs Open Colpopexy

Abdominal vs. Laparoscopic sacrocolpopexy

56 patients who underwent laparoscopic sacral colpopexy

- Mean follow-up: 13.5 +/- 12.1 months
- Mean operating time: 269 +/- 65 minutes
- Estimated blood loss: 172 +/- 166 ml
- Hospital stay: 1.8 +/- 1.0 days

61 patients who underwent open sacral colpopexy

- Mean follow-up was 15.7 +/- 18.1 months
- Mean operating time: 218 +/- 60 minutes
- Estimated blood loss: 234 +/- 149 mL
- Hospital stay: 4.0 +/- 1.8 days

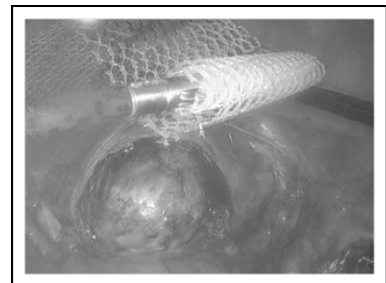
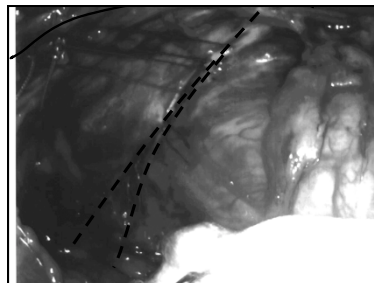
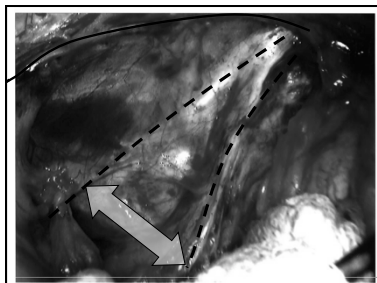
Complication and reoperation rates were similar

• Conclusion: Laparoscopic and open sacral colpopexies have comparable clinical outcomes.

Paraiso MF, et al. Am J Obstet Gynecol 2005;192:1752-1758.

### Costs of Prolapse Surgery

Procedure	Approximate Cost
Open SC	~10,000
LSC	~15,000
Robotic SC	~22,000





Sacral Colpopexy



## Assessment of Outcomes after Reconstructive Pelvic Surgery

Kimberly Kenton MD, MS, FACOG, FACS  
Associate Professor & Fellowship Director  
Female Pelvic Medicine & Reconstructive Surgery  
Departments of Obstetrics & Gynecology and Urology  
Loyola University Stritch School of Medicine

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## Learning Objectives

- ▶ List 4 types of outcomes that should be considered when evaluating RPS.
- ▶ Provide specific examples of each dimension.
- ▶ Discuss the role of patient oriented outcomes.

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## Best method for assessing outcomes?

- ▶ Optimal method is unclear
- ▶ No consensus of what constitutes "success"
- ▶ Wide variety of definitions for "success"
  - ▶ Results in highly variable estimates of success
- ▶ Shift toward patient centered outcomes

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## History of Outcomes Assessment



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## NIH Recommendations: *Objective*

2001 Workshop:  
Standardization of Terminology for Pelvic Floor Researchers

- ▶ "Optimal" = Stage 0 POP
- ▶ Satisfactory = Stage I POP
- ▶ "Definitions picked arbitrarily"

(Weber A et al 2001)

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## Epidemiology of POP

- ▶ Women presenting for routine GYN care
  - ▶ Stage 0 = 6%
  - ▶ Stage I = 43%
  - ▶ Stage II = 48%
- ▶ Nearly half would not meet NIH definition for "optimal" or "satisfactory" anatomic outcome

(Swift S et al, 2005)

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## How do symptoms relate to anatomy?

- ◆ Vaginal bulge = symptom that most strongly correlates with POP-Q
- ◆ Bulge at the hymen seem to be when patients notice it and become symptomatic

(Swift S et al 2003; Bradley CA et al 2005)

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## Outcomes By Definition of Success

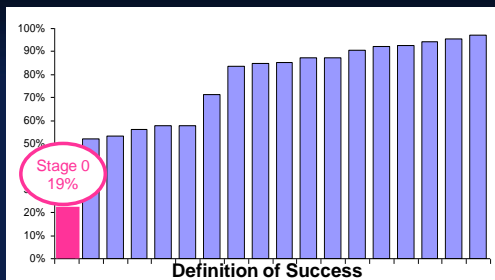
### Pelvic Floor Disorders Network

- ◆ Anatomic Definitions
  - ◆ Stage 0, Stage 0/I, No descent > hymen
- ◆ Subjective Definitions
  - ◆ Absence of vaginal bulge symptoms
  - ◆ Global Impression of Improvement
- ◆ Treatment outcomes, "success" by definition  
(Barber M 2009)

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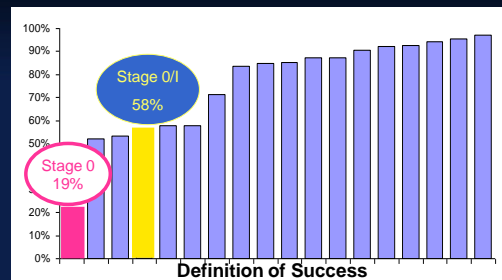
## Success Varied With Definition



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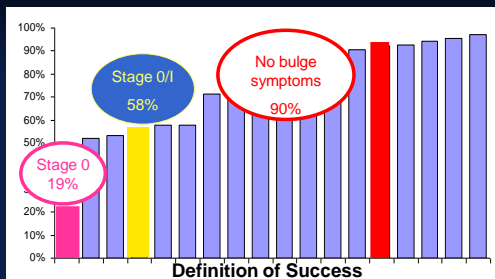
## Success Varied With Definition



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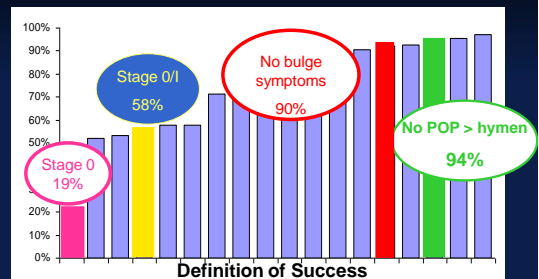
## Success Varied With Definition



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## Success Varied With Definition



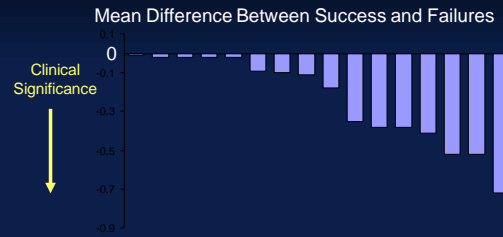
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## What's the Patient's Perspective?

- Compared patient's assessment of their outcome using PGI to each definition
- Treatment of your pelvic condition has been \_\_\_\_?
  - Very successful
  - Moderately successful
  - Somewhat successful
  - Not at all successful

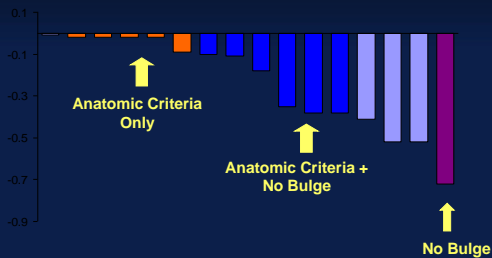
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## What's the Patient's Perspective?



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## What's the Patient's Perspective?



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## Bottom Line....

- Patient's want the "bulge" gone!
  - Relief of symptoms
- NOT**
- "I want my apex at -9 or my anterior vaginal wall at -3."

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## Bulge gone ≠ Patient satisfaction

- No bulge ..... but, NOW has
  - SUI
  - UUI
  - Dyspareunia
  - Complication
  - Mesh erosion .....



- Did we achieve patient's GOALS for surgery?

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## Patient's Goals & Expectations

- Always present and typically unstated
- Different
- Personal, often life-style related, and usually reasonable
- NEVER to have persistent or new post-op problems or symptoms

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## Post-operative Satisfaction

- ↗ Correlates strongly with achievement of self-described, pre-operative goals  
(Hullfish K 2005, Elkadry E 2003)
- ↗ Dissatisfaction (3 month & 1-year) correlates strongly with
  - ↗ Feeling "unprepared" for surgery
  - ↗ Perception of routine post-operative events as "complications"
  - ↗ Development of NEW symptoms, ie: OAB  
(Elkadry E 2003, Mahajan S 2006)

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## Can We Help Set "Realistic" Expectations?

- ↗ Asked women to rate their preparedness after surgical consent counseling & signing informed consent
- ↗ **42%** *still not* completely prepared for surgery
- ↗ "Prepared" vs. "Not Prepared"
  - ↗ Higher PGI-I
  - ↗ Higher PFDI scores
  - ↗ More satisfied
  - ↗ No difference in objective measures of cure
- ↗ "Not Prepared"
  - ↗ Complications – 44%
  - ↗ Physician documentation – 8%

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## Patient satisfaction

- ↗ "No better" ≠ "worse"
- ↗ Persistent symptoms ≠ persistent symptoms + new symptom?
- ↗ We may **modify expectations** more difficult to change attitudes & value
- ↗ Baseline personality
  - ↗ Happy in, happy out

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## Goals Change

- ↗ Goals can change!
  - ↗ Life intervenes, symptom control changes and a new symptom becomes predominant
- ↗ Desire for treatment changes
  - ↗ Not always based on symptom change

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## Adverse Outcomes

- ↗ Little time is spent on valuing adverse outcomes
- ↗ Side effects and complications are valued differently
- ↗ Most don't "hear" the negative side...

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## So Which Outcomes Matter? Those that Matter to That Patient

- ↗ Counsel primarily about adverse events, especially long-lasting symptoms
- ↗ LISTEN to what your patients experience – this will help your counseling
- ↗ This will help you counsel other patient, using patient language

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