

Approaches to Pelvic Organ Prolapse Surgery

W10, 29 August 2011 09:00 - 12:00

Start	End	Topic	Speakers
09:00	09:20	Surgical anatomy for the reconstructive surgeon	Christian Winters
09:20	09:50	Anterior compartment repair	Sandip Vasavada
09:50	10:30	Apical and posterior compartment repairs (including robotic repair)	Kimberly Kenton
10:30	11:00	Break	None
11:00	11:30	Mesh Repair: pros and cons	Christian Winters
11:30	12:00	Complications of prolapse repair based on case discussion	Philippe Zimmern

Aims of course/workshop

This course is intended to update the reconstructive pelvic surgeon and all interested trainees on the pros and cons of modern surgical approaches in the management of pelvic organ prolapse. This interactive course will feature short lectures on current debates with each approach, including robotic surgery. The course will include multiple surgical video clips, and provocative case discussions to enhance the interaction with the audience.

Educational Objectives

At the request of SUFU as a tribute to Dr Rodney Appell, this program was organized the past 2 years and was presented in San Francisco and in Toronto. Attendance was very good at both meetings. In fact, in Toronto, more people wanted to attend than were allowed to. The feedback from the attendees was overall positive. Syllabus issues came up each year, the first time because the syllabus was short and this year because it was available on-line but no one had a copy with them at the time of the meeting. In Toronto, we increased the surgical videos but more was wanted according to the comments received. Some video clips in Mac did not transfer well and caused delays during the course. So this is an area of needed improvement for our group. Speakers had acceptable scores, except for the substitute for Dr Winters. The meeting ended on time. All speakers gave their approval to attend next year's meeting, including Dr Winters.

ICS 2011: Female Pelvic Anatomy and Surgical Correction of Pelvic Organ Prolapse J. Christian Winters, MD.

Anatomy of Pelvic Support

The pelvic floor consists of muscular and fascial tissues acting as a supportive structure, which prevents the female pelvic organs from being pushed out by intra-abdominal pressure. There are three levels of vaginal support. The upper third of the vagina (level I) and uterus are supported by fibers from the uterosacral and cardinal ligaments. This supports the upper vagina above the pelvic diaphragm. These fibers mainly merge into the pericervical ring of connective tissue and into the upper vagina. The middle third of the vagina is attached by the mid portion of the endopelvic fascia (level II). The anterior wall of the vagina in this location is held in place by the lateral attachments of the pubocervical fascia to the fascia over the obturator internus muscle at the arcus tendineus fascia pelvis (white line). The posterior vaginal wall is supported laterally by the lateral attachments of the rectovaginal fascia to the fascia overlying the iliococcygeus muscle. At the lower third of the vagina (level III), the vagina merges with the fascia of the endopelvic fascia and pubourethral ligaments anteriorly to the medial margins of the pubococcygeus. The lower extent of the pubocervical fascia merges into the urogenital diaphragm and the rectovaginal fascia merges into the perineal body. Therefore, in the distal third of the vagina, the endopelvic fascia structures are inserting laterally to the pubourethral ligament and the arcus tendineus, and to the perineal body posteriorly.

Types of Prolapse

<u>Cystocele:</u> There are four different areas within the connective tissue support of the bladder that predispose one to cystocele if the connective tissue support fails. There are four anatomic defects that can account for the development of cystourethrocele:

- a. Paravaginal defect (lateral defect)
- b. Transverse defect
- c. Midline defect (central defect)
- d. Distal defect (urethrocele)

The paravaginal defect occurs when a separation of the pubocervical fascia from its lateral attachment to the fascia over the obturator internus muscle occurs at the level of the arcus tendineus fascia pelvis. This is represents a break of the pubocervical fascia from the white line. This loss of lateral attachments can occur both unilaterally or bilaterally. Usually, a cystourethrocele is seen when this lateral loss of support occurs, and this defect usually predisposes one to symptoms of stress urinary incontinence.

The transverse defect is a separation of the pubocervical fascia from its attachment to the pericervical ring of tissue at the apex of the vagina (level I).

The midline defect is any break in the central portion of the hammock-like sling of pubocervical fascia upon which the bladder is resting. Commonly, this condition can create stress incontinence as well because the hammock-like break in the pubocervical fascia does involve the area underneath the bladder neck. These occur commonly in patients with lateral defects

The distal defect is an avulsion of the urethral attachment to the urogenital diaphragm as it passes

under the pubic symphysis. Essentially, these patients lose the lateral attachment to the urethra, to the arcus tendineus, and pubourethral ligament. In addition, these patients lose the anterior attachment of the urethra to the pubic symphysis, and may predispose to SUI.

<u>Uterine or vaginal vault prolapse</u>: In patients with a loss of the level I support of the uterosacral ligaments and cardinal ligaments, the apex of the vagina (cervix or vaginal cuff) loses its attachment. This condition will lead to prolapse of the vaginal cuff and/or prolapse of the uterus.

Enterocele: An enterocele is a herniation of the cul de sac peritoneum with or without intraperitoneal contents into the fascial layers between the vagina and rectal walls. An enterocele may range from a small bulge posteriorly in the upper part of the vagina to a large defect which protrudes beyond the introitus with visible small bowel internally. The upper aspect of the posterior vaginal wall is where enteroceles occur as a result of a separation of the rectovaginal septum from the level I complex of support. Iatrogenic enteroceles develop after surgical procedures that distort the normal horizontal axis toward the vertical.

<u>Rectocele:</u> As the hammock of rectovaginal fascia overlying the rectum breaks, a bulge of the rectum into the vaginal canal occurs. A transverse defect rectocele occurs simply by a detachment of the perineal body from the rectovaginal fascia. The hammock of retovaginal fascia supporting the rectum remains intact but separates from the perineal body. A midline vertical defect is created by a midline separation of the rectovaginal fascia, and a separation of the rectovaginal fascia can occur from the it's lateral attachments. Rectoceles are more commonly situated in the mid to distal aspect of the posterior vaginal wall.

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Anterior defects (cystocele): A central defect cystocele is surgically repaired by the reduction of the prolapsing bladder and re-approximation of the attenuated pubocervical fascia using plicating sutures. This operation, the anterior colporraphy is the most frequently utilized procedure in the correction of cystocele, and is associated with success rates from 30-75%. The anterior colporraphy only corrects central defects, and does not correct other forms of prolapse.

A lateral defect cystocele is corrected by the reapproximation of the vagina to the pelvic sidewalls. This operation is completed by placing a row of interrupted sutures from the vagina into the pelvic sidewall at the arcus tendineus, extending all the way to the ischial spine. Multiple sutures are placed to provide support, and this is accomplished abdominally, laparoscopically or transvaginally. When 1 performs this repair through the vagina, a graft material is usually secured to each pelvic sidewall traversing under the bladder. This provides support to the central cystocele component as well. Utilizing these techniques, the success rates of these procedures is reported from 80-95%.

A transverse cystocele occurs when the pubocervical attachments separate from the level I (cardinal and uterosacral) support which stabilizes the apex of the vagina. In an isolated transverse defect, the cystocele is repaired simply by restoring this support. This is most commonly performed by reestablishing cuff support. This explains why many women with cystocele may have correction after an abdominal colpopexy or uterosacral cuff suspension.

<u>Posterior defects (rectocele):</u> A rectocele is repaired by re-approximating the rectovaginal fascia together, usually with interrupted sutures in an operation called a posterior colporraphy. The operation extends distally toward the perineal body, and involoves incorporating levator fascia into the repair distally. In fact, many posterior repairs involve placation and re-inforcement of the perineal body. One must take great care not to narrow the vagina excessively, as this may cause sexual dysfunction. Graft materials can be incorporated in this repair, and many have adopted the use of grafts, particularly for repeat repairs. A site-specific rectocele repair is accomplished when 1 re-approximates the rectovaginal fascia (which is intact) to the perineal body. This detachment can be responsible for large distal rectoceles that can become symptomatic. This can be accomplished through a small, distal transverse or diamond-type incision. Success rates of 66%-75% have been recorded, with the major complications being pain and/or sexual dysfunction.

<u>Enterocele</u>: The most common form of enterocele repair is that of transvaginal sac isolation and closure. The enterocele sac is isolated after making an incision near (or through) the cuff of the vagina. After the sac is dissected out, the bowel contents are reduced, and the sac is closed proximally near the "neck" of the sac. Following this the remaining sac is dissected out and discarded. The enterocele can also be repaired transabdominally. The bowel is lifted out of the pelvis, and a cul-deplasty is performed with permanent, interrupted sutures.

Apical Prolapse of the vaginal cuff: There are a wide number of procedures to correct apical vaginal prolapse. The importance of recognizing and correcting apical defects is important. This is the means by which the upper vagina is stabilized proximally, and this protects against widening of the genital hiatus. There are a number of abdominal, vaginal and laparoscopic approaches to the correction of apical prolapse, and the surgeon should be well versed to perform several of these procedures. The sacrospinous ligament fixation (SSLF) achieves a functional vagina and vault prolapse cure in 67-79% of patients. The sutures are placed directly into the body of the sacrospinous ligament as there is a potential for significant vascular or neurologic injury. The apex can be sutured directly to the iliococcygeus fascia, or to the uterosacral ligament remnants usually isolated via a transvaginal, intraperitoneal approach.

The abdominal sacral colpopexy is one of the most successful ways to correct apical prolapse. This procedure is accomplished via abdominal, laparoscopic, or robotic approaches. A graft is utilized to secure the apex of the vaginal to the sacrum. Most authors now fix the graft material to the sacral promontory. A synthetic mesh should be utilized, as there is Level I evidence demonstrating the superiority of permanent mesh materials to biologic graft materials in women undergoing colpopexy. All women should undergo a cul-de-plasty to prevent recurrent enterocele. Success rates as high as 95% have been reported by multiple authors, with an acceptably low graft erosion rate.

References

- 1. Herbst A, Mishell D, Stenchever M, Droegemueller W. Disorders of the abdominal wall and pelvic support, in Stenchever MA (Ed.) Comprehensive Gynecology, 2nd edition, Moseby Yearbook, Philadelphia, 1992, page 594.
- 2. Karram M, Miklos J, Sze E. Pelvic prolapse and lower urinary tract dysfunction in females in Urinary Incontinence, O'Donnell P (Ed.), 1st edition, Moseby Yearbook, Philadelphia, 1997, page 302.
- DeLancey J, Richardson A. Anatomy of genital support in Urogynecologic Surgery, Gathersberg Maryland, 1992, Aspen.

Pelvic Floor Prolapse: Anatomic, Functional and Surgical Principles J. Christian Winters, M.D. Professor and Chairman, Department of Urology Louisiana State University Health Sciences Center New Orleans, Louisiana

Slide 2

Pelvic Organ Support

- ${\boldsymbol{\cdot}}$ 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

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Pelvic Floor Musculature

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

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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.

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Posterior Levator Ani Group "Diaphragmatic"

- Illococcygeus 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 plate created by levator plate.



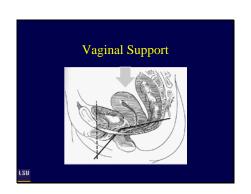
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Levator Ani – Muscle Composition

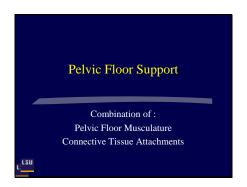
- Type I muscle fibers slow twitch and provide a sustained tone of pelvic floor.
 - $\bullet\,$ Support pelvis in normal activity.
- Type II fibers fast twitch fibers reflexively contract during sudden increases in intraabdominal pressure (ie cough etc).

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. Support of the variable o

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Endopelvic Fascia

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

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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



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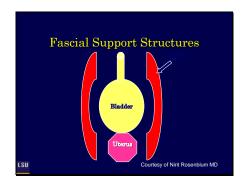
Uterosacral and Cardinal Ligaments

- 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 perfevesical fascia.

 Support cervis; (uterus) and upper vagina to maintain a posterior position over the levator plate, which pulls them away from genital hiatus.





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Lateral pelvic support

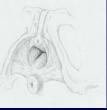
- Linear condensations of obturator and levator ani fascia:
 - Arcus tendineus fascia pelvis- fibrous band extending from pubic bone to ischial spine. Supporting structure of pubocervical and rectovaginal fascia.
 - Arcus tendineus levator ani fibrous band overlying obturator internus muscle from which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

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Perineal Membrane

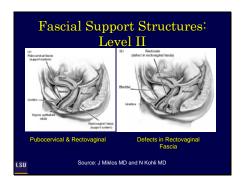
- Dense, triangular sheet of fascia.
- Extends from ischial pubic rami laterally and anterior to the pubic symphysis.
 The perineal body represents the central tendon between the 2 halves of perineal nembrane.
- The fibers of the perineal membrane tighten and resist against increased abdominal pressure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



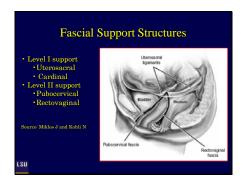
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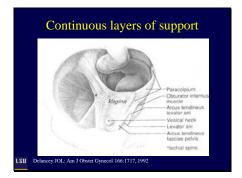


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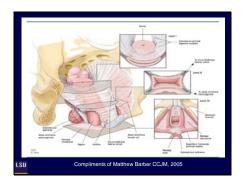


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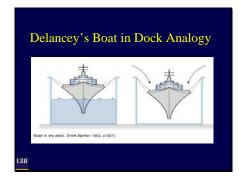


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POP – Multifactorial Nature

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

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Pelvic Floor Defects

- Urethrocele "Urethral Hypermobility"
- Cystocele
- Uterine Prolapse
- Vaginal vault or "cuff" Prolapse
- Enterocele
- Rectocele
- Perineal Body Defects

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Pelvic Floor Defects, think compartments

Anterior

- Urethrocele "Urethral Hypermobility"
- **■** Cystocele

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Pelvic Floor Defects, think compartments!!

Middle or Apical Compartment

- Uterine Prolapse
- Vaginal vault or "cuff" Prolapse
- Enterocele

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Pelvic Floor Defects, think compartments!!

Posterior Compartment

- Enterocele
- Rectocele
- Perineal body defects

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A lattice-like network of the endopelvic fascia divides and supports the wethre anteriorly and posteriorly. Anteriorly puboverical = pubourethral fascia Posteriorly: pubocervical = periwethral fascia Value | Laterally with the pubocervical | wit



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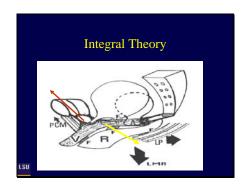
Integral Theory

- Pubourethral Ligament
- Suburethral Vaginal Hammock
- Pubococcygeus muscle

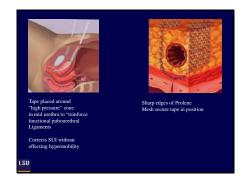
All three structures work together by drawing the urethra forward against the pubourethral ligament and closing the urethra.

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.

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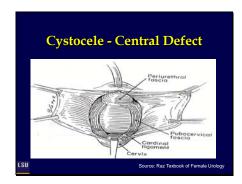


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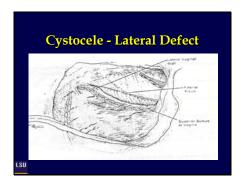


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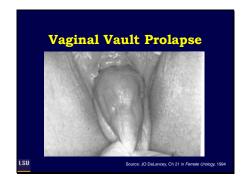


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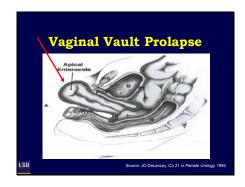
Enterocele

- A herniation of the cul-de-sac peritoneum with or without intra-peritoneal contents into the fascial layers between the vagina and rectal walls.
- An isolated enterocele may resulting from a transverse separation of the rectovaginal septum to the Level I area of support.

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Pelvic Exam: Objectives

- Inspection
- · Assess vaginal integrity
- Assess pelvic anatomy
 - · Normal vs abnormal
- Presence or absence of prolapse
- Assess presence or absence of SUI
- Rectal exam
- Supine vs Standing

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Prolapse: Classifications

- Pelvic organ prolapse quantitative (POPQ)
 - Accurate
- Time consuming & labor intensive
- Baden Walker Half-way
 - Easier
 - Some subjective

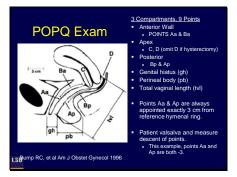
Bump RC, et al The standardisation of terminology of female pelvic organ prolapse and pelvic floor dysfunction Am J Obstet Gynecol 1996; 175:10-17.

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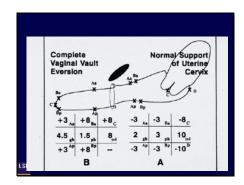
Baden Walker Classification

- Introitus is reference point
- Grade 0: No prolapse
- Grade 1: Prolapse descends toward introitus with strain
- Grade 2: Prolapse descends to introitus with strain
- Grade 3: Prolapse descends beyond introitus with strain
- Grade 4: Prolapse descents beyond introitus at rest

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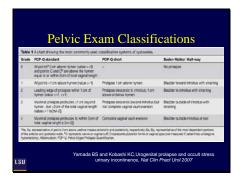


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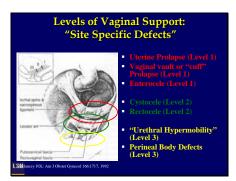


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Stages for POPQ • Stage 0 - no prolapse demonstrated, • All points are at their highest possible level above the hymen • Stage I -most distal portion of prolapse is more than 1 cm above the level of the hymen • Stage II - most distal portion of prolapse is 1 cm or less proximal to or distal to the hymen • Stage III - most distal portion of prolapse is more than 1 cm below the hymen but protrudes no further than two cm less than the total vaginal length • Stage IV - essentially complete eversion of the total length of the lower genital tract



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	Vaginal	Abdominal
Aa Urethra	Anterior repair	Retropubic urethropexy
	Pereyra	Sling
	Sling	
Ba Bladder	Anterior repair	Wedge colpectomy
Diddoci	Paravaginal repair	Paravaginal repair
	"Four point" suspension	
C Cervix/Cuff	Uterosacral ligament suspension	Uterosacral ligament suspension
Cervix Cuii	lleoccoccygeous suspension	
	Coccygeous suspension	Sacrocolpopexy
	Colpocliesis	
D Culdesac	McCall	Halban
Culuesac		Moschowitz
Pa and Pb Rectum	Site specific repair	Colpoperineopexy
Rectum	Classic 'plication'	

- 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 sitespecific defects.

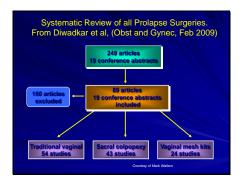
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Anterior Compartment Repairs

Sandip Vasavada, MD Center for Female Urology and Pelvic 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"
- Is this because traditional repairs are doomed to failure......



Results of Traditional Vaginal Repairs Diwadkar et al 2009. ■ 7827 patients ■ Longest mean follow-up of 32.6 months ■ Most common complications: - Urinary tract infection 3.5% - Hemorrhage or hematoma 2.8% - Dyspareunia

Results of Sacral Colpopexy 5639 patients Mean follow-up of 26.5 months Most common complications: Pain 2.3% Mesh erosion 2.2% Visceral injury 1.7% Wound complications 1.5%

Results of Vaginal Mesh Kits 3425 patients Mean follow-up of 17.1 months Most common complications: - Mesh erosion or infection - Fistulas - Dyspareunia 2.2%

	Traditional Vaginal Repairs			Sacral Colpopexy			Mesh Kits		
	%	95% CI	Range	%	95% CI	Range		95% CI	Range
Total complication rate	15.3	14.7- 16.3	0-52.8	17.1	16.1- 18.1	0-52.2	14.5	13.3- 15.7	0-23.1
Reoperation for prolapse recurrence	3.9	3.5- 4.4	0-29.1	2.3	1.9- 2.7	0-31.3	1.3	1.0-	0-16.0
Total reoperation rate	5.8	5.3- 6.3	0-29.2	7.1	6.4- 7.8	0-26.2	8.5	7.6- 9.4	0-30.0

	Traditional Vaginal Repairs			Sacral Colpopexy			Mesh Kits		
	%	95% CI	Range	%	95% CI	Range	%	95% CI	Range
Total complication rate	15.3	14.7- 16.3	0-52.8	17.1	16.1- 18.1	0-52.2	14.5	13.3- 15.7	0-23.1
Reoperation for prolapse recurrence	3.9	3.5- 4.4	0-29.1	2.3	1.9- 2.7	0-31.3	1.3	1.0- 1.7	0-16.0
Total reoperation rate	5.8	5.3- 6.3	0-29.2	7.1	6.4- 7.8	0-26.2	8.5	7.6- 9.4	0-30.0

	Traditional Vaginal Repairs		Sacral Colpopexy		Mesh Kits	
	%	95% CI	%	95% CI	%	95% CI
Dindo Grade I	6.2	5.7-6.7	5.5	4.9-6.1	3.9	3.3-4.6
Dindo Grade II	6.9	6.4-7.6	5.8	5.2-6.4	2.2	1.7-2.7
Dindo Grade Illa	0.2	0.1-0.4	1.0	0.7-1.2	1.3	0.9-1.6
Dindo Grade IIIb	1.9	1.7-2.3	4.8	4.2-5.4	7.2	6.3-8.0

Conclusions of Review Traditional vaginal procedures Highest reoperation rate for prolapse recurrence Lowest rates of complications that required surgical intervention Lowest total reoperation rate Vaginal mesh kits Shortest follow-up period Highest rate of complications that required surgical

intervention

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



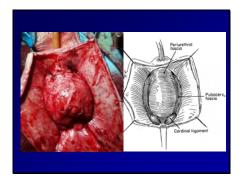
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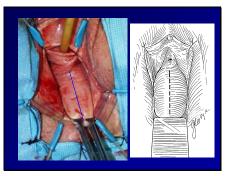
Four Defects of Anterior Vaginal Wall Prolapse

- 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

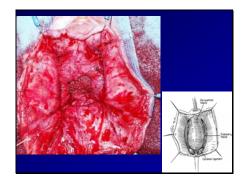
Anterior Vaginal Wall Prolapse

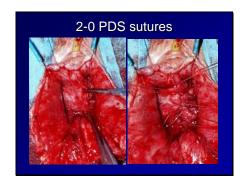
- Identify and correct all defects
- Evaluate potential other coexistent defects of pelvic organ support (e.g enterocele, rectocele, vault mobility)
- Assess and address potential urethral incompetence
- ? Patch augmentation of repairs

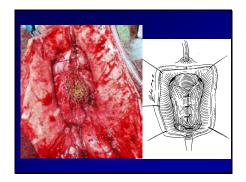


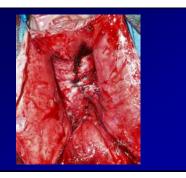














Anterior Colporraphy+/-Absorbable Mesh

- Weber, AM, Walters, MD, Piedmonte, MR, Ballard, LA (Am J Obstet Gyn 2001)

 109/114 patients underwent ant colporraphy 3 techniques

 Standard

 Standard + mesh (polyglactin)

 Ultralateral colporraphy

 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 colporraphy alone, 42% standard + mesh, and 46% ultralateral colporraphy

 VAS: symptom severity improved overall (6.0 +/- 2.7 → 1.1 +/- 0.8)

 Addition of mesh did not seem to make a difference

Anterior Colporraphy

- 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 2,6,12,62 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

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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

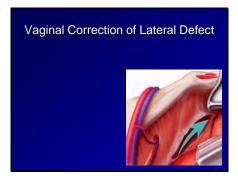
- Can be done open or laparoscopically
- Four to six non absorbable sutures
- Success rates good for retropubic and laparoscopic
- Minimal morbidity (aside from access route)

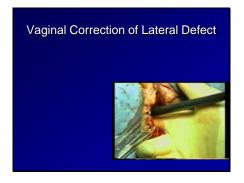
Paravaginal Defect Correction Vaginal

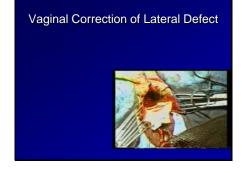
- Identify lateral defect
- Enter paravaginal space
- Re-approximate pubocervical fascia with ATFP (interrupted non absorbable sutures)

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Pa		•		fect F	Repairs pairs	3
Study (year)	No. of pts	Study design	Foll Mean	ow-up range	Cure * (%)	Failed (%)
White (1909) ⁴		Retrospect ive cohort	NR	Up to 3 years	100	
Shull et al (1994)32		Retrospect ive cohort	1.6 yrs	0.1 – 5.6 yrs		
Farrell & Ling (1997)31		Retrospect ive cohort	8 mo.	NR		
Nguyen & Bhatia (1999) ³³		Retrospect ive cohort		NR		
Elkins et al (2000) ²⁴		Retrospect ive cohort	NR	0.5 – 3 yrs		
Mallipeddi et al (2001) ²³		Retrospect ive cohort	20 mo.	8 – 35 mo		
Young (2001) ²⁵	100	Retrospect ive cohort	11 mo.	1 – 36 mo.		

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 rencapsulation - Synthetic (prolene, soft prolene mesh, marlex, gortex, etc.)

Defining success

- Some degree of loss of anatomic support is normal
- Perfect anatomic support is associated w/ worse HRQOL (PFIQ 10pts worse for Stage 0 than Stage 1 or greater)
- Symptomatic cure is more clinically relevant that anatomic cure
- Definitions of anatomic success commonly used are too strict and often not clinically relevant

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What is a failure after POP surgery? ■ Reoperation or retreatment? ■ Recurrence of symptoms? Anatomic recurrence Stage 2+?Beyond hymen? - Stage 3+?

Anterior colporrhaphy: A randomized trial of three surgical techniques

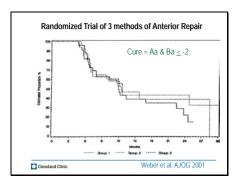
Anne M. Weber, MD, Mark D. Walters, MD, Marion R. Piedmonte, MA, and Lester A. Ballard, MD

- RCT, n = 114, May 1996 2000
- Cure: POPQ Aa & Ba ≤ -2
- % Cure at last follow-up
- -Standard -Standard + Polyglactin 910 mesh
- -"Ultralateral" anterior colporrhaphy
- Mean follow-up: 23.3 months (4.5 to 43 months)

Courtesy of Matt Barber

30%

42% NS



Definition of Cure

- 2001 NIH Workshop on Standardization:
- -"Optimal" anatomic outcome Stage 0
- -"Satisfactory" anatomic outcome Stage 1
- NIH definitions too strict

Cleveland Clinic

Swift et al, AJOG 2000 Swift et al, AJOG 2005

Definition of Cure The hymen is an important threshold for symptom development. The pelvic symptom that best correlates with advanced prolapse is a vaginal bulge that can be seen or felt. The absence of vaginal bulge symptoms postoperatively has a significant relationship with a patients assessment of treatment success and HRQOL while anatomic success alone does not. Cleveland Clinic NIH Pelvic Floor Disorders Network Recommendation Success after POP surgery: - No prolapse beyond the hymen (Aa, Ba, C, Ap, Bp \leq 0) - No vaginal bulge symptoms and - No retreatment Cleveland Clinic Barber et al, Obstet Gynecol 2010 Objective Reanalyze the results of the trial by Weber et al comparing three techniques for surgical correction of anterior vaginal prolapse using more clinically relevant definitions anatomic and symptomatic prolapse recurrence. Cleveland Clinic **Methods** Re-analysis of trial by Weber et al • 114 subjects undergoing surgery for anterior vaginal prolapse randomized (1:1:1) to one of three techniques Exclusions: any planned incontinence procedure other than suburethral Pre- and Post-operative data abstracted from original care report forms. Follow-up at 6, 12, 24 months: - POPQ exam by blinded examiner - Symptom questionnaires (VAS) Cleveland Clinic

Methods

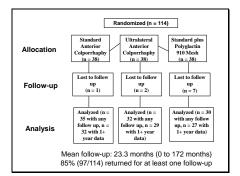
- Prolapse VAS: "How much are you bothered by symptoms related to vaginal prolapse" (0 "not at all" – 100 "extremely")
- Treatment success:
- POPQ Ba, Bp, C \leq 0 cm
- Absence of prolapse symptoms (VAS < 20)</p>
- No retreatment

Cleveland Clinic

Analysis

- Originally sample size adequate detect a 30% difference between groups w/ 80% power, alpha .05
- No differences between groups anticipated so primary analysis performed in aggregate.
- To minimize impact of missing data, primary analysis focused on outcomes at one year.
- Time to failure presented using Kaplan Meier survival curves

Cleveland Clinic



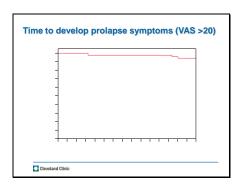
Concurrent Surgery

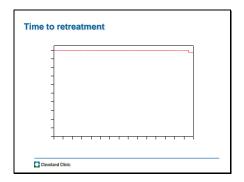
- TVH 53%
- Posterior colporrhaphy 94%
- Enterocele repair 26%
- Vaginal vault suspension 44%

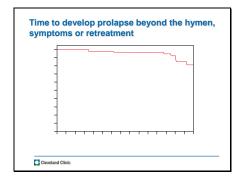
Cleveland Clinic

	Standard	Ultralateral	Mesh	Overall
Median POPQ value (range)				
Ba	-1.5 (-3 to +1)	-1.3 (-3 to +4)	-1 (-3 to +2)	-1 (-3 to 4)
С	-6 (-9 to +1)	-6 (-10 to +4)	-6 (-7.5 to -2)	-6 (-10 to 4)
Вр	-3 (-3 to +1)	-2.5 (-3 to +4)	-3 (-3 to 0)	-3 (-3 to 4)
No prolapse beyond the hymen	25/28 (89%)	22/26 (85%)	22/23 (96%)	69/77 (90%)
Absence of POP Symptoms	32/32 (100%)	27/29 (93%)	21/23 (91%)	80/84 (95%)
No reoperations for POP	32/32 (100%)	29/29 (100%)	27/27 (100%)	88/88 (100%)
No prolapse beyond hymen, no symptoms, no retreatment	25/28 (89%)	21/27 (78%)	21/23 (91%)	67/78 (86%)

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Limitations

- •Small sample size
- •Loss to follow-up
- Lack of validated HRQOL questionnaires available

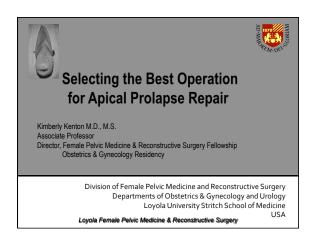
Conclusions

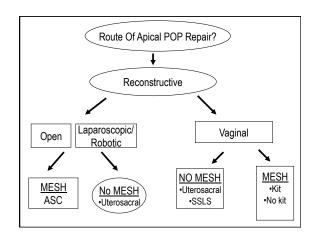
- The success rate of anterior colporrhaphy varies considerably depending upon the definition of treatment success used.
- When strict anatomic criteria are used, the success rate is low.
- When more clinically relevant criteria are used, treatment success is better with only 10% developing anatomic recurrence beyond the hymen, 5% developing symptomatic recurrence and 1% undergoing retreatment during the study follow-up.

Cleveland Clinic

Cystocele Conclusions

- Key to success is recognition and correction of all defects
 Address central and lateral defects (central more an issue)
 Good apical support cannot be overemphasized
 Patch augmentation for anterior repair with wide pore polypropylene mesh is encouraging
 Success rates may be better but at a cost for some complications
 Traditional repairs probably work better than we have quoted them to......





What is "Best" Operation Apical POP

- a. Colpocleisis
- b. Vaginal uterosacral suspension
- c. Sacrospinous ligament suspension
- d. Vaginal mesh repair
- e. Sacrocolpopexy



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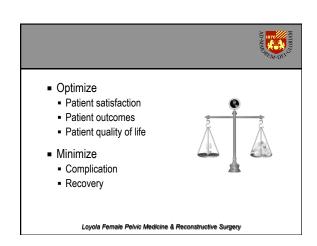
What is "Best" Operation for PO

- a. Colpocleisis
- b. Vaginal uterosacral suspension
- c. Sacrospinous ligament suspension
- d. Vaginal mesh repair
- e. Sacrocolpopexy

Answer: ALL OF THE ABOVE

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So, how should we select the best operation for prolapse repair? Determine outcomes meaningful to patients Know individual patient's goals Know procedures

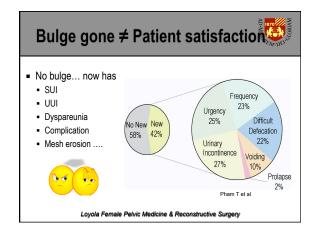


Post-operative Satisfaction Correlates with achievement of pre-operative goals

- (Hullfish K 2005, Elkadry E 2003)
- Inversely correlates (3 month & 1-year) 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)

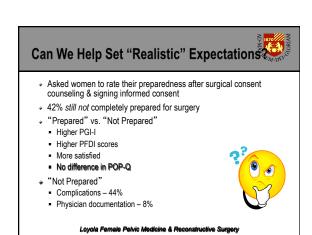


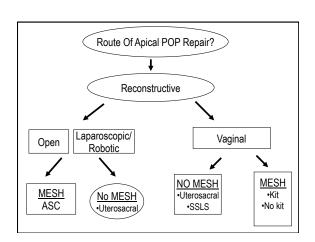
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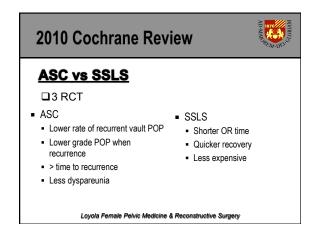


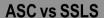
Magnitude & Consequences of Complications "NOT better" ≠ "WORSE" ■ Persistent symptoms ≠ Persistent + NEW symptoms

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- 101 RCT to ASC vs bilateral SSLS
- Composite outcome (N=80)
 - No POP symptoms, apex above levators, no POP > hymen
- ASC "cure" 58% vs SSLS 29%
- Trial stopped at interim analysis



Benson JT, Lucente V, McClellan E. Veginal versus abdominal reconstructive surgery for the treatment of pelvic surgery old for the macroscopic surgery of the treatment of pelvic surgery old for the macroscopic surgery of the treatment of positions and Gynecology 1996 175(6): 1418–22.

ASC vs SSLS



- 6 months: Apex ≥ Hymen
- N=89, vault

	Apex	Anterior	Posterior	Subjective
ASC	4%	7%	17%	94%
SSLS	19%	14%	7%	91%

Maher CF, et al. Abdominal sacral colpopexy or vaginal sacrospinous colpopexy for vaginal vault prolapse: A prospective randomized study. Am J Obstet Gynecol 2004;190:20-6.

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Technique •Mesh to anterior & posterior vagina •2 strips vs "Y" •Promontory vs S3

ASC: Symptoms Improve



- Bowel
 - Reductions of obstructive defecatory & other bowel symptoms
 - Concomitant posterior repair doesn't improve symptoms
- Sexual
 - More women were sexually active
 - Fewer women reported sexual interference from prolapse or dyspareunia

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Concomitant Repairs



- Typically not necessary
- Genital hiatus narrows with correction of apex
- No need for concomitant anterior/posterior repair
- Correction of apex corrects posterior and anterior vaginal wall defects
 - Guiahi M. Int Urogyn J 2008.

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ASC Morbidity



- Mesh erosion
- 5-fold increased risk of mesh erosion with concomitant TAH
 - With 14-27%
 - Without TAH 0-1.3%
- Erosion rates in literature 3% with polypropylene; higher with other meshes



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Minimally Invasive ASC



- Nearly all Level III evidence
 - Short-term
 - Outcomes similar to open
- Duplicate open technique
- Improved durability
- Advantages
 - Decrease GI & incisional complications
 - Quicker recovery



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Open vs Robotic ASC



Case-series

N=178: 73 robot & 105 open

- 6-weeks
- Anatomic outcomes good and similar (POP-Q)
- Robotic
- Longer OR times
- Less blood loss
- Shorter hospital stay
- N=28: 89%, 1-year follow-up
 - Validated Measures
 - Pelvic floor symptoms improved
 - Sexual function improved
 - 100 % anatomic cure

Geller E et all 2008, 2011

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Minimally Invasive ASC



Laparoscopic vs Robotic ASC: 1 RCT

- Anatomic & functional outcomes similar
- Robotic
 - Longer OR time
 - û post-opertive pain

Paraiso M et al 2010

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Laparoscopic ASC



Video

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Hysteropexy



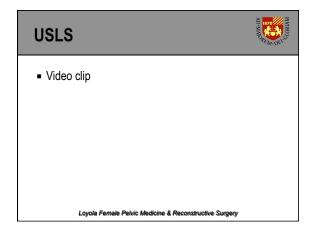
- Uterine preservation
 - Minimize risk of hysterectomy-associated mesh erosion
 - Patient desire
- Single Level 1 RCT (1-year)
 - HysteroPEXY inferior to VH + USLS
 - 3x 企 POP symptoms
 - 23% reoperation apical or anterior POP
 - 8-years: Reoperation 26% vs 14%
- Conflicting Level 2 & 3

Roovers et al 2004, 2008

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Uterosacral Ligament Suspension (USS)

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USLS Case Series Follow-up N Cure Jenkins 1997 50 6 - 48 mo 100% Webb 1998 693 11 - 22 mo 82% **Shull 2000** 289 2 - 6 yrs 87% Barber 2000 46 16 mo 90% Karram 2001 202 22 mo 95% Silva 2006 85% 72 5 yrs

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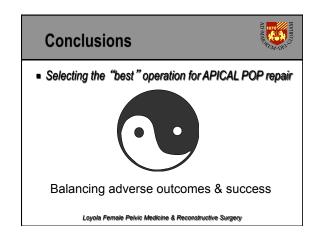
Complications: USLS ■ 1-11% ureteral obstruction rate • 0.9% requiring intervention • Neural pain S1-S4 trunks of sacral plexus Pain in buttock with numbness down post thigh requiring stitch removal Small bowel injury/pelvic abscess Suture erosion

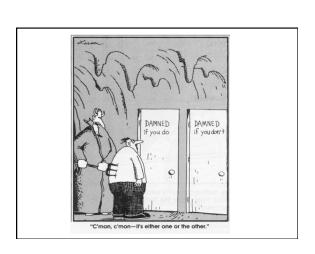
Apical Vaginal Mesh No adequately powered comparative studies outcomes



- demonstrate improved anatomic or functional
- ? Increased risks
 - Dysapareunia
 - Pain
 - Mesh erosion

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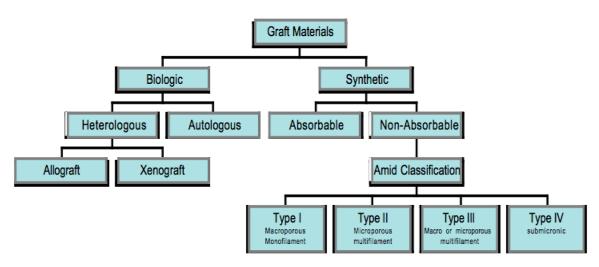


ICS 2011: Synthetic Materials and the Use of Grafts in Prolapse Surgery J. Christian Winters, MD.

CLASSIFICATION OF GRAFT MATERIALS

The ideal implant should be readily available and affordable. More importantly the graft material should be biocompatible, chemically inert, noncarcinogenic, mechanically strong, sterile, and have minimal risk of infection or rejection. The optimal implant, once healed, would restore normal pelvic anatomy without a detrimental effect on function. It should be more or equally durable to autologous tissues. Currently, no grafts fulfill these ideal characteristics. Grafts can be categorized by source (synthetic and biologic). Synthetic graft materials are usually classified absorbable or non absorbable (permanent). Permanent graft materials are usually classified by pore size (macroporous, microporous, submicroporous and combined) and material structure (monofilament, multifilament). Biological grafts are classified by source: autologous, or heterologous, which are further categorized as allografts or xenografts.

Classification of Graft Materials



Synthetic Grafts:

These grafts are readily available, cost effective, have no potential for disease transmission, and do not require harvesting. In addition, these grafts have higher tensile strength and are flexible enough for pelvic surgery.

Host Response to Grafts: Translational Data

Many materials used for interposition grafts, are reported to be chemically and physically inert and non immunogenic. However, none are biologically inert. The presence of a graft induces a foreign body response, which follows a stepwise cascade regardless of the material. The degree of response and amount of tissue in-growth is determined by the nature of the material, its structure, and the amount implanted for biologic grafts. For long term biologic graft survival, it appears as though incorporation by the host through a process known as graft remodeling is necessary. Although synthetic mesh material is a permanent substrate, many of these principles of tissue incorporation (not remodeling) are necessary to prevent infection, extrusion or erosion.

SURGICAL TECHNIQUES USING GRAFT MATERIALS

While there is comparative evidence supporting the use of synthetic material in abdominal sacral colpopexies (ASC), routine use of synthetic or biologic implants in transvaginal reconstructive procedures has not been validated in the literature.

Vaginal Approach

Anterior compartment

A variety of methods have been described utilizing graft materials to reinforce vaginal approaches to prolapse repair. Procedures incorporating mesh without suture fixation, in addition

ICS 2011: Synthetic Materials and the Use of Grafts in Prolapse Surgery J. Christian Winters, MD.

to a traditional colporrhaphy procedure have been described. Ususally, after plicating the endopelvic fascia, mesh has been placed in the retropubic space without suture fixation or folded into the imbricated endopelvic connective tissue. More commonly, pelvic surgeons have adopted the use of suture fixation of graft materials to augment anterior compartment repairs. Based on the surgical principles of the vaginal paravaginal repair this procedure requires entry into the retropubic space and suture fixation of the lateral attachments of the graft material to the ATFP. Others have reported fixation of the graft materials to the obturator internus fascia and/or the ATFP. Plication of the central defect is generally performed at the author's discretion, with most performing an anterior colporrhaphy prior to securing the graft.

Posterior Compartment

Graft reinforcement of the posterior compartment is accomplished by augmenting the rectovaginal fascia. This is most commonly performed transvaginally in conjunction with posterior colporrhaphy or site specific repairs. After lateral extension of the dissection to expose the rectovaginal fascia, levator ani complex and perineal body, synthetic or biologic materials have been attached to these structures to reinforce the repair. Most commonly a trapezoid or triangular shaped graft is secured to the most proximal position of the rectovaginal fascia or iliococcygeus fascia and to the levator ani musculature or perineal body distally.

Abdominal Approach

The abdominal sacral colpopexy is the most commonly performed procedure via the abdominal route utilizing graft materials for the correction of vaginal prolapse. The components of a successful colpopexy include permanent mesh fixation to the vaginal apex, complete closure of the cul de sac, secure fixation of the mesh to the sacrum (or sacral promontory) and closure of the peritoneum over the graft material. In a comparative study, Culligan et al demonstrated that patients undergoing colpopexy with permanent mesh materials faired better than those who had cadaveric fascia placed as the supportive graft to the vaginal apex. Numerous authors reporting multiple variations of the techniques of abdominal sacral colpopexy with permanent materials have reported universally excellent success rates.

Prosthetic Systems and Kits

Based on the success of transobturator midurethral slings, several kits have been introduced for the management of pelvic organ prolapse. These include Prolift® (Gynecare, Ethicon, Somerville, NJ) and Apogee® (vaginal vault and posterior repair system)/Perigee® (transobturator anterior prolapse repair system) (American Medical Systems, Minnetonka, MN) and Avaulta® (Bard, Covington, GA). Graft materials are more commonly polypropylene mesh (Prolift®, Avaulta® and Apogee®/Perigee®), however, the Apogee/Perigee system also has the option of using porcine dermis (Intexene®). Full thickness vaginal dissection is first completed. Access to the retropubic space is then obtained. The surgeon should be able to easily palpate the obturator membrane behind the inferior pubic ramus and the ischial spine. Anteriorly, the distal arms are placed after passing the trocar through the obturator membrane, arcus tendineus fascia pelvis and exits beneath the inferior pubic ramus. This pass is nearly identical to that performed for the outside in transobturator suburethral sling. Proximally, the trocar is passed through the obturator membrane inferolaterally, through the iliococcygeus muscle exiting just anterior to the ipsilateral ischial spine. The grafts can then be positioned in the anterior compartment following plication of the central defect (at the surgeon's discretion) to complete the anterior compartment repair. Posteriorly the trocar is introduced through the buttock inferior and lateral to the anus through the ischiorectal fossa and exits the iliococcygeus at the level of the ischial spine or through the sacral spinous ligament. A total compartmental repair is completed by placement of both anterior and posterior systems.

Reference:

Togami J, Krlin R, Winters J: Graft materials in prolapse surgery. In, AUA Update Series. Vol XXVII, Lesson XXXI, 2008

GRAFT MATERIALS IN VAGINAL SURGERY: CURRENT CLINICAL IMPLICATIONS J. Christian Winters, M.D. H Eustis Relly Professor of Urology and Gynecology Chairman, Department of Urology Louisians State University Health Sciences Center New Orleans, Louisians. USA cwinte®Isuhsc.edu

Slide 2

ICI, 2009

- Grade A Evidence:
 - The use of PPM for transvaginal anterior wall repair improves 1 year anatomic outcomes. This advantage should be weighed against the risk of mesh-related complications and uncertainty regarding long-term functional outcomes.
 - Synthetic grafts are superior in AS Colpopexy, less complications than transvaginal placement

LSU

Slide 3

ICI, 2009

- Grade B evidence:
 - There is no evidence to support the use of synthetic mesh for transvaginal repair (or augmentation of repair) in the posterior vaginal wall.

LSU

Graft Materials: Implications

- Biologic grafts "remodel"-Transformation
- ☐ Synthetic grafts "incorporate" Bioacceptance
- $\ {\scriptstyle \boxdot}$ Synthetic grafts are superior in AS Colpopexy
- Synthetic reinforcement of the anterior compartment MAY be more efficacious than conventional repair
- Role for posterior grafts unknown

Slide 5

Failure of surgical procedures

- Risk factors:

 - AgeConditions that challenge the repair:
 - chronic constipation
 COPD / smoking

 - COPD / smoking
 Obesity
 vaginal parity
 impaired wound healing (diabetes mellitus, steroid use)
 Deficient tissue quality.
 Abnormal collagen matrix
 Deficient fibroblasts

Slide 6

Ideal Implant

- $\ {\scriptstyle \blacksquare} \$ 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

Host Response to Graft: Translational

- NO graft materialis biologically inert
- Foreign body response REGARDLESS of material.
- Variable biofilm forms (important)
- ☐ Influx of proteins follows (immunoglobulins / fibrinogen)
- $lue{}$ Protiens undergo conformational change
 - Bind antibodies, macrophages and fibroblasts and Neovasularization then occurs

LSU

Slide 8

Host Response

- $\ \ \square$ Incorporation: Infiltration of host tissue into graft
 - "Bioacceptance"
- $\hfill \blacksquare$ Remodeling, infiltration of host tissue into graft and transforming material into host
 - "Bioacceptance"
 - Transformation of function

LSU

Slide 9

Tissue Ingrowth

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





Slide 11

Host Tissue Incorporation It appears that for long-term biologic graft survival, host tissue incorporation must occur to facilitate a process of graft remodeling, "transformation" into host. Graft remodeling" Assumes function of host

Slide 12

Biologic Materials Definition of the state of the state

Processing of Graft Material

- Federal guidelines direct the harvesting and transplantation of tissues.
- No guidelines for tissue processing and packaging:
 - Sterilization: Proprietary process to destroy bacteria and viruses.
 - Packaging:

Freeze-dried Solvent Dehydrated Cryopreservation

Slide 14

Allografts: Antigenicity

- $\hfill \square$ The risk of transmission of HIV from soft tissue allografts is 1 / 8,000,000.
- □ Commercially available fascial allografts contain traces of genetic material.
 - The integrity of the genetic material and potential for amplification are unknown.

 Sadhukhan P, et al. J Und 161.290(A.) 1999.
 Chee J. Bell T. J Und 161.22242, 2001.

☑ Processed tissue retains donor antigens, however after implantation these antigens are replaced by host antigens.
Figure M.M. of all BIO Instructions (Section 2002)

Slide 15

Xenografts

- Porcine dermis most frequently utilized.
- Standardized preparation methods decrease variability of grafts.
- $\ {\scriptstyle \boxdot}$ Fenestrated grafts facilitate incorporation
- What about cross-linking?
 - Stabilize the implant
- Prevent incorporation

What happens to graft material after implantation?

- $\ {\scriptstyle \blacksquare} \$ Potential mechanisms for failure:
- Tissue failure (rupture)Tissue rejection
- Tissue degeneration.

It appears that tissue remodeling is necessary for long-term implant durability.

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Tissue Failure

- Much early emphasis placed on biomechanical comparison of graft strength.
 Biomechanical testing endpoints:

 Stiffness [elongation (displacement) of material during load]
 Maximum load to failure
- ☐ Major limitation is that testing process does not replicate forces placed on sling after implantation.
- Little data demonstrating graft rupture as mechanism of failure.

Slide 18

Tissue Rejection

- $\hfill \square$ Very little data demonstrating host rejection of allograft.
- Inflammatory cells around allograft more commonly represent generalized inflammation, not rejection.

•		
•		

Tissue Degeneration

 Many authors describe the graft material as thinned, or frankly absent upon reexploration.

> Carbone J, et al: J Urol 165:1605-1611 Fitzgerald M, et al: Am J Obstet Gynecol 181: 1339-1346, 1999

- This appears to be the most common appearance of the failed allografts.
- "Autolysis"... Fitzgerald, et al 1999.

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Slide 20

Allografts: Poor Results

- Failure as a result of "autolysis" in 20% of freeze-dried gamma irradiated fascia lata grafts.
 - Objective cure rate using allograft was the same as autologous fascia.

Fitzgerald M, et al: BJU Int 84: 785-788, 1999. Fitzgerald M, et al: Am J Obstet Gynecol 181: 1339-1346, 1999.

 28 - 38% failure rate using freeze-dried irradiated and solvent dehydrated irradiated grafts.

> Carbone J, et al: J Urol 165:1605-1611. Huang Y-H et al: Urology 58: 943-946, 2001

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Slide 21

Synthetic Graft Materials

Case for Synthetics:

- 1. Readily available
- 2. Inexpensive
- 3. Favorable tensile strength
- 4. Permanent, durable material
- 5. No potential disease transmission
- 6. Does not emulate function of host tissue

Incorporation, not remodeling

aeiing 21

Mesh Characteristics

■ Amid Classification:

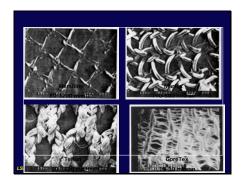
- Amid Classification:

 Type 1: Macroporous and Monofilament
 Obesirable for vaginal surgery: large pores promote
 tissue ingrowth and host defenses against bacteria.
 Flexible, easier to implant.

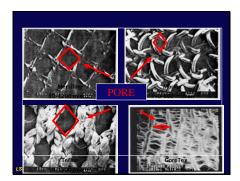
 Type 2: Microporous with small pore size
 Type 3: Macroporous, multifilament mesh—small interstices

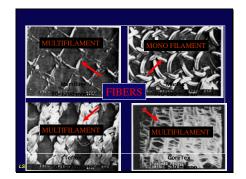
 Type 4: "Coated" biomaterials with extremely small pore size

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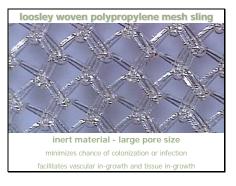


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Slide 26



Slide 27

Time-Dependent variations in graft materials: Animal model 6 different graft materials Time controlled explant in an animal model Immunohistochemical analysis Degree of inflammation varied • Significant differences with mesh having lowest degree Degree of scarring varied • Mesh having highest degree

Histopathologic Comparison

- Compare the histopathologic characteristics of these various sling materials after explantation during sling revision surgery.
 Sling grafts removed following sling revision surgery
- 2 Sites:
- LSU, New OrleansVanderbilt Medical Center
- Systematic gross and microscopic assessment
 1pathologist (ENB) for control

Slide 29

Results

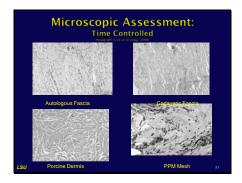
- Varying degrees of:■ graft degradation

 - gross appearance
 host tissue infiltration

 - Fibroblast count
 - Neovascularity
- Differential host response amongst various

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Slide 32

Clinical Implications

- Host tissue infiltration greatest in PPM
 Mesh material not causing "rejection"
 Mesh material does not encapsulate

 - Mesh acts as a scaffold promoting host tissue infiltration.
- Degradation highest in cadaveric tissues
- ☐ Encapsulation most common in porcine dermis
 - PD tissue not inert, local complications may follow.

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Comparison of Studies Difficult

- Apples = Oranges
- oxdot Procedures differ:
 - Mesh procedures tend to be multi-compartmental repair

 - Colporraphy doesn't address the apex
 Mesh procedures are free graft or "kit" procedures
 Variabilty in biologics
- $\ {\scriptstyle \boxdot}$ Definition of success not uniform

Allograft Slings: Intermediate **Failures**

- $\ \square \ 11 \ / \ 121$ intermediate failures using fresh frozen cadaveric fascia.
 - No intermediate failures identified No intermediate rangers, following autologous slings,
 O'Reilly K and Govier F. J Urol 167: 1356-1358, 2002
 Gooder F. et al. AIA 2002 # 419
- Failure rate of 5.7% at 6 months increased to 32% at 14 months using dermal allograft.

Slide 35

Synthetic Slings: Outcomes Author Ref F/U Cure Imp Fail n I/U cw lmp Fall 3 yr 86% 12% 2% 2% 131 1yr 91% 7% 2% 70 <18m</td> 87% 4% 9% 51 3 yr 90% 6% 4% 40 1yr 80% 17% 3% 20 3wk 85% 10% 5% 156 1-3yr 89% 4% 4% 42 5yr 85% 11% 5% 5yr 81% 15% 3% 1 Ulmsten BJOG 9950 Ulmsten IUJ98 Wang JRM98 Wang JRM98 Olsson GObinv99 Moran BJUInt00 Uro100 Klutke Jacquetin JObBio00 Maltau TidNor99 Ulmsten IUJ 01 Nilsson ObGyn0464

Slide 36

Synthetic Slings: **Complications**

- Erosion after sling reported btw. 0-23% of patients, most undergoing synthetic sling.
 Type of mesh and technique of mesh placement seems to effect rates of erosion.

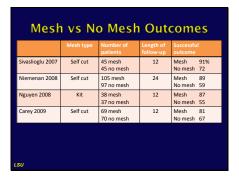
 - Erosion of midurethral slings appears rare:
 - True incidence unknown due to underreporting.
 More frequent than biologic or autologous grafts
 - Extrusion occurs from 0-13.8% of patients.
 - Higher rates reported with unwoven, bonded Obtape

	# Pts	Material	Success Rates
Chancellor	19	Cadaveric Dermis	85%
Groutz	21	Cadaveric Fascia	91%
Kobashi	132	Cadaveric Fascia	76%
Gahndi	76	Cadaveric Fascia	79%
Clemons	33	Cadaveric Dermis	59%
Wheeler	36	Porcine Dermis	50%
Gomelski	70	Porcine Dermis	80%

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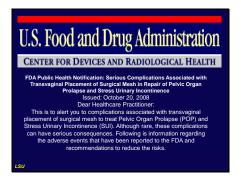
Synthetic Mesh: Case Series Outcomes						
	Mesh type	Number of patients	Length of follow-up	Successful outcome		
Dwyer 2004	Self cut	97	29 months	94%		
Amrute 2007	Self cut	76	30	95%		
de Tayrac 2007	Kit	143	13	92.3%		
Gauruder-B 2007	Kit	120	12	93%		
Rane 2008	Kit	70	24	96%		
de Vita 2008	Self cut	80	21	100%		
van Raalte 2008	Kit	97	19	87%		
Elmer 2009	Kit	261	12	80%		
Milani 2009	Kit	46	12	93%		
Wetta 2009	Kit	48	14	98%		
Feiner 2009	Kit	100	12	87%		
Carey 2009	Kit + VSD	95	12	85%		
Ebou 2010	Self cut	123	12	97%		

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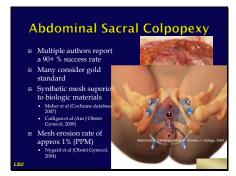
	Extrusion	Dyspareunia
Sivaslioglu 2007	7%	Mesh 4.6% No mesh 0
Niemenan 2008	8	Mesh score improved No mesh score decrease
Nguyen 2008	5	Mesh 9% No mesh 16
Carey 2009	5.6	Mesh 16.7 No mesh 15.2

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	Recommendations for Physicians
0	Obtain specialized training for each mesh placement technique, and be aware of its risks.
•	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.gow/cdrh/safety/102008-surgicalmesh.html
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Graft Materials: Implications

- Biologic grafts undergo a process of "remodeling" Transformation
- ☐ Synthetic grafts undergo a process of "incorporation" *Bioacceptance*

Slide 45

Contemporary Principles for the **Practicing Clinician**

- Synthetic grafts have been shown to be superior to biologic grafts for abdominal sacrocolpopexy and suburethral sling procedures in the literature through prospective randomized trials and prospective case
- series.
 2) Macroprous monofilament synthetic grafts and non-cross linked biologic grafts appear to have the best integration into native tissues. Microprorus synthetic grafts are more likely to become infected.
 3) Solvent delydration and irradiation of biologic grafts appear to weaken the integrity of the material and may prevent proper tissue integration.
 4) Level I and II data seem to support the use of grafts (biologic or synthetic) for anterior repair but crossion rates are higher, especially with the non-absorbable meshes.
 5) There is no conclusive data to recommend the use of grafts prostrictly.
- 5) There is no conclusive data to recommend the use of grafts posteriorly.

Summary

- Biologic Materials:
 Variability in outcomes btw grafts
 Intermediate failures more common
 Think Transformation

- Synthetic Mesh

 Type I Macroporous monofilament most desirable

 Abdominal sacrocolopeeys;

 Nonabsorbable mesh is fairly standard

 Recent adverse publicity is not about this

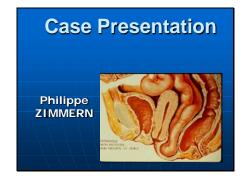
 Posterior vaginal repair: mesh disadvantages appear to outweigh advantages

 Anterior vaginal repair:

 Balance pros and cons

 Inform patient; involve her in choice

 Think technique and volume!



Slide 2



Slide 3

MANAGEMENT

- One year since mesh placement
- 3 Prior excisions in the office
- Pain over exposed mesh and at vaginal apex
- Recurrent cystocele
 - => What do you recommend?



Slide 5

Case 2: 52 y old; 2 years after mesh placement with dyspareunia and left pelvic and gluteal pain along a mesh arm

- Presents with EMG data/neuro
- No improvement after multiple sessions of physical therapy
- =>Consider Mesh removal
 - Vaginal approach
 - Open or laparoscopic dissection

Slide 6

Case 3:

Cystocele recurrence despite 2 vaginal meshes on top of each other (with double sub-urethral tape! and persistent SUI) in a 57 y old sexually active patient.

- Management???:
- Removal of meshes
- Add a third one
- Open or robotic sacrocolpopexy

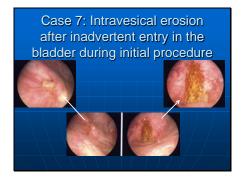
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Slide 7 Case 4: Vaginal mesh extrusion and vesico-vaginal fistula in trigone Vaginal repair Open repair, with possible ureteric reimplants Tissue interposition/SP tube Slide 8 Case 5: Cystocele with prophylactic tape placement with complications Slide 9 Case 6: 47 y old OR nurse. 3 prior cystocele with SUI. Options?

Mgt Options: Recurrent cystocele after mesh removal

- . Pessary
- . Colpocleisis
- . Anterior vaginal wall suspension
- Open or robotic mesh repair. Very difficult clivage plane, with risk of bladder injury and secondary mesh erosion in the bladder

Slide 11



Slide 12

Approach

- Transvaginal
 - Open ended ureteral catheters
 - Inverted U shape anterior vaginal flap
 - Divide the mesh on the midline
 - Dissect the bladder off the mesh both sides
 - Close bladder in multiple layers
 - Verify watertightness
 - Close vaginal wall flap
 - Catheter indwelling for 3 weeks

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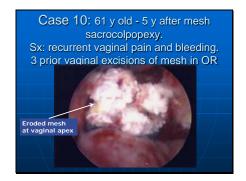




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Slide 16



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