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Preventing Mesh Complications What Can the Pelvic Reconstructive Surgeon Do?

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- Grant/Research Study and Consultant
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- Grant/Research Study
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–Cogentix



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Scope of the Problem

Pelvic Organ Prolapse and Stress Urinary Incontinence

- 3-6% of parous women who demonstrate POP on examination exhibit symptoms¹
 - 19% lifetime risk of surgery for POP²
- As many as 20% of women report SUI by the age of 40³
- US women have a 1 in 5 lifetime chance of electing surgery for POP or SUI⁴



1. Mittu et al. Evidence-Based outcomes for mesh-based surgery for pelvic organ prolapse. Curr Opin Urol 2014;24:370-4.
2. Australian Cohort study 2010¹
3. Dooly et al. Urinary incontinence prevalence: results from the National Health and Nutrition Examination Survey. J Urol 2008;179:656-61
4. Wu et al. Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery. Obstet Gynecol 2014;123:1205-6



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Why Use Mesh?

- Up to 29% of women experience failure after surgical intervention and require another procedure¹
- Benefits of Mesh
 - Avoid using structurally deficient tissue
 - Synthetic material=possibly durable repair
 - Readily available=avoids time and morbidity of fascial harvest
- Reduced risk of anatomic recurrence when used in POP repair
 - Anterior compartment
- TRADE OFF: 2x higher rate of complication when compared with native tissue repair²

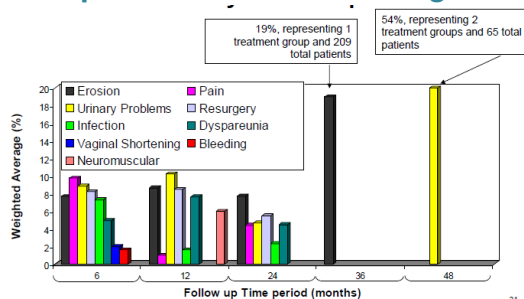
1. Olsen et al. Epidemiology of surgically managed pelvic organ prolapse in women. Cochrane Database Syst Rev 2013;CD004014
2. Møller et al. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev 2013;CD004014



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Complications for POP Using Mesh

Sept 2011 FDA Meeting of OB/GYN Devices Panel



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FDA Advisory Panel Findings 2011

	Panel Findings	Approval Process
Mid-urethral slings	All products reviewed. Safety/efficacy confirmed.	Class II (510k)
Mini-slings	All products reviewed. Safety/efficacy require further investigation.**	New products will require pre- and post-market data (existing products grandfathered)
POP kits	Significant safety concerns.	Class III (PMA)

Erosion and contraction are unique complication of mesh procedures
No proven anatomic or clinical benefit in apical or posterior compartment repairs
Anatomic "benefit" to anterior compartment, but no proven clinical benefit – no clear benefit
RR of re-operation for revision was 2.26x greater in women with mesh
1-2 year follow-up bias re-op rate to mesh procedures

*Source: Advamed SUI Presentation – Sept 2011 FDA Meeting of OB/GYN Devices Panel

**Source: Medical News: FDA Panel wants more data on mesh Tx for incontinence

***Reference: A randomized trial of a retro pubic tension-free vaginal tape versus mini-sling for stress incontinence (2010 Feb. Urogynecology. Bassu, Duckett)



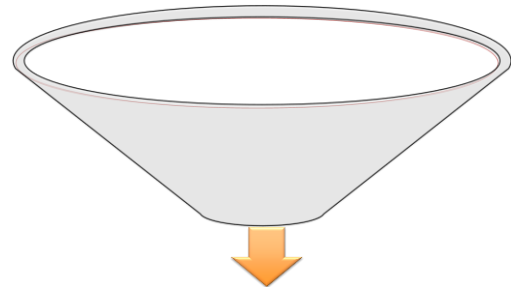
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What Have We Learned Mesh Can Become a “Mess”

- When:
 - The mesh (post implant) has undesired biomechanical properties
 - Patients are not properly and fully informed of the risk and benefits of the procedure
 - There is suboptimal execution of the surgery
 - Dissection = exposure
 - Delivery/placement = pain and failure
 - Setting/adjustment = pain



Keys to Avoid Complications 3 P's that Determine Success



Optimal Patient Outcomes



Keys to Avoid Complications Choose the Right Mesh



Best Outcomes



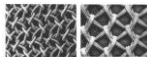
Choose the Right Mesh Ideal Properties of Vaginal Mesh

- Recreate and maintain the physical characteristics of the supple and distensible vaginal wall
 - Placement - facilitates implantation
- In Situ:
 - Inert
 - Resist infection – minimal foreign body problems
 - Resist undesirable configuration changes
 - Stretch
 - Shrinkage/contract



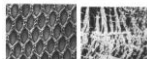
Choose the Right Mesh Commonly Used Synthetic Materials

Marlex®



Prolene®

Mersilene®



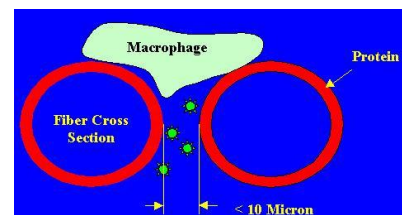
Gore-Tex®

Descriptive Characteristics of Mesh

- Type of polymer
- Weave
- Type of filament
- Pore size--key factor in determining inflammatory response, fibrocollagenous tissue ingrowth, flexibility, and strength.
- Weight



Choose the Right Mesh Fiber Interstices



Pore Size < 10 Microns Allows Bacteria to “Hide”

Most bacteria < 1 micron

Macrophages and granulocytes > 10 microns



Choose the Right Mesh

Low Mesh Density and Increased Porosity

The lightest possible weight consistent with:

- Good surgical handling
- Strength holding requirement

Macroporous

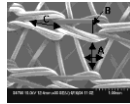
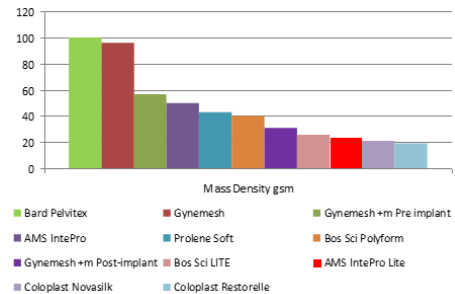
- Allows for light weight properties
- Improve in-growth
- Attempts to reduce complications (inflammation)

Interstitial pores

- 75-200 microns
- Defence mechanism against infection/chronic inflammation

Current meshes have haphazard architecture

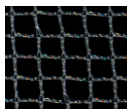
- Potential to create shearing forces

Varying Fiber Densities for Multiple Surgical Meshes
(Hernia and Prolapse Meshes)

Choose the Right Mesh

Mesh Density and Porosity

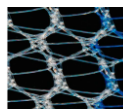
- 46% reduction in mesh extrusion rates for Intepro (50 gsm) vs InteproLite (25.5 gsm), Moore, R. AUGS 2010
- Lighter weight mesh decreased fibroblast proliferation, less fibrosis, less foreign body reaction and greater tissue incorporation in a canine study. (Smartmesh, Greca 2005)



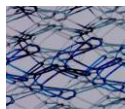
Smartmesh



Polyform



Gynemesh PS



Bard Alyte

Choose the Right Mesh

Avoid Contraction and Shrinkage

- Lightweight meshes=less inflammatory response and reduced shrinkage compared to heavier mesh (Klinge, 1999)
- Theories: graft shrinkage to be physical consequence of inflammatory response (Gracia-Urena et al, 2007), result of inadequate tissue ingrowth into the mesh (Gonzales et al, 2005)
- Clinical study: contraction present w/vaginal pain, dyspareunia (100%), on exam: tense focal areas of under epithelium, banding, vaginal tightness, foreshortened vagina (30%), mesh erosions (53%) (Feiner 2010)

Choose the Right Mesh

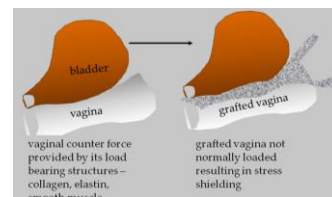
Low Mesh Stiffness

- Increased fibrosis and deposits of unorganized collagen create an increased stiffness (Klinge, 1999)
- Stiffness has been linked to clinical complications-heavier, stiffer meshes having higher complications (Dietz, 2003)
- Stiffer meshes showed decreases in smooth muscle, collagen and structural proteins following implantation (Moalli, P. AUGS 2011)
- Heavier stiffer meshes showed a greater propensity for stress shielding which in turn could cause reoccurrences of prolapse (Moalli, P. AUGS 2011)

Choose the Right Mesh

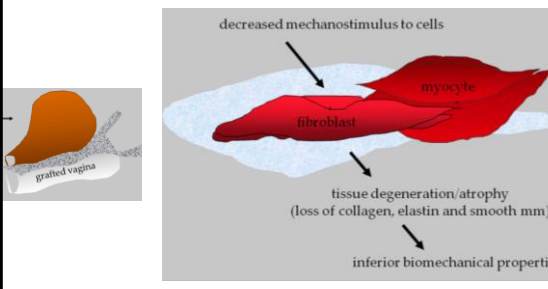
Avoid Stress Shielding

- The less the vagina moves post implantation, the > risk of complications



Choose the Right Mesh

Stress Shielding Impairs Vaginal Function



decreased mechanostimulus to cells

myocyte

fibroblast

tissue degeneration/atrophy
(loss of collagen, elastin and smooth mm)

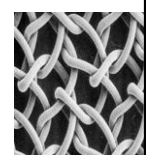
inferior biomechanical properties

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Stress Shielding Impairs Vaginal Function

- Factors that increase stress shielding effect
 - Increased stiffness of graft (heavier materials, , heat sealed, small pores)
 - Multiple fixation points (vaginal vs abdominal)
 - Tensioning too tight
 - Increased mesh area relative to the native tissue



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Choose the Right Mesh

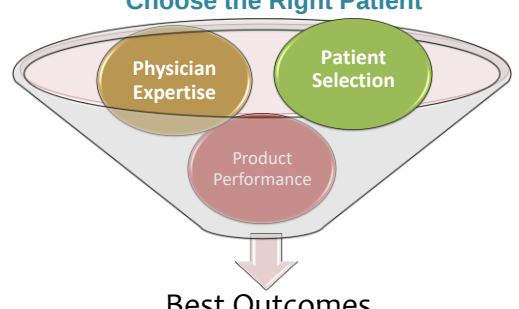
Key Mesh Considerations

2017 TV Mesh ✓ Inert ✓ Biocompatible ✓ Mechanically durable ✓ Macroporous ✓ Low Density ✓ Low Stiffness ▪ Avoid erosion ▪ Avoid contracture	Superior Characteristics ▪ Maintains physiologic loading environment of vagina ▪ vaginal elasticity ▪ No de novo dyspareunia ▪ Maintains same supportive capacity as nonprolapsed vagina ▪ Clinical data showing superiority
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How to Avoid Complications

Choose the Right Patient



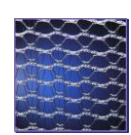
Best Outcomes

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Choose the Right Patient

Mesh for Selected Cases

- Patient selection important – not all clear
- Indications for mesh
 - Previous failed pelvic floor surgery, large prolapse, obesity, chronic pelvic floor stress (e.g., asthma), deficient connective tissue, and a combination of these factors.
- Contraindications for mesh
 - Immunosuppressed
 - pelvic irradiation
 - chronic high dose steroid therapy



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Choose the Right Patient

Mesh for Selected Cases

In quality of life conditions such as POP, patient goals, preferences and tolerance for varied adverse event profiles should be aligned between doctor and patient.

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Choose the Right Patient

Use Patient Centered Approach in Decision Making Process

The diagram shows three overlapping circles: Patient (orange), Evidence (blue), and Surgeon (green). The intersection of all three is the central area for decision making.

Patient's estimation, desires, goals and preferences

Surgeon's skills / repertoire

Surgeon's opinion and experiences

Scientific evidence / studies

Patient-related factors:
Previous pelvic floor surgery
Pelvic floor muscle damage
Connective tissue deficiency
Obesity
Profession
Smoking habits

The more the surgeon's and the patient's views as well as the scientific evidence overlap, the easier the decision-making process should be

Kaven Baessler World J Urol Nov 2011

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Choose the Right Patient

Informed Consent

- Informed consent should be complete and thorough as standard
 - Inform of potential mesh benefit (why)
 - Inform of non-mesh alternatives
 - Inform of potential permanence of procedure
 - Inform of mesh related complications
 - Utilize Manufacturer's IFU
 - some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.

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Choose the Right Patient

Potential Adverse Events

- Adhesion formation
- Mild to severe bleeding (hematoma, perforation of vessels)
- Constipation
- Complete failure of the procedure resulting in recurrent pelvic organ prolapse
- Dyspareunia
- De novo prolapse of an untreated compartment
- Fecal incontinence
- Foreign body reaction
- Infection
 - Graft erosion
 - Graft extrusion
 - Graft migration
- Nerve damage
- Obstruction of the ureter
- Pain
- Perforation of: bladder, bowel, ureter, urethra, and other pelvic structures
- Urinary tract infection
- Vaginal contracture
- Voiding dysfunction
- Wound dehiscence

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Eliminate instructions for Use

Choose the Right Patient

When Informed Consent Is Not Enough

With a lack of clear guidelines for mesh use and avoidance, emphasis must be placed on individual patient risk assessment and open counseling between the patient and physician.

CAUTION
THIS SIGN HAS SHARP EDGES
DO NOT TOUCH THE EDGES OF THIS SIGN
ALSO, THE BRIDGE IS OUT AHEAD

http://ix.bh.bplaced.net/BDMMWgR0Y7Tt0agqTYP1RAAAAAAAY1RP0QW/03EY1500/Caution-This-Sign-Has-Sharp-Edges.jpg

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Choose the Right Patient

Understand that Patient Factors Impact Outcomes

- Age – advanced elderly (>80 y.o.)
 - Higher rates of postoperative urge incontinence, bladder outlet obstruction and surgical failure compared to “young” elderly (65 – 80 y.o.).
- Urogenital atrophy (poor tissue)
 - Increased risk of vaginal erosion, sexual dysfunction
- Smoking history – increased risk of vaginal erosion
- Diabetes - 8.3 times more at risk of developing vaginal erosion

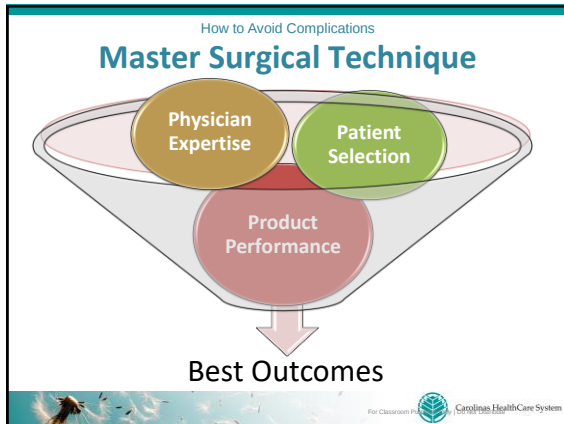
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Choose the Right Patient

Correct Modifiable Factors

- Identify baseline pelvic pain, dyspareunia
- Vaginal ulcerations/excoriations should be allowed to heal
- Treat vaginal atrophy with 4 weeks of topical estrogen
- Remove pessary 4 weeks prior to surgery

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"The Success Equation" *

- Expertise : *'you have a model, a structured process that you apply that accurately predicts an outcome in the future...'*
- Experience: ... *'you have done a lot over time, but yet you have failed to create such a model...'*

* Mike Macbousson (professional investor, author, professor)

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How to Avoid Complications

Keys to Surgical Technique

- The most common complications of vaginal mesh use is exposure and dyspareunia, both of which can be minimized by optimal surgical technique
 - **Hydrodissection** is critical to developing proper anatomical true spaces
 - **Dissection** is the key step to minimize exposure
 - **Sizing, placement and setting** are critical to minimize de novo pain
- Surgeon should have the knowledge to readily identify complications and the skill set to properly manage most all of them

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Master Surgical Technique

Find the True Vesicovaginal Space

- **Arguably the most important aspect of transvaginal mesh augmentation**
 - Access to the correct anatomic spaces
 - minimizes bleeding
 - mobilizes/avoids hazards (ureters, bladder, blood vessels)
 - allows anatomically correct graft placement
 - Potentially minimizes exposure risk
- **Anterior Compartment¹**
 - Literature review 80 articles anterior repair
 - "Dissection during anterior colporrhaphy splits vaginal muscularis, and repair involves plication of the muscularis and adventitia (not vaginal "fascia")"
- **Posterior compartment¹**
 - Cadaveric dissection of the RV "septum"
 - "It is the splitting of the adventitial layer from the overlying vaginal wall that accounts for the "fascial layer" seen surgically"

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Vaginal Dissection Techniques

Histology of Vaginal "Fascia"

Full thickness: vaginal epithelium is NOT separated from underlying Stratified squamous epithelium. The entire thickness of vaginal wall is composed of dense irregular connective tissue, muscle, and fascia creating an artificial surgical plane.

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Master Surgical Technique

Find the True Vesicovaginal Space

True vesicovaginal space

Full thickness vaginal wall

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3 Steps of Dissection



Hydrodissection:
Develops the space (this is very contained)



Sharp Dissection:
Expands the space, but not beyond the line of sight.



Blunt Dissection:
Completes the dissection

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Master Surgical Technique Hydrodissection Guidance

- Set yourself up for success with manipulation of the vaginal wall and palpation of bladder through it
- Place 2 allis clamps on the vaginal wall
- Pinch back against the bladder to potentiate space
- Use a 22g bevel or 18g Touhey needle
 - Use at least ≥ 60 cc per dissected compartment
 - 60cc marcaine w/ epi diluted with 60cc injectable saline
 - Little resistance should be encountered
 - No "wheal" in epithelium (too superficial)
 - Extend laterally using standard needle

Hydrodissection:
Develops the space (this is very contained)



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Master Surgical Technique Dissection Technique: Hydrodissection

- Touhey needle
 - 18g Epidural needle
 - 1 cm gradations for depth reference
 - Rounded (non-cutting) tip




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Master Surgical Technique Dissection Technique: Finding the True Vesicovaginal Space

- Midline incision
 - Electrocautery or scalpel
- Incise down to grey fluid bubble
 - Yellow fat – visual confirmation of correct space (plane)
 - Never grossly seen within bladder or vaginal wall



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Master Surgical Technique Dissection Technique: Sharp Dissection

- Lateral sharp dissection
 - Counter-traction on bubble (Atsons or gauze)
 - Use sharp dissection to separate bubble from vaginal wall
 - Tenotomy scissors: sharp Metzenbaum's
 - Small nips – 'Open and Spread' technique
 - Keep scissor parallel to vaginal wall
 - Avoid "digging" into vaginal wall
 - YOU MUST SEE AND 'FOLLOW' THE FAT!!

Sharp Dissection:
Expands the space, but not beyond the line of sight.



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Master Surgical Technique Blunt Dissection

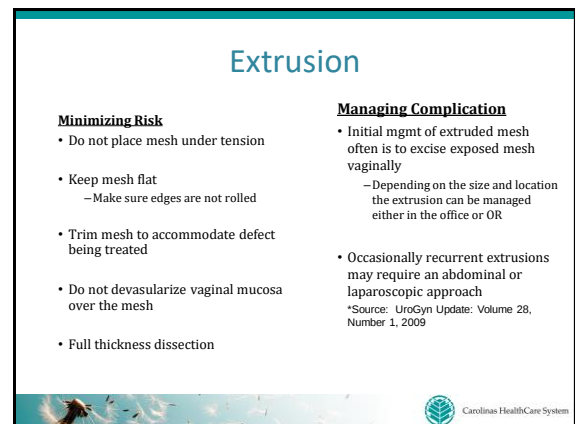
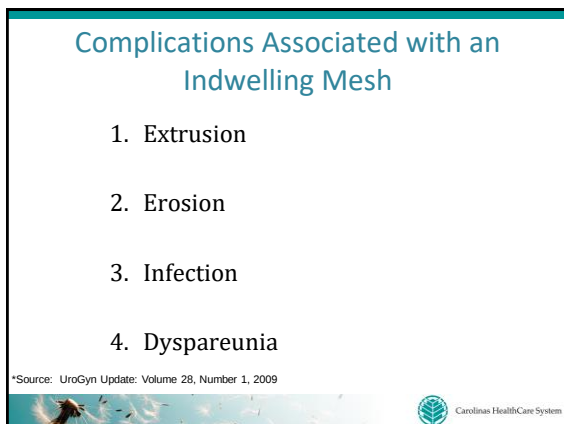
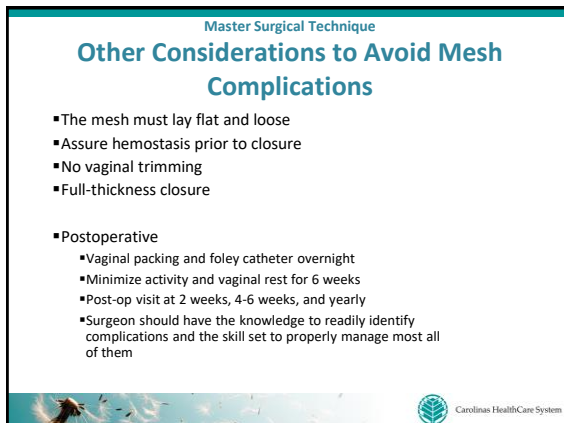
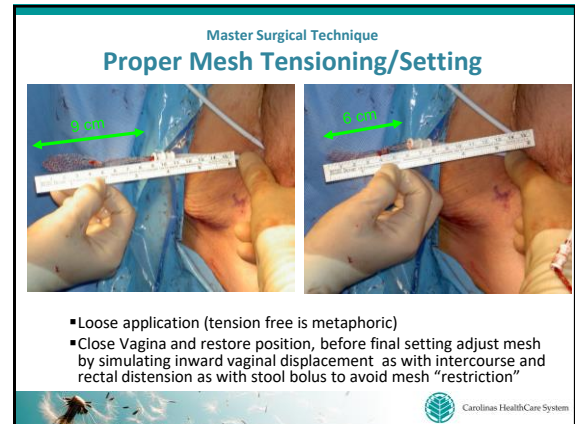
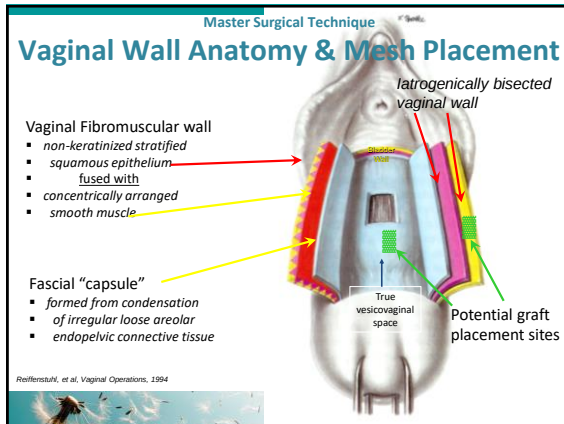
GOAL: Blunt dissection with finger completes the dissection.




TIPS:

1. Use lateral pressure to avoid visceral injury, and use the flat portion on the inside of the finger to dissect the tissue in a sweeping motion.
2. If using the tip of your finger to burrow into the tissue, always make sure you do so with a bony backstop to prevent visceral injury.
 - Backside of the pubic symphysis at the midline
 - Directly over the ischial spine

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Erosion

Minimizing Risk

- Do not place mesh under tension
- Keep mesh flat
 - Make sure edges are not rolled
- Trim mesh to accommodate defect being treated
- Do not devascularize vaginal mucosa over the mesh
- Full thickness dissection

Managing Complication

- When mesh is found in a vicer, the eroded mesh needs to be surgically removed
- Defect created by eroded mesh is best repaired in a layered closure when possible

*Source: UroGyn Update: Volume 28, Number 1, 2009



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Infection

Minimizing Risk

- Potentially minimize risk of erosions or extrusions
- Potentially the use of monofilament mesh

Managing Complication

- In the case that infection is identified at site of previous inserted mesh, material may need to be removed in its entirety if possible

*Source: UroGyn Update: Volume 28, Number 1, 2009



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Dyspareunia

Minimizing Risk

- Do not over tension mesh

Managing Complication

- Transection of mesh arms
- Conservative measures include; treatment of localized inflammatory reactions that may lead to myalgia, such as anti-inflammatory medications, local injections, and physical therapy

*Source: UroGyn Update: Volume 28, Number 1, 2009



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Complications Associated with Changes in Implanted Mesh Over Time

- Mesh Materials may change over time
- Synthetic meshes are thought to shrink as fibrosis progresses (15-20%)
- Biologic materials may undergo remodeling and ultimately resorption
- Permanent synthetic mesh is thought to undergo various forms of tissue ingrowth and fibrosis
- How contracture or shrinkage of material in the vagina over time may effect migration, extrusions, erosions, or dyspareunia is unknown

*Source: UroGyn Update: Volume 28, Number 1, 2009



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Summary

Keys to Preventing Vaginal Mesh Complications

- Understand Mesh Properties / Data
 - All meshes are NOT created equal
- Patient selection critical
 - Individualize Treatment - Do what is in the best interest of the Patient and be sure she has all options fully discussed with her
 - Use Informed Consent and document it well!!
- Strive for technical expertise
 - Obtain specialized training for each mesh placement technique
 - Master the techniques of:
 - Hydrodissection
 - Dissection to find the true vesicovaginal space
 - Sizing, placement and setting are critical to minimize de novo pain



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Preventing Mesh Complications What Can the Pelvic Reconstructive Surgeon Do?



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