THE MESH CONTROVERSY

From Female Urology and Urogynecology Symposium, sponsored by OBG Management, TTMed Urology, and The Christ Hospital

Current Concerns About Mesh for Repair of Prolapse

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Transvaginal synthetic mesh: many randomized trials, including those studying separate apical suspension, demonstrated better objective outcomes in patients receiving mesh, and some demonstrated better subjective outcomes. Complications: extrusion rates 3% to 10%; small extrusion in older, sexually inactive woman may not require treatment; extrusion requires further treatment in 3% to 8%; in some studies, rates of dyspareunia same or lower in patients receiving mesh than those treated without mesh. Measures of success: patient satisfaction more important than anatomic outcome; Colpopexy and Urinary Reduction Efforts (CARE) trial — ~20% of patients achieved stage 0 pelvic organ prolapse (POP); stage 0 or 1 considered satisfactory by patients and achieved by 57%; anatomic support proximal to hymen achieved in ~50%; no POP beyond hymen in ~94%; no bulge symptoms in ~92%; no retreatment required at 2 yr in ~100%; absence of vaginal bulge correlates best with patient perception of success; bulge crucial factor and often first sign of POP. Randomized trials: 1) prospective, randomized study of colporrhaphy vs PeriGeex mesh defined anatomic success as point Ba of -2 or above; mesh group had higher success rate (86% vs 47%), less de novo dyspareunia, and greater improvement in quality of life; 2) study (65 patients) comparing mesh with nonmesh repairs halted early due to extrusion rate of 15% in 3 mo in mesh group; found higher recurrence rate at 3 mo in nonmesh group; in this study, surgeons possibly inexperienced; most erosions diagnosed within first week; 3) another study of colporrhaphy vs vaginal mesh used composite measure of success at 12 mo, encompassing anatomy and absence of bulge; success rates 61% in mesh group and 35% in colporrhaphy group; bulge reported by 25% in mesh group and 40% in nonmesh group; 3% had exposures requiring surgery at 1 yr; POP/Urinary Incontinence Sexual Questionnaire findings at 1 yr same in both groups. Recurrent prolapse: higher rates of anatomic failure in patients treated with plication than with mesh; subjective failures similar in both groups; 17% reported exposures, but most asymptomatic and required no treatment; exposure rate for individual surgeons ranged from 0% to 100%, suggesting outcomes surgeon-dependent; more dyspareunia reported at 1 yr in conventional group; 4% in nonmesh group needed surgery for recurrent prolapse at 1 yr. Dyspareunia: in study including 18 patients with dyspareunia, problem resolved in 13 after mesh placement, and only 1 of 43 patients developed dyspareunia postoperatively. Transvaginal mesh series: among 600 patients receiving transvaginal mesh, additional surgery required in 3.6% for mesh-related complication, in 3% for recurrence of POP, and in 7% for stress urinary incontinence (SUI); mesh-related complications stabilized after 2 yr, but recurrence of POP continued out to 5 yr. Adverse events: Food and Drug Administration (FDA) states mesh for transvaginal repair of POP introduces risks not present in traditional surgery such as erosion, pain, infection, bleeding, pain during intercourse, organ perforation, and urinary problems; however, all these complications possible after any type of repair; only erosion unique to mesh. Surgical approach: although FDA states abdominally placed mesh for POP appears to result in fewer complications than transvaginal mesh, erosions also observed after abdominal sacrocolpopexy (ASC); exposures with ASC difficult to treat because good pelvic support after ASC makes apical access difficult; 3% to 4% rate of exposure or erosion after ASC similar to rate among surgeons experienced with transvaginal mesh procedures. Other complications: gastrointestinal complication rate 7% in CARE trial; FDA states that anterior repair with mesh may provide anatomic benefit but not better symptomatic results; however, studies refute this statement. Expertise of surgeon: complication rates vary widely and probably related to surgical technique, layer in which mesh placed, and correct dissection; perioperative complications decrease significantly with surgeon experience; one study found 25% rate of erosions in early part of series and 1.5% at 2 yr later. Informed consent: FDA states patient should understand risks and complications of mesh placement and limitations of outcome data; have realistic discussion with patient about benefits and complications of mesh. Data on mesh: although FDA says data not mature, 5-yr data now available, similar to quantity of data available for traditional repairs; FDA warning may have discouraged some patients who could have benefited from transvaginal mesh. Using transvaginal mesh: anterior compartment has highest rate of recurrence of POP; no role for mesh in posterior compartment; anterior mesh cannot support apex; patients with

Educational Objectives

The goal of this program is to improve management of vaginal mesh repairs and their complications. After hearing and assimilating this program, the clinician will be better able to:

1. Critically evaluate statements made by the Food and Drug Administration about vaginal mesh.
2. Select candidates for vaginal mesh repairs and counsel them appropriately.
3. Practice adequate dissection and cystoscopic follow-up assessment in patients treated with vaginal mesh.
4. Recognize subtle and overt signs and symptoms of obstruction, exposure, and other complications after mesh repairs.
5. Diagnose and manage a patient in whom mesh repair has failed.

Faculty Disclosure

In adherence to ACCME Standards for Commercial Support, Audio-Digest requires all faculty and members of the planning committee to disclose relevant financial relationships within the past 12 months that might create any personal conflicts of interest. Any identified conflicts were resolved to ensure that this educational activity promotes quality in health care and not a proprietary business or commercial interest. For this program, the following has been disclosed: Dr. Karram is a consultant for American Medical Systems (AMS) and Medtronic, and is on the Speakers’ Bureaus for American Medical Systems (AMS) and Astellas Pharma US; Dr. Goldman is a consultant/advisor for Allergan, American Medical Systems (AMS), Johnson & Johnson, Pfizer, and T-DOC Company; he is also on the Speakers’ Bureaus for Allergan, Astellas Pharma US, Johnson & Johnson, and Pfizer. The planning committee reported nothing to disclose.
significant cystocele accompanied by apical issue require independent apical support; risk factors for failure include recurrence, high-stage POP, collagen disorder, morbid obesity, and occupational weight bearing

Summary: objective outcomes superior with transvaginal mesh, and subjective outcomes also superior in most studies; kits attractive and standardized but costly; dyspareunia uncommon; extrusion rate 3% to 8%, of which half asymptomatic; removing mesh not major procedure

Specific recommendations: isolated rectocelect — perform plication; isolated stage 2 cystocele — perform plication; recurrent cystocele — discuss mesh; apical descent and cystocele stage ≥3 — place anterior mesh and do sacrosinous ligament (SSL) fixation, sacrocolpopexy, or traditional plication with SSL fixation; enterocele — enterosacral or SSL suspension; uterine prolapse — if uterus at leading edge of prolapse, do hysterectomy and enterosacral or SSL suspension; if uterus behind other prolapsing structures, suspend anterior portion of cervix to anteriorly placed mesh or do sacrosinous hysteropexy; mesh alone not adequate for apex

Questions and Answers

Mesh shrinkage: surrounding scarring may cause minimal shrinkage; banding and shrinkage due to inappropriate para-vaginal dissection or failure to place arms of mesh sufficiently far apart; to avoid excess tension when using trocars, before pulling sheaths off, push up on fornix until arm of mesh retracts, loosening repair

Kinking of trigone: occurs when large cystocele repaired with midline plication, but resolves by 6 mo; ureteral orifices sometimes difficult to see (confirmation by indigo carmine sufficient even if orientation altered)

Terminology: perforation — mesh in bladder, rectum, or urethra; erosion — mesh visible in vagina; exposure — recently opened process near suture line; erosion — no longer accepted term

Follow-up: see patients at 2 wk; with both anterior and posterior incisions, agglutination may develop along suture lines; waiting until 6 to 8 wk may make this difficult to lyse; do second postoperative visit 6 to 8 wk later

Role of estrogen: treat all patients with vaginal estrogen 4 to 6 wk before procedure and continue for 4 to 6 wk afterward

Activity restriction: no heavy lifting or strenuous exercise for 3 wk; may resume vaginal intercourse in 1 mo

Avoiding and Managing Mesh Complications

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Food and Drug Administration: reclassified vaginal mesh kits as class III instead of class II, requiring more stringent approval process; companies marketing mesh must complete randomized trials or cohort studies to maintain approval

Mesh complications: severe complications probably due to technical errors; devastating complications include vaginal pain, constriction, and erosion; other important outcomes include recurrent POP, visceral symptoms, and outcomes related to sexual activity; rate of exposure 5% to 17%; difficult management issues include vaginal pain, dyspareunia, scarring and loss of vaginal tissue, visceral injury, and thigh and referred pain; do not place more mesh in patients with recurrent POP after mesh repair

Case 1: 56-yr-old with anterior trocar-based repair with mesh kit 1 yr ago presents with vaginal discharge, pain, and 3 unsuccessful attempts to excise eroded mesh from anterior vaginal wall; must perform cystoscopy in such patients; patient has recurrent POP and mesh superficially in wall of bladder due to placement of mesh in incorrect plane; removal of mesh requires excision of vaginal wall; labia minora flap previously used for large vaginal defects requires extensive dissection; porcine SurgiGraft Biodesign designed as skin replacement but useful in vagina and perineum when native tissue inadequate; material sewn in place converts to anterior vaginal wall in 6 wk to 3 mo

Case 2: 62-yr-old with trocar-based mesh repair 2 yr ago has recurrent POP and dyspareunia; apical enterocoele outside introitus; mesh eroded into foreshortened anterior vaginal wall; pain and bunching of posterior mesh; cystoscopy negative; recurrent apical enterocoele and thin vaginal mucosa after repair with Total Prolift; mesh also bunched in anterior segment with small amount of erosion; all posterior mesh bunched in rec-tovaginal space resulting in extreme pain; treated with suture repair, high intraperitoneal suspension, and excision of mesh

Case 3: 49-yr-old with recurrent POP 1 yr after Perigee for recurrent symptomatic cystocele; had vaginal hysterectomy with anterior and posterior repair 4 yr ago; has vaginal bleeding, dyspareunia, recurrent prolapse of anterior segment and apex, and large vaginal erosion; cystoscopy negative; arms of mesh too close to one another when passed through obturator membrane, producing bunching of mesh; difficult dissection in such cases may require entering bladder; transect midline of mesh and remove; patient treated with traditional suture repair; peritoneum entered, mesh excised from apex of vagina, and high intraperitoneal suspension performed; delayed absorbable suture used and brought out through full thickness of posterior vaginal wall; apex suspended with minimal distortion of vaginal canal, providing adequate length; posterior colpoporrhaphy also performed

Case 4: patient seen 18 mo after trocar-based mesh repair with intermittent purulent discharge from perirectal trocar sites; rectal examination revealed arm of mesh transecting rectum and rectovaginal fistula present; mesh excised posteriorly; patient recovered without colorectal diversion

Case 5: patient with anterior repair with Total Prolift, uterine preservation, and cystoscopy returned 1 yr later for vaginal hysterectomy due to elongation of cervix; difficulty during hysterectomy prompted cystoscopy that revealed intravesical mesh; mesh removed after placing bilateral ureteral stents; procedure easier to do vaginally than abdominally, and cannot be accomplished laparoscopically or cystoscopically; foreign body removed; to close, use only muscular layer of vagina to avoid distorting trigone; must remove all mesh from vesica; removal associated with bleeding due to tissue ingrowth; catheterize for 2 wk, then do cystography

Managing Sling Failures

Dr. Goldman

Failure after synthetic sling: midurethral synthetic sling (MUS) fails in 5% to 15% of patients; in Trial of Midurethral Slings (TOMUS) comparing transobturator with retropubic slings, 5% to 8% in both arms required retreatment

Treating failures: leaking — rule out persistent overactive bladder (OAB); de novo OAB — perform cystoscopy to assess bladder injury and rule out obstruction; SUI — options include no treatment, bulking agents, tightening existing sling, another sling, or another procedure

Bulking agents: one-third of patients dry, another third improved, and another third remain same; retreatment typically required; useful as temporizing measure immediately after surgery

Tightening sling: dissect out sling, fold, and use permanent sutures to shorten sling; can also place stitch on either side of mesh to avoid bulk in midline; dissect out, grasp sides 2 cm from midline with Allis, then place Prolene stitch on each side to shorten sling; ≤50% success rate

Replacing sling: type — in most cases, replace with synthetic MUS; if urethra fixed, use autologous fascial sling; approach — for severe SUI, retropubic sling superior to transobturator sling or minisling; in patients with maximum urethral closure pressure (MUCP) <42 cm H2O, 1 of 37 transvaginal tape
procedures failed, but 7 of 44 transobturator (Monarc) procedures failed; patients with intrinsic sphincteric deficiency (ISD) benefit from retropubic approach; patients with failure of initial sling may have advanced ISD or too-loose sling placement; original sling — ignore first sling if retropubic, but cut it if de novo OAB or obstruction present; if old transobturator sling interferes with passage of new retropubic sling, wiggle trocar slightly to avoid old sling or cut sling in midline, partially dissect, and place new sling beneath it.

Iatrogenic obstruction: patients with retention after sling probably obstructed; elevated postvoid residual (PVR), slowed force of stream, need to bend forward to empty bladder, recurrent urinary tract infection (UTI), and de novo OAB suggest obstruction; determine whether de novo OAB truly new; evaluate for obstruction, UTI, or sling in bladder or urethra: 0% to 5% of patients have some degree of obstruction after MUS, but problem not always significant; ascertain temporal relationship of symptoms to procedure and perform cystoscopy.

Urodynamics: unnecessary unless patient referred from elsewhere or long time elapsed since procedure; patient with good contractility of bladder may not have increased PVR despite obstruction; urodynamics may show trabeculation; high-pressure voiding with low flow and dilation of proximal urethra with voiding suggest obstruction; urodynamics not always helpful for diagnosing obstruction; detrusor pressure and maximal flow do not predict outcome; patients with voiding difficulties often respond to transsection of sling, even if urodynamic findings unremarkable; if symptoms temporally related to procedure, consider incision of sling or urethropysis; patient with MUS should void normally in hours or days unless extensive repair done.

Loosen sling: can loosen within first 1 to 2 wk, but after that may need full urethropysis to transect sling; begin incision 1 cm proximal to meatus in midline and slowly carry back toward bladder neck while attempting to feel sling; can also use sheath of cystoscope; slowly withdraw sheath with downward pressure to detect location of sling; can sometimes can feel sling with fingers during incision.

Outcomes: obstruction resolves in most patients but irritative, OAB complaints may remain; about one-third of patients have recurrent SUI; soft tissue infection rare, but UTI common; patients receiving single perioperative dose of cefazolin (Ancef) have same incidence of UTI as patients receiving additional days of oral antibiotics, but fewer antibiotic-related events such as yeast infection and colitis.

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Suggested Reading

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1. The finding most closely correlated with patient satisfaction after vaginal mesh repairs for pelvic organ prolapse (POP) is:
   (A) Absence of reported dyspareunia
   (B) Patient perception of absence of vaginal bulge
   (C) Absence of symptoms of obstruction
   (D) Achievement of stage 0 or 1 POP

2. Among women treated surgically for recurrent POP, anatomic failure rates are higher in those treated with _______ than with _______.
   (A) Vaginal mesh; traditional repair
   (B) Traditional repair; vaginal mesh

3. Food and Drug Administration communications regarding use of mesh for POP state which of the following?
   (A) Mesh introduces risks not present in traditional surgery
   (B) Abdominally placed mesh appears to result in fewer complications than transvaginal mesh
   (C) The patient should understand the risks of mesh placement
   (D) All the above

4. There is no role for the use of mesh in:
   (A) The anterior compartment
   (B) Suspending the vaginal apex
   (C) The posterior compartment
   (D) Patients with dyspareunia

5. Presence of mesh in the bladder after repair of POP is called:
   (A) Exposure
   (B) Extrusion
   (C) Erosion
   (D) Perforation

6. Severe complications following placement of vaginal mesh are most likely due to:
   (A) Patient obesity
   (B) Technical errors by surgeon
   (C) Soft tissue infection
   (D) Intrinsic sphincteric deficiency

7. The incidence of failure of midurethral slings is approximately:
   (A) 3% to 10%
   (B) 5% to 15%
   (C) 25% to 35%
   (D) >50%

8. For a patient with severe stress urinary incontinence, which type of urethral sling is preferred?
   (A) Transobturator
   (B) Retropubic
   (C) Minisling

9. Slowed force of stream and need to bend forward to empty the bladder after midurethral sling placement suggest:
   (A) De novo overactive bladder
   (B) Urinary tract infection
   (C) Urinary obstruction
   (D) Mesh exposure

10. Patients undergoing placement of a midurethral sling should receive a single perioperative dose of an antibiotic.
    (A) True
    (B) False

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