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Advancing Female Pelvic Medicine and Reconstructive Surgery

Vaginal Placement of Synthetic Mesh for Pelvic Organ Prolapse

ABSTRACT: Since 2004, use of synthetic mesh has increased in vaginal surgery for the treatment of pelvic organ prolapse. However, concerns exist about the safety and efficacy of transvaginally placed mesh. Based on the currently available limited data, although many patients undergoing mesh-augmented vaginal repairs heal well without problems, there seems to be a small but significant group of patients who experience permanent and life-altering sequelae, including pain and dyspareunia, from the use of vaginal mesh. The American College of Obstetricians and Gynecologists and the American Urogynecologic Society provide background information on the use of vaginally placed mesh for the treatment of pelvic organ prolapse and offer recommendations for practice.

Since 2004, use of synthetic mesh has increased in vaginal surgery for the treatment of pelvic organ prolapse (POP). However, concerns exist about the safety and efficacy of transvaginally placed mesh. Surgeons who perform these procedures may have many questions related to a U.S. Food and Drug Administration (FDA) Safety Communication released in July 2011 (1), which updates a 2008 FDA Public Health Notification (2), as well as published reports describing variable experience with mesh. The purpose of this joint document developed by the American College of Obstetricians and Gynecologists and the American Urogynecologic Society is to provide background information on the use of vaginally placed mesh for the treatment of POP and offer recommendations for practice. This report does not address the subject of synthetic mesh used for abdominal or minimally invasive sacrocolpopexy or for midurethral slings to treat stress urinary incontinence.

How does the U.S. Food and Drug Administration currently regulate surgical mesh products?

Surgical mesh is a medical device, currently regulated by the FDA as Class II Special Controls. Instead of the premarket approval review process reserved for Class III devices, Class II devices are introduced to the market by way of the regulatory pathway of Section 510(k) of the Federal Food, Drug and Cosmetic Act. In the 510(k) Premarket Notification Program (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm), a manufacturer attempts to demonstrate that a new device is "substantially equivalent" to a predicate device (ie, a similar Class II device already on the market). In making such a determination, the FDA reviews a comparison of the new device and the predicate device in terms of intended use and product design. This review typically addresses labeling and performance data, including material safety, mechanical performance, and animal testing, but, for some devices, it may also include clinical data.

In 2001, the FDA reviewed the first surgical mesh indicated for repair of POP and found it substantially equivalent to surgical mesh indicated for hernia repair. This finding was done without clinical data, and, since then, many subsequent mesh products have been cleared for the same indication without clinical data. Currently, an estimated 100 synthetic mesh devices or kits have been cleared by the FDA for use in surgery for POP, but only approximately 20% are actively marketed and sold. Modification of mesh devices continues. Compared with existing mesh products and devices, new products should not be assumed to have equal or improved safety and efficacy unless clinical long-term data are available. However, the FDA is currently re-evaluating the process it uses to evaluate mesh intended for vaginal repair of POP and is considering whether to reclassify it from Class II to

Class III, which would allow the FDA to require clinical trials comparing procedures with mesh with those in which mesh is not used.

As with all medical devices, the adverse events associated with use of surgical mesh should be reported in the FDA's Manufacturer and User Facility Device Experience database (http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/FormsandInstructions/default.htm). This reporting is voluntary for physicians and mandatory for manufacturers, but underreporting of complications is acknowledged. The complication rate related to vaginally placed mesh is not fully known because of incomplete knowledge of the total number of adverse events and the total number of vaginal mesh delivery systems that have been implanted.

What outcome data exist for vaginal placement of synthetic mesh for pelvic organ prolapse?

Vaginal mesh kits were first marketed to urologists and gynecologists as a way to improve success rates for POP repairs with native tissue, but without well-designed trials to establish the safety and efficacy of these devices. The body of literature is increasing for vaginal mesh, yet, case series and prospective cohort studies greatly outnumber randomized trials. These smaller series document good short-term surgical success in the hands of individual surgeons, but longer follow-up of procedures performed by surgeons from multiple centers is lacking.

Several systematic reviews draw on a similar pool of studies of vaginal mesh repairs, but these studies are based on short-term follow-up and have variable outcome measures. Systematic reviews by the Society of Gynecologic Surgeons and the World Health Organization-sponsored International Consultation on Incontinence found weak evidence for improved anterior anatomy when vaginal prolapse repairs were performed with synthetic mesh compared with native tissue (3–5). There are insufficient data on the use of mesh for the posterior or apical compartments. Although the risk of mesh erosion varied, it was a risk that did not exist for native tissue repairs.

One systematic review evaluated 30 studies totaling 2,653 patients who had undergone one of several apical prolapse kit repairs (6). Success was defined variably and ranged from 87% to 95%, with follow-up ranging from 26 weeks to 78 weeks. Another systematic review analyzed the complications and reoperation rates for surgical procedures specifically performed to correct apical POP: 1) native tissue vaginal repairs, 2) abdominal sacrocolpopexy, and 3) vaginal mesh kits (7). In this review, the rate of reoperation to correct complications as well as the total reoperation rate was highest for vaginal mesh kits compared with vaginal native tissue and abdominal repairs, despite shorter overall follow-up.

A 2010 Cochrane review evaluated 3,773 participants in 40 trials of different surgical procedures for POP and concluded that mesh grafts improved anterior anatomy more than native tissue repairs, but the abdominal approaches offered the best anatomic result (8). There was a higher rate of complications associated with vaginal mesh compared with native tissue vaginal repairs, including a 10% mesh erosion rate.

In Canada, the Society of Obstetricians and Gynaecologists of Canada (SOGC) reviewed 18 published studies of vaginal mesh for POP, of which 9 were observational or case series with 3–12-month follow-up, and only 1 was a randomized trial (9). Anatomic cure was typically defined as less than stage II of the POP quantification system (leading edge of prolapse within 1 cm of hymenal ring) and reported as 79–100%. The SOGC recommended that transvaginal mesh procedures be considered novel techniques that can demonstrate high rates of anatomic cure in uncontrolled short-term case series. It advocated surgeon training specific to each device before vaginal mesh repair for POP is performed and called for thorough individual patient counseling regarding the risks and benefits of these surgical procedures.

In a recent randomized controlled trial (RCT) of 389 women assigned to anterior mesh or anterior colporrhaphy, higher success rates based on a composite outcome of subjective absence of a bulge and anatomic stage 0 or stage I prolapse were seen with anterior mesh (60.8%) compared with colporrhaphy (34.5%) at 1 year (10). Rates of intraoperative bladder injury and hemorrhage were higher in the mesh group, and de novo stress incontinence also was higher (12.3% versus 6.3%). Surgical reintervention for mesh exposure was 3.2%.

What are the complications of vaginal mesh in surgery for pelvic organ prolapse?

The complications of vaginal mesh in surgery for POP range from transient pain and small mesh erosions to larger vaginal mesh exposures or extrusions or perforations into the bladder or bowel (11). Some complications can be managed in the office, but others that involve bladder and bowel injury, fistulae, abscess formation, and debilitating pain may require repeat surgery under anesthesia. Table 1 is adapted from the SOGC review and reports additional case studies and randomized trials of mesh for POP published since the Canadian review that analyzed literature published through May 2010. In the previously described reviews, mesh erosion was the most common complication, occurring in 5–19% of vaginal repairs using mesh (2–11% in the SOGC report). Some acknowledged risk factors for mesh erosion include urogenital atrophy and smoking, and vaginal or topical estrogen and smoking cessation may be helpful for affected women (12). Overall, complication rates from vaginal mesh range from less than 1% to 15%; however, because most of the studies cited in the SOGC report were observational and of short follow-up, there is concern that the complication rates could be higher than those estimated from these reviews.

Table 1. Range of Percentage of Mesh-Related Complications

Reported Complication	Range Based on Case Series (%)	Range Based on Randomized Controlled Trials (%)
Mesh erosion (exposure)	1–18.8	5–19
Buttock, groin, or pelvic pain	2.9–18.3	0–10
De novo dyspareunia	2.2–15	8–27.8
Reoperation*	1.3–7.6	3.2–22

*Does not include reoperation for stress urinary incontinence.

Data from Transvaginal mesh procedures for pelvic organ prolapse. SOGC Technical Update No. 254. Society of Obstetricians and Gynaecologists of Canada. J Obstet Gynaecol Can 2011;33:168–74; Carey M, Higgs P, Goh J, Lim J, Leong A, Krause H, et al. Vaginal repair with mesh versus colporrhaphy for prolapse: a randomised controlled trial. BJOG 2009;116:1380–6; Nieminen K, Hiltunen R, Takala T, Heiskanen E, Merikari M, Niemi K, et al. Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up. Am J Obstet Gynecol 2010;203:235.e1–235.e8; Miller D, Lucente V, Babin E, Beach P, Jones P, Robinson D. Prospective clinical assessment of the transvaginal mesh technique for treatment of pelvic organ prolapse-5-year results. Female Pelvic Med Reconstr Surg 2011;17:139–43; Jacquetin B, Fatton B, Rosenthal C, Clave H, Debodinance P, Hinoul P, et al. Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 3-year prospective follow-up study. Int Urogynecol J Pelvic Floor Dysfunct 2010;21:1455–62; Nguyen JN, Burchette RJ. Outcome after anterior vaginal prolapse repair: a randomized controlled trial. Obstet Gynecol 2008;111:891–8; Iglesia CB, Sokol AI, Sokol ER, Kudish BI, Gutman RE, Peterson JL, et al. Vaginal mesh for prolapse: a randomized controlled trial. Obstet Gynecol 2010;116:293–303; Withagen MI, Milani AL, den Boon J, Vervest HA, Vierhout ME. Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial. Obstet Gynecol 2011;117:242–50; Maher C, Feiner B, Baessler K, Glazener CM. Surgical management of pelvic organ prolapse in women. Cochrane Database of Systematic Reviews 2010, Issue 4. Art. No.: CD004014. DOI: 10.1002/14651858.CD004014.pub4; *and* Altman D, Vayrynen T, Engh ME, Axelsen S, Falconer C. Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. Nordic Transvaginal Mesh Group. N Engl J Med 2011;364:1826–36.

Several recent retrospective reports provide longer follow-up. One reported that vaginal erosion rates for anterior mesh repairs ranged from 7% to 20% (13) with one half of the cases managed with vaginal estrogen and antibiotics and the other half requiring surgical mesh removal (partial or complete). Another reported 5-year follow-up in a cohort of 85 women after vaginal mesh surgery (14). The overall rate of mesh exposure was 18.8% with 56% (9/16 patients) requiring reintervention for partial mesh excision. Anatomic success rate (defined as less than POP quantification system stage II) at 5 years was 66.7%. One report evaluated a cohort of 355 women after vaginal mesh procedures (15). Eighteen percent of the women developed pelvic muscle dysfunction and pain; of these, one quarter continued to have symptoms after 6 months of therapy.

Pelvic pain, groin pain, and dyspareunia can occur with pelvic reconstructive surgery regardless of the use or nonuse of mesh. However, a complication unique to mesh is erosion (also described as exposure or extrusion), which seems to be the most common complication, and may sometimes present several years after the index procedure. There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh; 11.7% of patients were found to have retracted mesh in a large retrospective multicenter cohort (16). Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

Risk factors for developing intractable pain after vaginal mesh placement are not understood. Mesh grafts for abdominal hernia repair, which are placed in clean surgical planes with intervening tissue layers, can cause pain in one quarter of individuals 1 year after repair; in one half of these cases there was functional impairment (17). Hernia mesh also is known to undergo retraction (18), and pain persists in patients at 5 years (19). Mesh grafts in the vagina are placed in a clean–contaminated field with a single vaginal incision, and the "arms" of some mesh configurations pass into the obturator internus and levator ani muscles. Shrinkage or contraction of mesh around these structures or excess tension on the mesh arms can cause vaginal pain in some individuals. All vaginal surgery can potentially affect vaginal length and function; however, the addition of synthetic mesh could make the vagina, a cylindrical organ that expands and contracts, less pliable and perhaps more prone to pain or dyspareunia. One ultrasound study evaluating women at 3 months after anterior vaginal mesh placement found severe contraction or shrinkage, defined as a decrease of more than 50% of the size of the mesh, in 9.3% of patients (20).

Based on the currently available limited data, although many patients who undergo mesh-augmented vaginal repairs heal well without problems, there seems to be a small but significant group of patients who experience permanent and life-altering sequelae, including pain and dyspareunia, from the use of vaginal mesh. These problems emerge in studies with longer follow-up, similar to hernia literature. Large-scale registries are urgently needed to understand the number of mesh-augmented vaginal procedures that are being performed with POP repair and how many of them are associated with vaginal mesh complications as well as to balance the risks and benefits of mesh-augmented vaginal procedures.

How effective and safe are native tissue repairs for pelvic organ prolapse?

Native tissue repair may have better success rates than previously thought. However, like repairs augmented with mesh, native tissue repairs also may be associated with complications, including pain, dyspareunia, granulation tissue formation, and recurrences, all of which may also require subsequent intervention. Older definitions of surgical success from prolapse repairs were more anatomically based (eg, no prolapse beyond -1 cm from the

hymenal ring) and may not be the best assessment of outcome compared with newer definitions of surgical success, which include the absence of bulge symptoms or rates of retreatment (21). Previous studies used definitions of success that may have been too stringent. A 2001 randomized trial of three methods of anterior wall repair, including native tissue, ultralateral anterior colporrhaphy, and absorbable vaginal mesh, reported success rates (based on anatomic success definitions) of only 30–46% (22). These low success rates were frequently cited as a reason why innovations such as vaginal mesh were needed to decrease failure rates. The original data from this study were recently reanalyzed using modern outcome measures (a composite of anatomic outcomes and subjective success), and the revised success rates for the three arms of this RCT were comparable, with 89% of women having no objective prolapse beyond the hymen. Overall, only 5% of those with 1-year follow-up data were symptomatic, and there were no reoperations either for recurrence or complications at 1 year (23). Patient "success" is more than an anatomic outcome; subjective patient-oriented success and quality of life outcomes need to be considered as well. The ideal method for comparing vaginal surgical procedures using native tissues and those using vaginal mesh kits remains an RCT with an adequate length of follow-up and blinded assessment of outcome using several complementary outcome measures, including cost–benefit analysis.

Who are the best patients for transvaginally placed mesh?

Few data exist as to who are the best patients for transvaginally placed mesh. Pelvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse (particularly of the anterior compartment) or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures. The approach to the repair of POP should take into account the patient's medical and surgical history, severity of prolapse, and patient preference after education regarding the benefits and risks of the surgical and nonsurgical alternatives.

How can patient safety be maximized by physicians who perform pelvic organ prolapse repairs with vaginal mesh?

Surgeons performing complex pelvic floor reconstructive surgery should have adequate experience and training in native tissue repairs as well as repairs using mesh augmentation specific to each device, should have a thorough understanding of pelvic anatomy, and should be able to counsel patients regarding the risk/benefit ratio on the use of mesh compared with native tissue repairs. In its 2011 Safety Communication, the FDA identified transvaginal placement of surgical mesh for POP repair as an area of "continuing serious concern" (1). The FDA's 2011 Safety Communication reaffirmed its 2008 recommendation that clinicians inform patients about the potential for serious complications and the effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall in POP repair using surgical mesh, and provide a copy of the patient labeling from the surgical mesh manufacturer if available. Clinicians should be vigilant for possible adverse events from mesh. Additionally, the FDA made several new recommendations for health care providers, including that they recognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications; that they choose mesh surgery only after weighing the risks and benefits of surgery with mesh versus all surgical and nonsurgical alternatives; and that they consider that the removal of mesh because of mesh complications may involve multiple surgical procedures and significantly impair the patient's quality of life. Complete removal of mesh may not be possible and may not result in complete resolution of complications, including pain.

As a surgeon, one should have a thorough understanding of pelvic anatomy and have training in the technique. Patients need to be counseled that there are alternative native tissue repairs and that synthetic mesh is permanent. Some patients may not realize that vaginal bleeding, pain, and dyspareunia may be related to vaginal mesh, and such reports should prompt a thorough vaginal examination, and an examination under anesthesia if needed.

Summary

Mesh kits for repair of POP were first marketed to urologists and gynecologists as a way to improve success rates for POP repairs with native tissue, but without well-designed trials to establish the safety and efficacy of these devices. However, prolapse surgical procedures, with or without mesh, are not always successful.

With the use of a composite of anatomic success, patient-oriented improvement and satisfaction, and total reoperation rates, success rates of native tissue repairs may be higher than previously thought. Based on available data, transvaginally placed mesh may improve the anatomic support of the anterior compartment compared with native tissue repairs; however, there are insufficient data on the use of mesh for the posterior or apical compartments. The risk/benefit ratio for mesh-augmented vaginal repairs must balance improved anatomic support of the anterior vaginal wall against the cost of the devices and increased complications such as mesh erosion, exposure, or extrusion; pelvic pain; groin pain; and dyspareunia.

Recommendations

The American College of Obstetricians and Gynecologists and the American Urogynecologic Society make the fol-

lowing recommendations for the safe and effective use of vaginal mesh for the repair of POP:

- Outcome reporting for prolapse surgical techniques must clearly define success, both objectively (anatomic results) and subjectively (patient satisfaction or symptomatic return of bulge causing bother or requiring reoperation). Complications and total reoperation rates (for recurrence or complications) should be reported as outcomes.
- Pelvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse (particularly of the anterior compartment) or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures.
- Surgeons placing vaginal mesh should undergo training specific to each device and have experience with reconstructive surgical procedures and a thorough understanding of pelvic anatomy.
- Compared with existing mesh products and devices, new products should not be assumed to have equal or improved safety and efficacy unless clinical long-term data are available.
- The American College of Obstetricians and Gynecologists and the American Urogynecologic Society strongly support continued audit and review of outcomes, as well as the development of a registry for surveillance for all current and future vaginal mesh implants.
- Rigorous comparative effectiveness randomized trials of synthetic mesh and native tissue repair and long-term follow-up are ideal.
- Patients should provide their informed consent after reviewing the risks and benefits of the procedure, as well as discussing alternative repairs.

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