

Surgery for Apical Vaginal Prolapse after Hysterectomy

Transvaginal Mesh-Based Repair



Shannon L. Wallace, MD^{a,*}, Raveen Syan, MD^b,
Eric R. Sokol, MD^{c,d}

KEYWORDS

• Transvaginal mesh • Apical prolapse • Outcomes • Vaginal vault prolapse • Prolapse repair

KEY POINTS

- Numerous mesh products have been made available for transvaginal apical prolapse repair.
- Although data are limited, studies indicate that transvaginal mesh placement does not result in superior anatomic or subjective outcomes compared with native tissue for apical prolapse.
- Given unique complications specific to mesh use, it is reasonable to reserve mesh use for high-risk cases.
- Current trials are underway comparing native tissue with ultralightweight mesh for transvaginal apical prolapse repair.
- American Urogynecologic Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction have recommended that surgeons thoroughly counsel their patients, and those performing these procedures should have additional specialized expertise.

INTRODUCTION

There has been a rapid development of surgical innovations to improve outcomes and reduce prolapse recurrence rates in female pelvic reconstructive surgery.¹ The success of mesh-augmented repairs in abdominal hernia surgeries led vaginal prolapse surgeons to hypothesize that synthetic mesh would improve the durability of apical repair,² especially given consistent and robust evidence that mesh use in the sacrocolpopexy

approach provides superior anatomic outcomes for apical vaginal prolapse compared with native tissue vaginal prolapse repair. Given the requirement for abdominal entry and a longer operating time with sacrocolpopexy, surgeons adapted this mesh-based technology to a transvaginal approach.³ In 2001, the Food and Drug Administration (FDA) approved the use of commercial mesh kits for transvaginal prolapse repair. Vaginal mesh and associated kits were first introduced in the United States in 2005 for augmentation of

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^a Department of Obstetrics and Gynecology, Division of Urogynecology and Pelvic Reconstructive Surgery, Stanford University School of Medicine, 300 Pasteur Drive, Grant S287, Stanford, CA 94305, USA;

^b Department of Urology, Stanford University School of Medicine, 300 Pasteur Drive, Grant S287, Stanford, CA 94305, USA; ^c Department of Obstetrics and Gynecology (by Courtesy), Division of Urogynecology and Pelvic Reconstructive Surgery, Stanford University School of Medicine, 300 Pasteur Drive, Room G304a, Stanford, CA 94305, USA; ^d Department of Urology (by Courtesy), Stanford University School of Medicine, 300 Pasteur Drive, Room G304a, Stanford, CA 94305, USA

* Corresponding author.

E-mail address: shanwall@stanford.edu

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suture-based native tissue repair of anterior, posterior, and apical vaginal prolapse.

Initial observational studies of synthetic implants suggested comparable apical anatomic results, lower failure rates, shorter operative time, and lower morbidity. However, short-term safety data and long-term outcome data were insufficient when these products were brought to market. Increasing reports of mesh-related complications including vaginal erosions, infections, granulomas, dyspareunia, vesicovaginal fistulas, and chronic pain, and a lack of superior functional outcomes, led to public warnings from the FDA about their safety.⁴

The future of transvaginal mesh in female pelvic reconstructive surgery is uncertain and placement has become controversial in the face of complications and litigation. Here we review the history of the introduction of transvaginal mesh, mesh classifications, outcome data, the FDA investigations and warnings, and finally statements from the American Congress of Obstetricians and Gynecologists, the American Urogynecologic Society (AUGS), the Society of Gynecologic Surgeons, and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction.

TYPES OF MESH PRODUCTS

Synthetic and biologic grafts have been used for the treatment of pelvic organ prolapse. Although mesh is usually used to refer to synthetic mesh, "transvaginal mesh" is used to describe synthetic mesh, xenografts, allografts, and autografts.

SYNTHETIC MESH

Synthetic meshes were initially categorized into four types based on pore size (macroporous or microporous), filament type (monofilament or multifilament), surface properties (coated or non-coated), and architecture (knit or woven). Pore size determines which cells can enter the mesh and affects infection risk, mesh density, and flexibility. Transvaginal mesh is usually classified by pore size, where pore size greater than 75 μm is considered macroporous, and less than 10 μm is considered microporous. Type 1 mesh is macroporous, type 2 mesh is microporous, type 3 has macroporous and microporous components, and type 4 has very small pores. Most mesh used in pelvic floor reconstruction is type 1 monofilament, macroporous, polypropylene mesh. The large pore size and monofilaments in this mesh encourage tissue ingrowth and integration, and also allow macrophages to permeate through the mesh and prevent bacterial adherence. Synthetic

meshes have minimal risk of donor-to-host immune reactions but have increased risk of foreign body bacterial colonization leading to infections and erosions.⁵⁻⁹

Initially, only anterior and posterior compartment repairs were augmented with mesh. Mesh was placed between the vaginal epithelium and underlying endopelvic connective tissue. Mesh was then developed to augment apical suspensions with attachment to pelvic supportive connective tissue structures, including the sacrospinous-coccygeus ligament complex, arcus tendineus fascia pelvis (ATFP), iliococcygeus fascia, and obturator membrane.¹⁰

Mesh Patches

Small mesh patches were first used in transvaginal prolapse repair of a single compartment. In apical repair, these small patches were fixed to the iliococcygeus fascia, the ATFP, or the sacrospinous ligament. Mesh patches were then developed into tension-free vaginal kits.

Early Mesh Kits

Early transvaginal mesh kits used metal trocars to guide placement of mesh arms through the obturator membrane. These kits used a standardized piece of mesh and a consistent approach reducing the likelihood of excessive tension on the mesh arms. In some cases, once the mesh was placed, the endopelvic fascia was sutured, creating a double-layer closure to reinforce the apical mesh suspension. The vagina was then closed without trimming the vaginal wall to minimize the occurrence of vaginal mesh exposure. The first kits that targeted apical vaginal compartment repair included the Gynecare Prolift (Ethicon, Inc, Somerville, NJ), the Perigee and the Apogee (American Medical Systems, Minnetonka, MN), and the Avaulta (BARD, Covington, GA). Currently, all early mesh kits have been discontinued and withdrawn from the market.

- The Prolift system was available as a four-armed anterior implant, a two-armed posterior implant, or a six-armed combined implant. This system used a metal trocar with a flexible mesh retrieval device that was passed through the obturator foramen and through the sacrospinous ligament bilaterally to correct apical vaginal wall defects.
- The Perigee system was designed to treat anterior and apical vaginal compartment defects. This system used four transobturator side-specific trocars that were passed through the ATFP just proximal to the level of the ischial spine and to the level of the bladder neck.

- The Apogee system was designed to treat posterior and apical vaginal compartment defects. This system used two side-specific trocars passed through the ATRF to the level of the ischial spines via the ischioanal fossa.
- The Avaulta anterior system was designed to treat anterior and apical vaginal compartment defects. This system had compartment-specific trocars with a flexible InSnare retrieval device that was passed anteriorly through the obturator foramen to place the proximal mesh arms near the ischial spine and the distal arms at the level of the bladder neck. There were two additional distal posterior arms that attached bilaterally to the junction of the bulbocavernosus and transverse perineal muscles. The mesh was available with or without an acellular collagen barrier.

Second-Generation Mesh Kits

The subsequent second-generation mesh kits use either a pulley stitch or self-fixating tips to attach mesh to the sacrospinous ligament and ATRF. These newer kits include the Pinnacle (Boston Scientific, Marlborough, MA), the Elevate (American Medical Systems, Minnetonka, MN), the Uphold system (Boston Scientific, Marlborough, MA) and Coloplast Restorelle Direct Fix (Coloplast, Minneapolis, MN). The Prosima (Ethicon, Inc, Somerville, NJ) system was a single-incision, fixation-less system that was held into place by a pessary-like vaginal support device for 3 weeks postoperatively.

- The Pinnacle system was designed to treat anterior and apical prolapse. The Capio needle driver device secured four mesh arms through the sacrospinous ligament and the ATRF bilaterally. This system has been withdrawn from the market.
- The Elevate system was designed to treat apical and either anterior or posterior prolapse. The mesh was placed with self-fixating tips through the sacrospinous ligaments (and the obturator foramen for the anterior system) bilaterally. This system has been withdrawn from the market.
- The anterior Prosima was the first fixation-less vaginal mesh system. The mesh was laid in place with an inserter such that the arms extended just anterior and superior to the ischial spines and lay across the ATRF. A pessary-like vaginal support device was sewn into place at the time of surgery and stayed in place for 3 to 4 weeks to allow tissue ingrowth into the graft. This system has been withdrawn from the market.

- The Uphold system is designed to treat apical prolapse with or without the uterus in situ. The Capio needle driver secures two mesh arms through the sacrospinous ligament and the mesh is secured to the vaginal vault or cervix and under the bladder. This system is currently on the market and is the subject of an FDA 522 postmarket surveillance study.
- The Coloplast Restorelle Direct Fix is designed to treat apical and either anterior or posterior prolapse. This ultralightweight mesh is secured by two mesh arms to the sacrospinous ligament with the Digitex suture delivery device. Additional mesh arms are secured to the obturator internus fixation point for distal anterior fixation or to the ATRF for distal posterior fixation. This system is currently on the market and is the subject of an FDA 522 postmarket surveillance study.

BIOLOGIC MESH GRAFTS

Several biologic grafts have been marketed to augment vaginal prolapse repair. Surgeons may choose to use biologic mesh in patients who have a high recurrence risk, such as those with poor tissue quality, increased intra-abdominal pressure from obesity, chronic constipation, chronic coughing or heavy lifting, or those who have failed previous native tissue repairs. The complications and success rates of biologic mesh grafts are varied because these meshes differ in origin (autograft, allograft, xenograft) and source (dermis, fascia, pericardium, small intestinal submucosa) with different degradation rates and tissue rebuilding processes.¹¹ However, there is currently no evidence that biologic grafts improve prolapse outcomes or reduce risks compared with native-tissue prolapse repair.

XENOGRAFT MESH

Xenograft meshes consist of acellular extracts of collagen harvested from nonhuman (bovine, porcine) sources. They pose a foreign body infection risk and some patients may refuse the implantation of animal-derived material because of cultural or religious beliefs.

ACell MatriStem

MatriStem Pelvic Floor Matrix (ACell, Columbia, MD) is composed of a porcine-derived extracellular matrix and is intended for implantation during anterior, posterior, and apical defect repair to reinforce soft tissue. The device is supplied in a multi-layer sheet configuration in sizes up to 10 cm × 15 cm. ACell MatriStem is currently being

compared with native tissue prolapse repair as part of an FDA 522 postmarket surveillance study, but the company recently announced that it was putting pursuit of the pelvic organ prolapse market on hold.

ALLOGRAFTS

Allograft mesh is composed of tissue transplanted between genetically nonidentical individuals of the same species and is most often derived from cadaveric fascia of human donors. Allograft mesh is biocompatible, but still may trigger a host immunologic response, even after decellularization removes nonhost antigens. By using allograft mesh, the morbidity of autologous fascia harvest is avoided but multiple prospective studies have shown that outcomes are less beneficial when compared with autologous fascia and synthetic meshes.

AUTOGRAFTS

Autograft meshes are donor tissues that are harvested from a different site on the same individual's body. The most commonly used autografts are fascia lata and rectus fascia. Autograft mesh does not trigger a host-immune response but clear disadvantages are that a surgical procedure is necessary to harvest an unpredictable quantity and quality of tissue.¹²

INDICATIONS AND CONTRAINDICATIONS OF TRANSVAGINAL MESH FOR APICAL PROLAPSE

Transvaginal mesh for apical vaginal repair still remains a durable option for high-risk patients with severe or recurrent prolapse. There are no evidence-based guidelines regarding absolute contraindications for the use of vaginal mesh, so surgeons performing apical repair with transvaginal mesh should use good judgment when selecting patients. Increasing body mass index has been associated with increased risk of mesh exposure and wound infections.¹³ Diabetes and smoking are associated with decreased vascularity, poor tissue healing, and increased mesh exposure, so placement of a foreign body may not be recommended in these patients. Additionally, patients with severe vaginal atrophy or chronic pelvic pain may not be candidates for mesh because placement may exacerbate these symptoms.¹³ Patients undergoing transvaginal mesh prolapse surgery should be thoroughly counseled and informed about the risks and benefits of mesh use.^{14,15}

OUTCOMES ASSOCIATED WITH TRANSVAGINAL APICAL MESH REPAIR

The benefit of transvaginal mesh placement has been assessed with respect to the separate compartments of repair. A large meta-analysis performed by the Society of Gynecologic Surgeons' Systematic Review Group¹⁶ found that, when directly comparing the benefit of transvaginal apical mesh-based repair with suture-based repair, outcomes were similar. The benefit of mesh-based repair was only obvious in the anterior compartment, but the group notes that high-quality studies directly comparing apical suspension alone are limited. Overall, 3% to 10% of patients who undergo apical surgical repair have recurrent vaginal vault prolapse.^{17,18} It is difficult to directly compare studies because of differences in type of mesh, type of repair, and surgical technique, although overall trends can be elucidated.¹⁹

ANATOMIC AND SUBJECTIVE OUTCOMES

Type of Apical Repair

There have been limited studies comparing the role of transvaginal mesh placement for treatment of apical prolapse with different types of apical suspension. A study by de Tayrac and colleagues²⁰ compared fixation of a polypropylene intravaginal sling with an infracoccygeal sacropepy versus a sacrospinous suspension for uterine or vaginal vault suspension. With 24 patients randomized to infracoccygeal sacropepy and 25 patients randomized to sacrospinous suspension, they found that prolapse cure rates and symptom scores were equivalent between the groups. They did note that infracoccygeal sacropepy was associated with a reduced rate of postoperative pain and cystocele recurrence.

Comparison with Native Tissue Repair

Only one study compared the role of mesh with native repair for the treatment of the apical compartment alone. Cosma and colleagues²¹ performed a retrospective case control study of outcomes in patients with stage III-IV pelvic organ prolapse who underwent uterosacral ligament suspension without mesh with those who received posterior intravaginal slingplasty (included multifilament and monofilament polypropylene mesh types). At a mean follow-up of more than 4 years, they found recurrent vault prolapse rates were higher in patients who had uterosacral ligament suspension without mesh in stage IV prolapse; however, reoperation rates and subjective cure rates were equivalent. They concluded that the first-line intervention should be a non-mesh-

based vault repair, with mesh reserved for select severe cases.

Vaginal Kits

Several vaginal kits that involved apical suspension have been created. Of these, a couple are still on the market and are proceeding with FDA-mandated postmarket surveillance studies. However, we provide a brief summary of the findings of these kits before their removal, because they help to understand the role of vaginal mesh in apical repairs.

Prolift

Many studies have been performed that examine the benefit of the Prolift vaginal kit. Iglesia and colleagues²² randomized patients with stage 2 to 4 prolapse to vaginal colpopexy with or without synthetic monofilament polypropylene mesh. Sixty-five patients were recruited before the study was halted, as vaginal mesh erosion rates reached 15.6% (the predetermined stopping criteria was 15%). They showed at 3 months that objective and subjective cure rates were similar between the groups. Equivalency was confirmed in this study population at 12-month follow-up²³; however, repeat operations at 1 year were performed only in the mesh group because of mesh erosion. Given this finding, the authors concluded that risks associated with the Prolift system may outweigh the benefits of its use. A subsequent 3-year outcomes study by this group confirmed that long-term cure rates remained similar between groups.²⁴

Withagen and colleagues¹⁹ compared native tissue repair (sacrospinous or uterosacral ligament suspension) with Prolift and similarly showed that 6- and 12-month outcomes for treatment of the apical compartment and failure rates (defined as stage II prolapse or greater or repeat surgery in the apical compartment) were similar between groups. Improvements in symptoms and quality of life were the same between the groups.

Halaska and colleagues²⁵ showed that patients randomized to Prolift had lower prolapse recurrence rates than patients who underwent a sacrospinous ligament fixation (SSLF) at 12 months, where the most common compartment of recurrence was anterior. Svabik and colleagues²⁶ compared patients with known levator ani avulsion injury who were randomized to Prolift or SSLF native tissue repair, and also found higher recurrence rates with SSLF at 12 months follow-up. They do note, however, that subjective cure rates were equivalent. Dos Reis Brandão da Silveira and colleagues²⁷ also showed higher recurrence rate in the anterior compartment at 12 months

when comparing patients randomized to Prolift versus native tissue repair. Similar to other studies, subjective improvement was similar between groups, although they did note that improvements in the Prolapse Quality-of-Life Questionnaire were higher in the mesh group compared with the native tissue group.

Elevate

The Elevate anterior and posterior mesh kit was compared with native tissue repair for stage 2 or higher prolapse.²⁸ Anatomic success rates in the anterior compartment were significantly higher in the Elevate group, as seen in Prolift studies. This was not maintained for the apical compartment.

Perigee

A retrospective review was performed comparing patients who underwent Perigee anterior repair with synthetic mesh plus SSLF versus patients with native tissue anterior repair and SSLF.²⁹ At 3 years follow-up, they showed that cumulative cure rates were higher in the anterior compartment and the apical compartment in the mesh group. They also found higher subjective success rates in the mesh group.

Uphold

The Uphold system is still available on the market and is part of an FDA-mandated multicenter postmarket surveillance study. This product has been assessed in multiple prospective studies but has not been compared with native tissue alone. A 5-year follow-up of patients treated with Uphold apical repair, with or without anterior repair, reported good anatomic outcomes (Pelvic Organ Prolapse Quantification (POPQ) stage <2 in 83%) and improvements in quality of life.³⁰ However, they note that three patients (1.5% of the study group) had severe pain that persisted despite treatment. This same group showed that Uphold without anterior colporrhaphy had significantly higher risk of prolapse-related bother compared with those who received concomitant anterior colporrhaphy.³¹

Comparison of Vaginal Kits

Despite the previously mentioned retrospective review showing subjective and objective improvements in the Perigee group compared with native tissue,²⁹ which was not seen in most Prolift studies, a prospective study by Long and colleagues³² showed that success rates were similar between patients receiving Perigee or Prolift systems, as were mesh-related complications. A prospective study comparing Prolift and Gynecare mesh found that despite similar anatomic outcomes, patients reported higher improvements

on the Pelvic Floor Disability Index-20 questionnaire in the Prolift group.³³ Mesh complications were similar. The authors conclude that Gynecare mesh should be considered more than Prolift given the lower cost of this product.

Studies comparing different mesh kits are limited, but they seem to have similar anatomic outcomes and cure rates. There is not sufficient evidence to consider one superior to the other.

Biologic Grafts

Studies examining outcomes with biologic grafts are limited. Ramanah and colleagues³⁴ performed a retrospective review comparing the use of InteXen (American Medical Systems) porcine dermis graft with native tissue repair and noted equivalent objective and subjective recurrence rates. No mesh erosion was seen in the graft group. A retrospective review of cystocele repair using porcine dermis interposition grafts noted no apical recurrences in the 71% of patients who had received concomitant vaginal vault prolapse repair.³⁵

Sexual Outcomes

There have been mixed findings regarding sexual outcomes with use of transvaginal mesh placement. When comparing polypropylene mesh placement with an infracoccygeal sacropey versus sacrospinous suspension, there was no difference in dyspareunia rates.²⁰ When comparing patients who had posterior intravaginal slingplasty versus native tissue, Cosma and colleagues²¹ showed that there was no overall difference in questionnaire data looking at urinary, sexual health, and quality of life measures between the groups. However, they noted that in the five patients who had mesh erosion, this resulted in worsening quality of life measures and sexual function.

Several studies examining the use of the Prolift system showed no difference in sexual questionnaires or dyspareunia rates.^{19,22,23} By comparison, Milani and colleagues³⁶ specifically focused on sexual function outcomes when patients were randomized to native tissue versus mesh-based repair (Prolift). All patients were sexually active at time of enrollment. They found that despite equivalency in total scores from the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PSIQ-12), sexual function actually improved in the native tissue repair group, which did not occur in the mesh group. They also noted that mesh exposure seemed to be independently associated with lower PSIQ-12 scores, which was similar to what was described by Cosma and colleagues.²¹ This study suggests that

complications related to mesh use may worsen sexual outcomes.

With regards to the Uphold system, the Nordic TVM Group found that in patients who completed preoperative sexual function questionnaires (PISQ-12), 66% had a worsening of sexual function.³¹ This was mainly related to a decline in scores in the partner-related domain. They found that performing a concomitant anterior repair did not predict worse sexual function.

With regards to biologic mesh, Ramanah and colleagues³⁴ showed no vaginal erosion or retraction with biologic graft (InteXen porcine dermis graft).

COMPLICATIONS

Numerous complications have been described that are specific to use of mesh, which include vaginal erosion, urinary tract erosions, immobility of the vagina, pain, and vaginal shortening.¹⁷

Erosion rates in the VAMP Study using Prolift were 15.6% at 3 months, and some patients required intraoperative intervention.²² At 12 months, the only patients who required reoperation were in the mesh group, for mesh erosion.²³ Withagen's group reported similar rates of erosion of 16.9%.¹⁹

With regards to pain, Withagen and colleagues¹⁹ reported similar rates of de novo pain between native tissue repair and the Prolift repair system. The Nordic TVM Group showed that 1.5% of their study population who received Uphold had persistent severe pain despite treatment, although they did not have a comparison group to determine pain attributable to the Uphold system.³⁰ Bowel injury was seen in one patient in the Prolift study performed by Dos Reis Brandão da Silveira and colleagues.²⁷ They also reported a single case of rectal extrusion at 6 months post-operatively that, although asymptomatic, did require vaginal and transrectal surgical removal, with reported uneventful recovery. Su and colleagues²⁸ showed that the Elevate system had longer hospital stay and higher estimated intraoperative blood loss. Type of vaginal kit was not associated with worse mesh-related complications.^{16,17}

Outcomes following a 1-year prospective study of use of Uphold for treatment of apical prolapse with or without concomitant anterior repair reported rates of serious complications to be 4.7%, and minor complications 9.7%.³¹ They comment that these rates are comparable with complication rates seen in other transvaginal mesh kits.

Overall, several studies comparing mesh use with native tissue repair report similar overall complication rates; however, mesh-specific complications, such as erosion/extrusion, pain, and rectal extrusion, have been reported, and must be considered when using transvaginal mesh.

FOOD AND DRUG ADMINISTRATION HISTORY

When transvaginal mesh was presented to the FDA, it was approved as a class II medical device. A class II device (low- to moderate-risk) poses slightly higher risks than a class I device (low-risk) and has special controls concerning labeling and postmarket surveillance. However, class II devices do not need premarket long-term safety and efficacy trials as would have been needed for a class III device (high-risk device). In 2001, the FDA found vaginal mesh to be similar to mesh used for abdominal hernia repair and approved its use without premarket clinical data or scientific review.

Between 2005 and 2008, the FDA received more than 1000 reports of complications from nine surgical mesh manufacturers. In October 2008, the FDA issued a Public Health Notification warning that “although rare, these complications can have serious consequences, including erosion, infection, and perforation of bowel and vessels associated with the kits designed for transvaginal placement.” The FDA issued recommendations on how to properly counsel patients about complications and how to report nonserious adverse events, such as mesh erosion and dyspareunia.

After reviewing data from its Manufacturer and User Device Experience database, the FDA released an update in July 2011 stating that “serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse are not rare and it is not clear that transvaginal prolapse repair with mesh is more effective than traditional nonmesh repair.”³⁷ In the 2011 update, the FDA listed recommendations for patients that included specific questions to ask their surgeon regarding mesh, alternative options, how complications are handled, and surgical follow-up. After the FDA notification, estimates of transvaginal mesh procedures significantly declined. In 2014, the FDA reclassified surgical mesh for transvaginal prolapse repair from class II to class III.³⁸ This new reclassification required manufacturers of transvaginal mesh for pelvic organ prolapse to obtain premarket approval and undergo rigorous testing of their devices to increase assurance of safety and efficacy. Of note, this reclassification excluded mesh used for either stress

urinary incontinence or transabdominal pelvic organ prolapse repair, such as sacrocolpopexy.

SOCIETY OPINIONS

In December 2011, The American Congress of Obstetricians and Gynecologists and the AUGS released a committee opinion offering recommendations for safe and effective use of vaginal mesh for pelvic organ prolapse repair. They recommended restricting transvaginal mesh to high-risk patients with recurrent prolapse or medical conditions. They also agreed with the FDA assessment that long-term clinical trials and follow-up were needed to compare the benefits and safety of transvaginal mesh repair with native tissue repair.³⁹

Since the initial FDA statements, public awareness of mesh complications has been raised and numerous litigious claims have been filed against surgeons and device manufacturers. Many hospitals and surgeons have moved away from transvaginal mesh use because of fears of litigation. In response to the FDA warnings and the decrease in transvaginal mesh procedures, AUGS and the Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction published a joint position statement on vaginal mesh.⁴⁰ In their position statement they emphasized that these devices should not be removed from the market or restricted because they may be a good option in the right patient. They encouraged surgeons to thoroughly counsel their patients and recommended that surgeons performing these procedures should have additional specialized expertise. Finally, they specified that the FDA warnings exclude mesh placed transvaginally for midurethral slings or abdominally for sacrocolpopexy.

The transvaginal mesh litigation and controversy also shrouds the international pelvic surgery community. In 2017, Australia removed transvaginal mesh and single-incision mesh slings from the market and New Zealand has banned all manufacturers of mesh, including midurethral slings. Many countries are considering waiting for evidence of safety and efficacy before allowing the marketing of these products.

SUMMARY

Many transvaginal mesh products have been created to address vaginal vault suspension. These synthetic-based mesh products have not been shown to reliably improve outcomes with respect to apical compartment repair. Although data are limited, recurrence rates and subjective measures of improvement are equivalent

compared with native tissue repair, and the different types of vaginal kits have not proven superior to one another. Given the known unique complications specific to mesh with equivalent outcomes with respect to the apical compartment, it is reasonable to reserve mesh use for specific cases, such as recurrence after native-tissue repair or for patient-specific risk factors, where mesh may have a more defined benefit.

REFERENCES

1. Jelovsek JE, Maher C, Barber MD. Pelvic organ prolapse. *Lancet* 2007;369:1027–38.
2. Sung VW, Rogers RG, Schaffer JI, et al. Graft use in transvaginal pelvic organ prolapse repair: a systematic review. *Obstet Gynecol* 2008;112:1131–42.
3. Barber MD, Maher C. Apical prolapse. *Int Urogynecol J* 2013;24:1815–33.
4. Maher C, Feiner B, Baessler K, et al. Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. *Cochrane Database Syst Rev* 2016;(2):CD012079.
5. Amid P. Classification of biomaterials and their related complications in abdominal wall hernia surgery. *Hernia* 1997;1:15–21.
6. Greca FH, Souza-Filho ZA, Giovanini A, et al. The influence of porosity on the integration histology of two polypropylene meshes for the treatment of abdominal wall defects in dogs. *Hernia* 2008;12:45–9.
7. Klinge UKB. Modified classification of surgical meshes for hernia repair based on the analysis of 1000 explanted meshes. *Hernia* 2011;16:251–8.
8. Weyhe D, Schmitz I, Belyaev O, et al. Experimental comparison of monofilament light and heavy polypropylene meshes: less weight does not mean less biological response. *World J Surg* 2006;30:1586–91.
9. Dietz HP, Vancaillie P, Svehla M, et al. Mechanical properties of urogynecologic implant materials. *Int Urogynecol J Pelvic Floor Dysfunct* 2003;14:239–43.
10. Larouche M, Merovitz L, Correa JA, et al. Outcomes of trocar-guided Gynemesh PS™ versus single-incision trocarless Polyform™ transvaginal mesh procedures. *Int Urogynecol J* 2015;26:71–7.
11. Schimpf MO, Abed H, Sanses T, et al. Graft and mesh use in transvaginal prolapse repair: a systematic review. *Obstet Gynecol* 2016;28:81–91.
12. Patel H, Ostergard D, Sternschuss G. Polypropylene mesh and the host response. *Int Urogynecol J Pelvic Floor Dysfunct* 2012;23:669–79.
13. Bako A, Dhar R. Review of synthetic mesh-related complication in pelvic floor reconstructive surgery. *Int Urogynecol J Pelvic Floor Dysfunct* 2008;20:103–11.
14. Deffieux X, Letouzey V, Savary D, et al. Prevention of complications related to the use of prosthetic meshes in prolapse surgery: guidelines for clinical practice. *Eur J Obstet Gynecol Reprod Biol* 2012;165:170–80.
15. Miller D, Milani AL, Sutherland SE, et al. Informed surgical consent for a mesh/graft-augmented vaginal repair of pelvic organ prolapse. Consensus of the 2nd IUGA Grafts Roundtable: optimizing safety and appropriateness of graft use in transvaginal pelvic reconstructive surgery. *Int Urogynecol J* 2012;23:S33–42.
16. Schimpf MO, Abed H, Sanses T, et al. Society of gynecologic surgeons systematic review group. graft and mesh use in transvaginal prolapse repair: a systematic review. *Obstet Gynecol* 2016;128:81–91.
17. Klauschie JL, Cornella JL. Surgical treatment of vaginal vault prolapse: a historic summary and review of outcomes. *Female Pelvic Med Reconstr Surg* 2012;18:10–7.
18. Prodigalidad LT, Peled Y, Stanton SL, et al. Longterm results of prolapse recurrence and functional outcome after vaginal hysterectomy. *Int J Gynaecol Obstet* 2013;120(1):57–60.
19. Withagen MI, Milani AL, den Boon J, et al. Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial. *Obstet Gynecol* 2011;117:242–50.
20. de Tayrac R, Mathe ML, Bader G, et al. Infracoccygeal sacropexy or sacrospinous suspension for uterine or vaginal vault prolapse. *Int J Gynaecol Obstet* 2008;100:154–9.
21. Cosma S, Menato G, Preti M, et al. Advanced uterovaginal prolapse and vaginal vault suspension: synthetic mesh vs native tissue repair. *Arch Gynecol Obstet* 2014;289:1053–60.
22. Iglesia CB, Sokol AI, Sokol ER, et al. Vaginal mesh for prolapse: a randomized controlled trial. *Obstet Gynecol* 2010;116:93–303.
23. Sokol AI, Iglesia CB, Kudish BI, et al. One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse. *Am J Obstet Gynecol* 2012;206:86.e1–9.
24. Gutman RE, Nosti PA, Sokol AI, et al. Three-year outcomes of vaginal mesh for prolapse: a randomized controlled trial. *Obstet Gynecol* 2013;122:770–7.
25. Halaska M, Maxova K, Sottner O, et al. A multicenter, randomized, prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of posthysterectomy vaginal vault prolapse. *Am J Obstet Gynecol* 2012;207:301.e1–7.
26. Svabik K, Martan A, Masata J, et al. Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial. *Ultrasound Obstet Gynecol* 2014;43:365–71.
27. Dos Reis Brandão da Silveira S, Haddad J, de Jármy-Di Bella ZI NF, et al. Multicenter, randomized

- trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment. *Int Urogynecol J* 2015;26:335–42.
28. Su TH, Lau HH, Huang WC, et al. Single-incision mesh repair versus traditional native tissue repair for pelvic organ prolapse: results of a cohort study. *Int Urogynecol J* 2014;25:901–8.
 29. Lo TS, Pue LB, Tan YL, et al. Long-term outcomes of synthetic transobturator nonabsorbable anterior mesh versus anterior colporrhaphy in symptomatic, advanced pelvic organ prolapse surgery. *Int Urogynecol J* 2014;25:257–64.
 30. Rahkola-Soisalo P, Mikkola TS, Altman D, et al. Pelvic organ prolapse repair using the uphold vaginal support system: 5-year follow-up. *Female Pelvic Med Reconstr Surg* 2017. [Epub ahead of print].
 31. Rahkola-Soisalo P, Altman D, Falconer C, et al. Quality of life after Uphold™ Vaginal Support System surgery for apical pelvic organ prolapse—A prospective multicenter study. *Eur J Obstet Gynecol Reprod Biol* 2017;208:86–90.
 32. Long CY, Hsu CS, Jang MY, et al. Comparison of clinical outcome and urodynamic findings using “Perigee and/or Apogee” versus “Prolift anterior and/or posterior” system devices for the treatment of pelvic organ prolapse. *Int Urogynecol J* 2011; 22:233–9.
 33. Chen YS, Cao Q, Ding JX, et al. Midterm prospective comparison of vaginal repair with mesh vs Prolift system devices for prolapse. *Eur J Obstet Gynecol Reprod Biol* 2012;164:221–6.
 34. Ramanah R, Mairot J, Clement MC, et al. Evaluating the porcine dermis graft InteXen in three-compartment transvaginal pelvic organ prolapse repair. *Int Urogynecol J* 2010;21:1151–6.
 35. Gomelsky A, Rudy DC, Dmochowski RR. Porcine dermis interposition graft for repair of high grade anterior compartment defects with or without concomitant pelvic organ prolapse procedures. *J Urol* 2004;171:1581–4.
 36. Milani AL, Withagen MI, The HS, et al. Sexual function following trocar-guided mesh or vaginal native tissue repair in recurrent prolapse: a randomized controlled trial. *J Sex Med* 2011;8:2944–53.
 37. FDA update on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse: FDA safety communication. Silver Spring (MD): United States Food and Drug Administration; 2011.
 38. FDA reclassification of surgical mesh for transvaginal pelvic organ prolapse repair and surgical instrumentation for urogynecologic surgical mesh procedures; designation of special controls for urogynecological surgical mesh instrumentation. Silver Spring (MD): United States Food and Drug Administration; 2014.
 39. ACOG Committee Opinion No.513. Vaginal placement of synthetic mesh for pelvic organ prolapse. *Obstet Gynecol* 2011;118(6):1459–64.
 40. AUGS (American Urogynecological Society). Position statement on restriction of surgical options for pelvic floor disorders. *Female Pelvic Med Reconstr Surg* 2013;19(4):199–201.