Guidelines for Providing Privileges and Credentials to Physicians for Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse

American Urogynecologic Society’s Guidelines Development Committee

EXECUTIVE SUMMARY

The adoption of new technology or procedures into a clinician’s surgical armamentarium is driven by multiple factors. Patient safety and anticipated long-term improvement in outcomes should be the primary objective that guides a surgeon’s decision to deliver care involving new procedures. Surgically complex procedures require a balance of knowledge, surgical skill, and experience, with appropriate ongoing surgical volume and monitoring of outcomes and adverse events. Transvaginal placement of surgical mesh for pelvic organ prolapse has the potential to improve quality of life and anatomic outcomes (especially in the anterior compartment), but also has potential serious adverse events as outlined by the FDA’s July 2011 Safety Communication. This document provides Guidelines for privileging and credentialing of physicians planning to implement or continue using this new technology in clinical practice.

KEY POINTS

- Transvaginal placement of surgical mesh for pelvic organ prolapse should only be performed by surgeons who are Board certified or Board eligible in Obstetrics and Gynecology or Urology and also have requisite knowledge, surgical skills, and experience in pelvic reconstructive surgery.
- Outcomes and complications of transvaginal placement of surgical mesh for pelvic organ prolapse and other prolapse procedures should be monitored by annual audit at the local institution or statewide or national registry.
- Informed consent should highlight:
  - Potential benefits and complications of transvaginal mesh
  - Alternatives including nonsurgical options (eg, pessary) and other surgical treatments such as native tissue repairs (vaginal repairs without mesh), abdominal and endoscopic repairs (eg, sacrococcygeal).

- Potential complications of transvaginal placement of surgical mesh for pelvic organ prolapse including mesh exposure/extrusion/erosion, vaginal scarring/stricture/contracture, fistula formation, dyspareunia, and/or pelvic pain which may require additional intervention and may not be completely resolved with mesh removal.

BACKGROUND

Over 300,000 surgeries for prolapse are performed each year in the United States, and a woman’s lifetime risk of surgery for pelvic organ prolapse is approximately 7%.1,2 Of those who receive surgery, an estimated 13% will require a repeat operation within 5 years, and as many as 29% will undergo another surgery for genital prolapse or a related condition at some point during their life.2,3 Reinforcement of vaginal repairs with synthetic mesh has been widely employed in the hope of improving the effectiveness and durability of vaginal prolapse repairs, with almost one-quarter of all prolapse repairs currently involving the placement of transvaginal mesh. In July 2011, concerns regarding the long-term safety of vaginally placed synthetic mesh prompted an FDA Safety Communication (http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm262435.htm) that serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse are not rare. The FDA’s literature review found that erosion of mesh through the vagina is the most common and consistently reported mesh-related complication from transvaginal placement of surgical mesh for pelvic organ prolapse. Although many mesh erosions may be conservatively managed, some mesh erosions can require multiple surgeries to repair and can be debilitating for some women. In some cases, even multiple surgeries will not resolve the complication. The FDA further emphasized that transvaginal placement of surgical mesh for pelvic organ prolapse requires adequate training, surgical expertise, proper patient selection and counseling.4

The American Urogynecologic Society (AUGS) and the American College of Obstetricians and Gynecologists (ACOG) recommended in their December 2011 Committee Opinion on Vaginal Placement of Synthetic Mesh for Pelvic Organ Prolapse5 that:

- Surgeons performing transvaginal placement of surgical mesh for pelvic organ prolapse should undergo training specific to each device and have experience with reconstructive surgical procedures and a thorough understanding of pelvic anatomy.
- Transvaginal placement of surgical mesh for pelvic organ prolapse should be reserved for high-risk individuals in whom the benefits of mesh placement may justify the risk, such as individuals with recurrent prolapse (particularly of the anterior compartment) or with medical comorbidities that precluded more invasive and lengthier open and endoscopic procedures.

This document provides guidance for quality assurance when physicians implement transvaginal placement of surgical
mesh for pelvic organ prolapse into their practice. This document refers to mesh grafts placed vaginally to correct pelvic organ prolapse. It does not apply to mesh used for treatment of stress urinary incontinence (mid-urethral slings) or mesh placed by open or endoscopic procedures such as sacrocolpopexy. Placement of transvaginal mesh for pelvic organ prolapse should only be performed by surgeons who are Board certified or Board eligible in Obstetrics and Gynecology or Urology who also have requisite knowledge, surgical skills, and experience in reconstructive pelvic surgery. An internal audit of the surgical experience at the local institution or via statewide or national registry is also recommended to maintain quality after implementation of this surgical procedure.

For surgeons who do not currently place transvaginal mesh for pelvic organ prolapse but wish to begin performing this procedure:

1. Documenting Knowledge

Prior to performing transvaginal placement of surgical mesh for pelvic organ prolapse, surgeons must demonstrate adequate general knowledge in pelvic anatomy and reconstructive pelvic surgery. Graduation from a fellowship training program in Urogynecology, Female Pelvic Medicine & Reconstructive Surgery or Female Urology provides adequate evidence of the general knowledge required for this purpose. Surgeons who have not graduated from a fellowship training program should provide documentation of knowledge of pelvic anatomy and fundamentals of pelvic reconstructive surgery through continuing medical education (CME) programs or other similar means. General knowledge encompasses:

- Preoperative Evaluation including appropriate patient selection for surgery and discussion of the relative risks and benefits of non-surgical prolapse treatment and different methods of surgical correction (e.g., vaginal without mesh, vaginal with mesh, sacrocolpopexy)
- Relevant Pelvic Surgical Anatomy
- Perioperative management including discussion of methods to prevent, identify and treat common complications of pelvic reconstructive surgery
- A discussion of the strengths and weaknesses of the existing comparative effectiveness studies of mesh placement for pelvic organ prolapse regardless of route
- A description of differences in biomechanical properties of marketed synthetic mesh and other grafts

In order to demonstrate specific knowledge of a particular mesh procedure or delivery system, surgeons should:

- Demonstrate understanding of relevant pelvic anatomy
- Read the manufacturer’s instructions for use (IFU)
- Observe steps involved in the procedure via animation, video, or live surgery
- Undergo hands on experience with the procedure using simulated models, animal or cadaveric models or other learning models
- Consider specific intraoperative and postoperative complications that may be unique to that procedure or device and the steps necessary to manage those complications
- Be familiar with the requirements for adequate informed consent for transvaginal placement of synthetic mesh for pelvic organ prolapse including:
  a) Specific indications for the choice of transvaginal mesh for prolapse repair, such as individuals with recurrent prolapse in the anterior compartment, known connective tissue disorders, or advanced prolapse in the presence of significant medical comorbidities precluding abdominal surgery
  b) Relative contraindications
  c) Alternatives including nonsurgical options (e.g., pessary) and other surgical treatments such as native tissue repairs (vaginal repairs without mesh), abdominal and endoscopic repairs (e.g., sacrocolpopexy)
  d) Potential benefits of mesh with review of available outcome data
  e) Potential complications of transvaginal mesh including mesh exposure/extrusion/erosion, vaginal scarring/stricture/contracture, fistula formation, dyspareunia, back, leg, buttock, and/or pelvic pain that may require additional intervention and may not be completely resolved with mesh removal.

2. Documenting Surgical Skills

A surgeon planning implementation of transvaginal placement of surgical mesh for pelvic organ prolapse in their practice should be observed by a surgical proctor as further described below to ensure that such surgeon demonstrates adequate surgical skills for performing a procedure independently. Graduates of fellowship training programs in Urogynecology, Female Pelvic Medicine & Reconstructive Surgery or Female Urology may meet this requirement by providing documentation of training in transvaginal placement of surgical mesh for pelvic organ prolapse or use of a particular mesh device during their fellowship. Surgeons who have not graduated from a fellowship training program or who did not receive training in transvaginal placement of surgical mesh for pelvic organ prolapse during fellowship should be proctored on no fewer than 5 cases or as many cases as is necessary to demonstrate that they can independently perform the specific procedure safely without being observed. The role of a surgical proctor is to assist the hospital’s credentialing process for these procedures. Surgical proctors should have unrestricted credentials to perform the procedure at their institution(s). The proctor must have significant experience with the specific procedure and should be able to perform an independent evaluation of the candidate surgeon. The surgical proctor must have the right to require as many proctored procedures as needed to ensure that the surgeon being proctored has met the requirements. At the time of proctoring the surgeon being proctored must demonstrate the following:

- The ability to explain the procedure, potential outcomes and potential complications at the time of informed consent
- The knowledge of appropriate pelvic anatomy and potential areas of safety/danger associated with the procedure
- The ability to perform the procedure safely and efficiently
- The capacity to track outcomes and complications

Surgical proctors should obtain written confirmation from the hospital regarding their role in the procedure, i.e. observational-only status versus assisting during proctored case. Proctors should either obtain written confirmation from the hospital indemnifying them from any claims or suits arising from their acts or omissions during proctored procedures or provide documentation that adequate malpractice coverage exists.

3. Documenting Experience

Surgeons planning implementation of transvaginal placement of surgical mesh for pelvic organ prolapse in their practice must demonstrate previous experience in the care and management of women with pelvic floor disorders, specifically pelvic
organ prolapse. Experienced surgeons have fewer mesh complications with transvaginal placement of surgical mesh for pelvic organ prolapse than those with less experience. Graduation from a fellowship training program in Urogynecology, Female Pelvic Medicine & Reconstructive Surgery or Female Urology provides adequate evidence of the experience required for this purpose. Surgeons who have not graduated from a fellowship training program must provide evidence of previous experience with reconstructive surgical procedures for pelvic organ prolapse (eg, case lists) including documentation that surgery for female pelvic floor disorders represents a significant portion (≥50%) of their current surgical practice including a minimum of 30 surgical cases annually for pelvic organ prolapse—any route, with or without transvaginal mesh. Surgeons should demonstrate experience in non-mesh vaginal repair of prolapse including anterior colporrhaphy, posterior colporrhaphy, and vaginal colpopexy (eg, uterosacral or sacrospinous ligament fixation), and experience and privileges to perform intraoperative cystoscopy to evaluate for bladder and ureteral integrity. It is strongly recommended that credentialing committees require this documentation from all surgeons, even those who have previously performed transvaginal placement of surgical mesh for pelvic organ prolapse mesh.

4. Internal Audits
Maintaining quality assurance after the implementation phase through ongoing annual internal audits at the local institutional level or statewide or national registry should be required of all surgeons performing transvaginal placement of surgical mesh for pelvic organ prolapse. Surgeons should follow their patients undergoing transvaginal placement of surgical mesh for pelvic organ prolapse postoperatively. Considerations should be given to tracking the following outcomes:

- Post-operative monitoring including:
  - Subjective symptoms of prolapse (patient-oriented improvement and satisfaction)
  - Objective measures of prolapse
  - Retreatment for recurrent prolapse including surgery and/or pessary use
  - Reoperation rates for complications related to the prolapse surgery

- Events to be tracked include:
  - Injury to the genito-urinary tract
  - Injury to the gastro-intestinal tract
  - Blood loss >500 ml for procedure
  - Time to perform index procedure
  - Documentation of mesh erosion, extrusion or exposure
  - New onset vaginal pain lasting greater than 6 weeks
  - New onset leg pain lasting greater than 6 weeks
  - Fistula formation
  - New onset or worsening dyspareunia
  - Persistent neurologic injury

**For surgeons who currently have privileges in transvaginal placement of surgical mesh for pelvic organ prolapse**

All surgeons who currently perform transvaginal placement of surgical mesh for pelvic organ prolapse should provide documentation of annual continuing medical education in Female Pelvic Medicine and Reconstructive Surgery. Additionally, they should demonstrate experience and privileges in non-mesh vaginal repair of prolapse including anterior colporrhaphy, posterior colporrhaphy, and vaginal colpopexy (eg, uterosacral or sacrospinous ligament fixation), and experience and privileges to perform intraoperative cystoscopy to evaluate for bladder and ureteral integrity. A minimum of 30 surgical cases for pelvic organ prolapse (any route, with or without transvaginal mesh) should be performed each year to maintain proficiency in pelvic reconstructive surgery. Annual internal audits as described above should be performed. Prior to adoption of a new transvaginal mesh technology or device for which the surgeon does not currently have privileges, specific knowledge of the new procedure should be demonstrated as previously described and the surgeon should be proctored on no fewer than 5 procedures or as many as is necessary to demonstrate that they can independently perform the newly adopted procedure or technique.

**SUMMARY OF RECOMMENDATIONS**

1. For surgeons who do not currently perform transvaginal placement of surgical mesh for pelvic organ prolapse, but wish to begin performing this procedure:
   a) General knowledge should be documented either by completing a fellowship training program in Urogynecology, Female Pelvic Medicine and Reconstructive Surgery, or Female Urology or by completing adequate CME in pelvic anatomy and reconstructive pelvic surgery.
   b) Specific knowledge for a particular procedure should be obtained
   c) Skill may be documented by surgeons who have completed a Urogynecology, Female Pelvic Medicine and Reconstructive Surgery or Female Urology fellowship program via cases lists showing experience with transvaginal placement of surgical mesh for pelvic organ prolapse. Surgeons who do not have documentation of prior training with a specific transvaginal mesh prolapse procedure should be proctored on no fewer than 5 procedures or as many as is necessary to demonstrate that they can independently perform the specific procedure.
   d) Experience in treating women with pelvic floor disorders should be documented either by completing a fellowship training program in Urogynecology, Female Pelvic Medicine and Reconstructive Surgery or Female Urology or by demonstrating that they offer a full spectrum of surgical options for pelvic floor disorders and that surgery for pelvic floor disorders represents >50% of their surgical practice including a minimum of 30 surgical cases for pelvic organ prolapse annually.
   e) Demonstrate experience and privileges in non-mesh vaginal repair of prolapse including anterior colporrhaphy, posterior colporrhaphy, and vaginal colpopexy (eg, uterosacral or sacrospinous ligament fixation), and experience and privileges to perform intraoperative cystoscopy to evaluate for bladder and ureteral integrity.
   f) Annual internal audits should be performed.

2. For surgeons who currently perform transvaginal placement of surgical mesh for pelvic organ prolapse and wish to maintain this privilege:
   a) Continuing medical education in female pelvic reconstructive surgery should be documented annually
   b) A minimum of 30 surgical cases for pelvic organ prolapse (any route, with or without transvaginal mesh) be performed each year
   c) Demonstrate experience and privileges in non-mesh vaginal repair of prolapse including anterior colporrhaphy, posterior colporrhaphy, and vaginal colpopexy (eg, uterosacral or sacrospinous ligament fixation), and experience and privileges to perform intraoperative cystoscopy to evaluate for bladder and ureteral integrity.
d) Annual internal audits should be performed
e) Prior to adoption of a new transvaginal mesh technology or device, specific knowledge of the new procedure should be demonstrated as previously described and the surgeon should be proctored on no fewer than 5 procedures or as many as is necessary to demonstrate that they can independently perform the newly adopted procedure.

REFERENCES