MASTER CLASS

Synthetic Mesh

BY CHARLES E. MILLER, M.D.

In the United States from 2005 to 2007, a reported total of 994,890 surgeries—363,000 procedures for pelvic floor prolapse and 631,890 procedures for stress urinary incontinence—utilized synthetic mesh. The impetus for mesh usage was based on the fact that conventional pelvic floor prolapse repair has an estimated failure rate of 30%-50%.

In October 2008, a Public Health Notification was issued by the Food and Drug Administration regarding complications with the transvaginal placement of surgical mesh for pelvic floor prolapse and stress urinary incontinence. Over a 3-year period, the FDA has received more than 1,000 reports of serious mesh-related complications from nine manufacturers. The most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence. Additional complications were noted due to bowel, bladder, and blood vessel perforation. In some cases, vaginal scarring and erosion led to decreased quality of life.

Because of the concerns noted above, I believe it is essential to review the proper technique that is involved with synthetic mesh placement for pelvic floor prolapse.

I have asked Dr. Robert M. Rogers to author this Master Class in Gynecologic Surgery. Dr. Rogers currently is in private practice in Kalispell, Mont. Committed to teaching, he serves as the chairman of the education committee of the Society of Gynecologic Surgeons. Not only is Dr. Rogers well known for his surgical prowess, especially in pelvic floor prolapse, but he also has lectured and written extensively on pelvic floor anatomy.

This Master Class will be a lesson not only in pelvic prolapse surgery, but in pelvic anatomy as well. ■

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Pelvic Organ Prolapse Repair With Prolift

BY ROBERT M. ROGERS, M.D.

About one of every nine women in the United States will have surgery for a vaginal support defect (pelvic organ prolapse). Our armamentarium of surgical options for helping these patients now includes improved mesh designs and new synthetic mesh kits for transvaginal repair.

The development of synthetic mesh is important, as we have learned over the years that some women have visceral connective tissues (the connective tissues that support the vagina, bladder, and rectum) that are not strong enough to maintain a conventional surgical repair. We have learned, moreover, that surgical repairs utilizing the patient's native tissue too often do not last: Failure rates of 20%-50% have been reported.

Although it's still unclear what constitutes the "perfect mesh," we have found that the use of a permanent, loosely woven polypropylene mesh can improve our operative results and significantly decrease the failure rates of our reparative vaginal surgery in women with vaginal support defects.

The failure of previous conventional reparative surgery for vaginal support defects is a clear indication for mesh. I operate on many patients who have recurrences of prolapse, and most of the time I use a permanent polypropylene mesh. For almost 4 years, I have been using the transvaginal Prolift systems for anterior, posterior, and total pelvic floor repair; other gynecologic surgeons favor different mesh kits that are currently available.

In October 2008, the Food and Drug Administration issued a Public Health Notification saying that it had received over 1,000 reports from surgical mesh manufacturers of complications associated with mesh devices that are used to repair pelvic organ prolapse and stress urinary incontinence. The warning lists the most frequent complications, such as erosion through vaginal epithelium, infection, pain, and urinary problems. However, the warning does not report which meshes were used—some meshes have been taken off the market—or provide a denominator of the number of total mesh placements.

The warning serves as a reminder of what gynecologic surgeons have advocated thus far: the need for significant experience in reparative vaginal surgery before using mesh implants. It is only in the last 10-15 years that gynecologic surgeons have acquired a detailed understanding of vaginal support anatomy, and of what happens to that anatomy to cause vaginal support defects.

To use mesh kits, the physician must both understand this anatomy and the variability in patients' connective tissues, and have experience in dissection techniques and the safe development of the proper dissection planes between the bladder and vagina, between the rectum and vagina, at the vaginal apex, and in the paravaginal and pararectal areas.

We must be able to dissect without causing undue bleeding or injury, and we must know how to minimize the exposure or erosion of mesh, which is usually through the vaginal wall. (Erosion of the mesh into the bladder or rectum is very rare.) Fortunately, we have access in the postgraduate arena to human cadaver courses that can give us valuable experience.

I have had very few complications in using mesh kits for pelvic floor repair, but I always tell patients that they have a 5% risk of infection, rejection of the mesh, or erosion or exposure of the mesh, as well as a 5%-10% chance of developing dyspareunia. I inform them, of course, that implantation of the mesh is permanent. And I always ask the patient to work with me in diagnosing or resolving any problem, complication, or unexpected outcome if it occurs.

Preparing for the Procedure

I use permanent polypropylene mesh for patients who have a recurring, symptomatic vaginal support defect. Even after the vagina is estrogenized, the vaginal wall in these patients is smooth and lacks the transverse ripples that are indicative, theoretically, of healthy connective tissue that could itself be used for repair.

The Prolift system that I use comprises precut nonabsorbable mesh implants (different precut implants for anterior, posterior, and total repairs) and a set of instruments (anatomical guides and retrieval devices with cannulas) to facilitate mesh placement.

The patient is placed in the dorsal lithotomy position, with her thighs at about 80 degrees to horizontal. She is not overly abducted, and her sacrum is well padded. I recommend using boot-type stirrups. A Foley catheter is inserted.

At 1 hour before anesthesia is administered, I give the patient a dose of prophylactic antibiotic. So far, I have not seen infection from mesh in any of the hundreds of Prolift procedures I've performed.

Anterior Prolapse Repair

The use of anatomical landmarks is critical to the mastery of dissection techniques.

For repair of an anterior vaginal prolapse (a cystocele), the two most important landmarks are the ischial spine and the junction of the inferior pubic ramus with the body of the pubic bone. This is because the "white line" of para-vaginal support goes from one of these points to the other. The anatomical orientation of the anterior vaginal wall must also be delineated. Overlying the lower third is the urethra, and overlying the middle third is the trigone of the bladder, an area of significant innervation. Overlying the upper third of the anterior vaginal wall is the bladder itself. The ureters travel across this upper third from lateral to medial, entering the bladder at the junction of the middle third and the upper third of the vagina.

A 3-cm anterior colpotomy incision is made in the upper third of the vagina. We stay away from the middle of the anterior vaginal wall so that innervation to the bladder is not disrupted, and so that the area underneath the urethra remains fresh for placement of a midurethral transvaginal tape, if needed.

The incision to the anterior vaginal wall should be a full-thickness incision that leaves the white, shiny pubocervical fascia on the back of the vaginal epithelium. Once you pass through this fascia, you are in the true vesicovaginal space, and the visceral fascia that surrounds the bladder can be seen.

A curved Mayo scissors, or your finger, can then be used to gently develop the lateral space between the bladder and the vaginal epithelium. There should be minimal bleeding. (If there is more than minimal bleeding, you're either in the wrong dissection plane or you're encountering significant scar tissue from your patient's previous surgery.)

Your goal is to work laterally, so that you can actually feel the tough parietal fascia that covers the obturator muscles.

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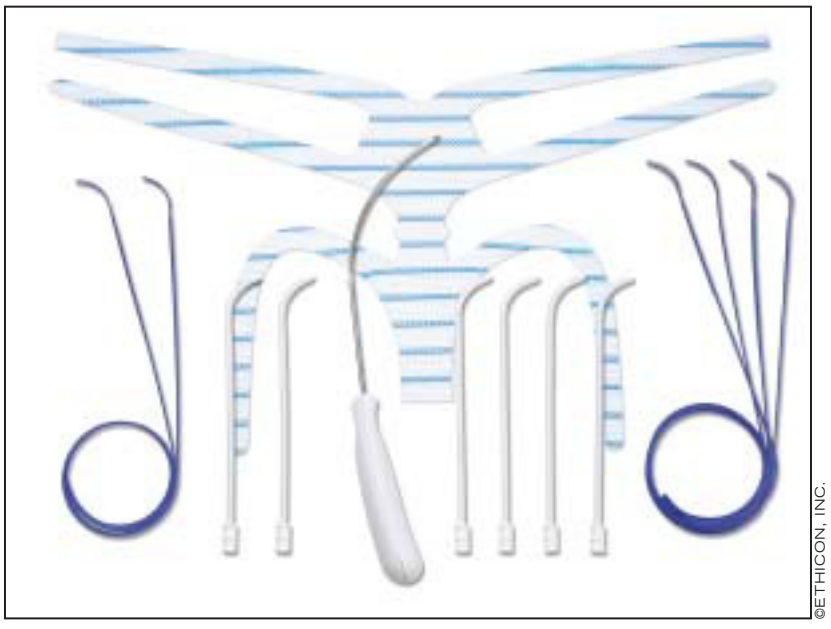

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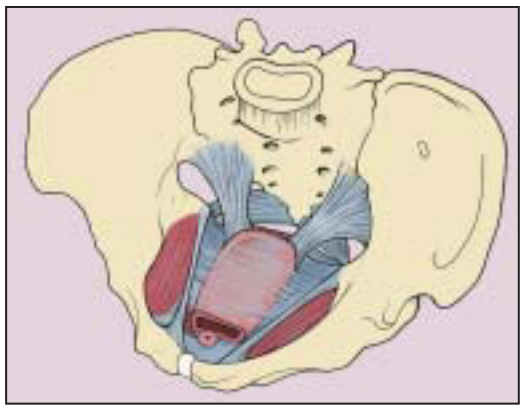
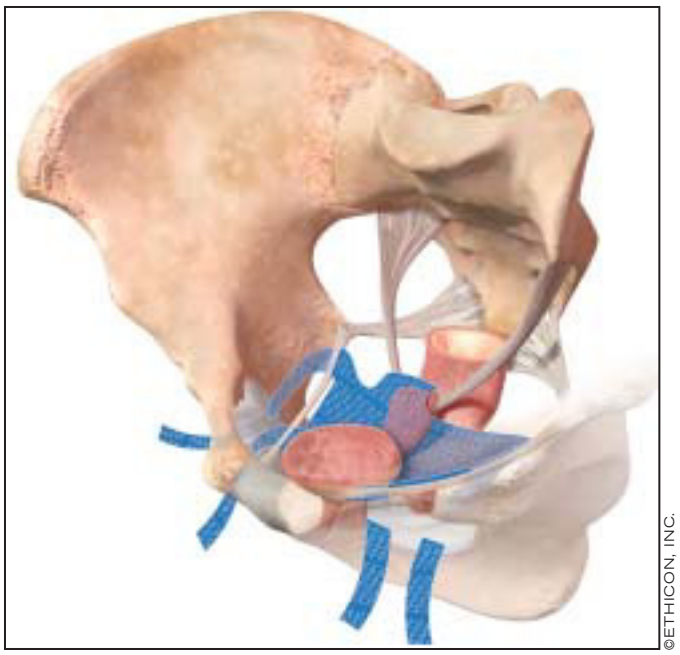
The Prolift mesh kit contains loosely woven polypropylene mesh, cannulas, a metal guide, and blue retrieval devices.



Vaginal support anatomy: The pubocervical fascia is fused with the anterior vaginal wall and attached to each uterosacral ligament. The bladder passively rests on this "hammock."



The mesh is placed in the vesicovaginal space and the arms are anchored through the obturator membranes.

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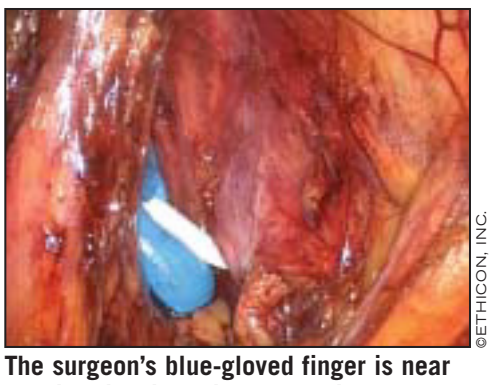
When you feel the junction of the inferior pubic ramus with the body of the pubic bone—one of the two most important landmarks—you then can slide your finger along the obturator internus fascia right down to the ischial spine. That distance is only about 5-6 cm. By doing so on both sides, the bladder is mobilized away from the anterior vaginal epithelium, and the bladder and ureters are mobilized away from the pelvic side walls. Again, there should be minimal blood loss (no more than 50 cc).

The cannula-equipped curved metal guides must then be passed through the inner thighs. A first incision (no more than 5 mm) is made at the level of the urethra, about 1 cm lateral to the inferior pubic ramus, which you can palpate through the skin of the thigh. This is for the anteromedial, or superficial, passage. The second incision (of the same size) is made at 1 cm lateral and 2 cm posterior to the first mark. This is for the posterolateral, or deep, passage. I always work through the deep passage first. With its tip perpendicular to the skin, I push the cannula-equipped guide straight in until I feel the tip pop through the fascia lata. I then bring the handle of the guide up, so that the directional force is parallel to the fascial white line.

The goal in this deep passage is to pass the guide through the posterior aspect of the obturator membrane and through the obturator internus muscle so that the tip of the cannula is about 1 cm inferior (and a bit anterior) to the ischial spine as it pops through the muscle into the paravaginal space. My finger waits there to feel the tip pass through the fascia of the obturator internus muscle. I then feed a small dull curette into the paravaginal space with my finger and slip it over the cannula, and my assistant carefully removes the guide.



The surgeon's blue-gloved finger is near the right ischial spine; the white cannula traverses the obturator internus muscle.

The retrieval device—a piece of long plastic tubing, in essence, with a loop at the end—can then be passed through the cannula. When I feel the loop come through, I entrap it against the end of the curette and pull both the loop and the retrieval device out of the vagina. (Some surgeons hook the loop with a finger, but I find the curette helpful.)

The superficial passage involves the same maneuvers, except this time I'm looking for the junction of the inferior pubic ramus with the body of the pubic bone. With my finger in the paravaginal space, I dissect any intervening tissue away from the fascia of the obturator internus muscle at this junction. I also ensure that the bladder is mobilized away from the central portion of the anterior vaginal epithelium, so that the proximal portion of the mesh—an apical flap—can be attached to the apex of the vagina. (This apical flap also helps repair the anterior enterocele that usually exists with the cystocele.)

When the dissection is complete, I have two cannulas in place on each side, each holding a retrieval device. To attach the mesh, I first place a delayed absorbable suture into the vesicovaginal space through the apex of the vagina, and attach the apical portion of the mesh onto the suture.

I then place each posterolateral, or deep, arm of the mesh by passing about 1 cm of the end of the arm through the loop of the retrieval device, and then pulling the loop back through the cannula. During these maneuvers, we must be sure that no tissue becomes caught in the mesh or the retrieval device loop. The superficial arms of the mesh are then similarly placed.

At this point, I remove the Foley catheter, inject about 300 cc of sterile water into the bladder, and use a 70-degree cystoscope to look through the urethra and into the bladder to confirm the absence of any mesh, perforation, or other injury to the bladder. I also check the functioning of the ureters, and check for any pathology in the bladder. I then empty the bladder and reinsert the Foley catheter before proceeding to finish the mesh placement.

The key to successful mesh placement—and a reduced risk of mesh erosion—lies in placing the mesh loosely in the vesicovaginal space.

I try to ensure loose placement by lifting up the mesh as I'm removing the cannula so that I can feel the back of the pubic bone. During cannula removal, you can also ensure that the edge of the mesh is at least one finger's breadth away from the pelvic side wall.

Loose placement of the mesh is necessary because the mesh–scar tissue complex that forms will shrink by about 25%-30%. If the mesh is too tight, the risk of erosion and exposure of that mesh to the anterior vaginal wall will rise significantly. It may even appear (if you look into the vagina at the end of the procedure) as if the patient still has a first- or second-degree cystocele. This is fine. Your goal is to have an anterior vaginal wall that is well supported but not straight and tight.

I close the incisions using a running, interlocking Vicryl stitch. I also use vaginal packing for 24 hours, and I send the patient home after the packing and Foley catheter are removed.

The vaginal packing is another key feature of this procedure, as it helps to prevent hematoma formation, which can lead to mesh erosion. It also facilitates the adherence of the mesh to the back of the vaginal epithelium. From my experience, 24 hours is all that is needed.

Most of my patients have reported pain levels of about 3 out of 10, and some are fine with an NSAID. Some are given ketorolac (Toradol) for several days, and others who have more severe pain may be given a conventional narcotic. Patients are seen in the office 2 weeks later and are counseled to call earlier in the case of a high fever, increased vaginal bleeding other than spotting, or significant pain.

Some physicians send patients home with instructions to use vaginal dilators on a daily basis in order to keep the mesh as pliable as possible as it integrates into the scar tissue that forms, but we don't have any studies on the effects of such a recommendation.

Posterior Prolapse Repair

If you are looking at the posterior vaginal wall, the lower third of the vagina overlies the perineal body, and the upper two-thirds overlie the rectum. A full-thickness incision is made either vertically in the middle third of the posterior vaginal wall or transversely through the vaginal epithelium at the junction of the middle-third and lower-third of the vagina.

Using curved Mayo scissors or my finger, I mobilize the rectum away from the vaginal epithelium. I then slide my finger laterally until I feel the iliococcygeus muscle, at which point I gently dissect down until I feel the ischial spine. Any filmy tissue on the sacrospinous ligament should be wiped away medially from the ischial spine at this point.

I also mobilize the rectum away from the underside of the posterior vaginal wall to allow access to the apex of the vagina. Just as with the anterior surgery, all of this dissection should involve minimal blood loss (no more than 50 cc).

The 5-mm incisions for passage of the cannula-equipped guides are made through the skin of the buttocks at 3 cm lateral and 3 cm posterior to the anus. I like to have the patient's back parallel to the floor and to lower the table accordingly so the cannula-equipped guide can be pushed straight in and the tip advanced toward the underside of the sacrospinous ligament.

Again, anatomical landmarks provide significant guidance. As I push the cannula-equipped guide through the ischioanal fossa with one hand, my nondominant finger is on the ischial spine waiting to feel the tip. (If the tip cannot be felt, you can stop and drop the handle of the guide, which will bring the tip up to where it can be felt through the levator ani muscle.)

The goal is to bring the tip of the guide up through the sacrospinous ligament into the dissected rectovaginal space. We want to be sure the tip is at least 2 cm medial to the ischial spine and 1 cm above the lower edge of the sacrospinous ligament. This keeps us far enough away from the pudendal nerve and the internal pudendal artery and vein that travel right underneath the ischial spine along the side wall of the pelvis, and away from the interior gluteal artery nerve and vein that travel near the upper edge of the sacrospinous ligament.

The posterior mesh is positioned by using techniques similar to those of an anterior repair. Again, I find that a dull curette is helpful for capturing the retrieval device.

After the mesh arms are placed, I examine the rectum to make sure there isn't any mesh perforating into the rectum or injury to the rectum. And just as with the anterior repair, the mesh must be placed loosely in the rectovaginal space to minimize erosion.

I often trim a bit of the mesh at the distal end and then place that end in the rectovaginal space to ensure its proximity to the apex of the perineal body. Again, I close the incision with a running interlocking stitch and use vaginal packing for 24 hours. I also often perform a perineorrhaphy to repair the perineal body and help with vaginal support.

When I first started using the Prolift transvaginal mesh kits, my erosion rate (when the mesh could be seen or felt through the vagina) was about 4%. Now, it is about 1%.. ■

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