ROUNDTABLE >> PART 2 OF 2

Using mesh to repair prolapse: Averting, managing complications

Some complications arise from faulty technique. A few may be caused by mesh itself. The expert panel differentiates those two sources of surgical problems.

Mickey M. Karram, MD

MODERATOR

Vincent Lucente, MD, MBA Shlomo Raz, MD Mark D. Walters, MD

- Dr. Karram receives research support from Ethicon Women's Health and Urology, Allergan, and Biosante and is a consultant and speaker for Astellas, Ethicon Women's Health and Urology, and CooperSurgical. He has a financial interest in Emedsco.
- Dr. Lucente receives grant or research support from and consults for Ethicon, AMS, and Bard and is a speaker for Ethicon and Bard.
- Dr. Raz reports no financial relationships relevant to this article.
- Dr. Walters is a consultant and speaker for AMS and Boston Scientific.

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What's your experience using mesh to repair prolapse? Tell us: E-MAIL obg@dowdenhealth.com FAX 201-391-2778 aginal placement of mesh for the correction of pelvic organ prolapse is not an entirely benign procedure, As Mickey M. Karram, MD, and an expert panel discuss in this article—the second of a two-part series—complications secondary to mesh placement can be a challenge to correct and often make life miserable for patients who experience them. Here, these experts address mesh erosion, extrusion, and other serious complications; discuss ways to prevent them; and offer strategies for managing them when they arise.

In Part 1, which appeared in the January 2009 issue of OBG Management, the panel discussed the increasing use of mesh in prolapse repair—in particular, the proliferation of mesh kits.

How common is erosion?

DR. KARRAM: The literature seems to indicate that, even in the best of hands, there is an extrusion, or erosion, rate of between 5% and 17% when mesh is used. Would you agree with this statistic?

DR. LUCENTE: Not completely. The vaginal exposure rate can be as low as 2%, as reported by our center and others, when the mesh is properly placed below all histologic layers of the vaginal wall, as it is when it is "delivered" to the pelvis via the transabdominal route. 1,2

At the other end of the scale, an exposure rate above 17% has been reported when mesh is improperly placed within the vaginal wall—that is, just below the mucosa, as some surgeons have described in the methodology section of their abstract or article.^{3,4}

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THE OBG MANAGEMENT EXPERT PANEL



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We have found that complete, full-thickness dissection of the vaginal wall into the true pelvic space (vesicovaginal and rectovaginal), utilizing small vaginal incisions and limiting hysterectomy and the trimming of vaginal mucosa, can promote a very low vaginal-exposure rate.

DR. WALTERS: Some surgeons tell me that their own extrusion or erosion rate is lower than the published rate of 5% to 17%, but it is impossible to be certain of the long-term outcome in any patient unless she is followed carefully. The patient may consult another physician about her complications. The primary surgeon-even an expert-often does not know the actual mesh complication rate.

That said, I am sure that some surgeons are particularly adept at using mesh kits for prolapse repair, thereby keeping their mesh complication rate low. The 5% to 17% number is what most gynecologic surgeons should expect for their patients.

DR. RAZ: The complication rates are clearly underreported since very few centers of excellence report on complications and the majority of users don't report them. Also, the reported complication rate concerns shortterm erosion. I imagine that, as time passes and vaginal tissue becomes more atrophic, the incidence of erosion will increase.

Are simple measures enough to resolve erosion?

DR. KARRAM: There seems to be a general perception that most extrusions or erosions can be easily managed in the office by placing estrogen or trimming. In our experience, that approach has been successful in a minority of cases only.

What have you seen?

DR. WALTERS: At the Cleveland Clinic, as at most tertiary care referral centers, we often see the worst cases of extrusion or erosion related to mesh. Estrogen helps in some cases of simple mesh exposure, especially after sacrocolpopexy. If estrogen is going to be effective, however, the problem should clear up relatively quickly; if it isn't effective after a month or two of therapy, estrogen is unlikely to ever be successful.

When it comes to related problems, such as ridges or strictures in the vagina, dyspareunia, penile pain with insertion, and vaginal burning pain, I have not found simple trimming and estrogen to be effective.

DR. KARRAM: It's also unlikely that simple excision or placement of estrogen will be successful over the long term. When an extrusion or erosion occurs, we are generally seeing only the tip of the iceberg. That's because mesh is placed in a certain plane. Although only part of the mesh may be exposed, the entire mesh is likely to be affected because it lies in the same plane.

Also, because of the special nature of vaginal flora, it is unlikely that a foreign body is going to be successfully managed by simple excision or placement of estrogen.

DR. LUCENTE: Management of vaginal exposure really depends on the size of the exposure, its location, and whether there is

"It is impossible to be certain of the long-term outcome in any patient unless she is followed carefully"

MARK D. WALTERS, MD

underlying infection or ischemia of host tissue. When the exposure is small (<1 cm in diameter) and in the midline, with the mesh lying flat below the plane of the vaginal wall, we have been very successful using a conservative approach.

However, even the tiniest of exposures needs to be surgically excised if it traverses the vaginal sulcus. Obviously, any mesh erosion into viscera such as the bladder and bowel also requires surgical intervention. Host-tissue factors always play a contributing role.

I also want to point out that the manner in which exposure is managed depends to some extent on whether the mesh was properly placed. Exposures that arise when mesh is implanted improperly are difficult to correct and usually require complete removal.

Although we, too, started off with an exposure rate around 8%, it is now very low, thanks to technical advancements.

DR. RAZ: A very small vaginal erosion of a mesh sling can sometimes be managed in the office by excision. The cases referred to our service generally involve more extensive areas of exposure that will not be resolved by local treatment.

Is risk of injury operatordependent?

DR. KARRAM: We're all seeing very severe complications secondary to mesh placement. Would each of you give your opinion as to whether the severe complications such as significant pain, dyspareunia, and injury of important structures are mostly technical or inherent to mesh placement. Would they happen in the best of hands?

DR. LUCENTE: The more severe complications, for the most part, are very much related to technique. Not that they cannot happen in the very best of hands, but they are extremely rare when technique is meticulous.

Over a 4-year period, after well over 1,000 transvaginal mesh surgeries at our center, we had no death, ICU admission, or transfusion, and our intraoperative complication rate was only 3%, most commonly involving

simple cystotomy without long-term consequence. This compares very favorably to the nearly 12% complication rate reported recently in the CARE trial for abdominal sacral colpopexy.⁵

Our primary challenge today is preventing postoperative dyspareunia. Our rate of new-onset dyspareunia is approximately 3.5%. This complication is, I think, more likely to be related to the inherent material properties of mesh, such as elasticity and flexural rigidity, and to host-tissue response to the material itself.

DR. RAZ: I think that the majority of complications are operator-dependent. Thin dissection of the vaginal wall and unrecognized bladder, urethral, and vaginal perforation are the most common reasons for the complications. Mesh does not move after surgery; if there is a problem, it means that the mesh was misplaced.

Another problem is that industry, in an effort to sell more kits, is pushing physicians who are unfamiliar with the principles of pelvic reconstruction to perform this complex procedure. Repair of major vaginal prolapse is not a simple sling procedure.

In addition, there is a greater likelihood of complications in patients who have severe atrophic tissues. These patients should not be candidates for mesh reconstruction.

DR. WALTERS: Many of the complications that we see with mesh are certainly operator-dependent. For example, mesh that is placed under too much tension leaves the vagina tight and stiff, and mesh that is placed with ripples and ridges causes irregularities in the vagina that are often painful, especially during intercourse.

I do not believe that mesh "erodes" into the bladder, urethra, or rectum, but that it is placed there inadvertently and overlooked intraoperatively (FIGURES 1 and 2, pages 25 and 26). Visceral erosion can occur if the primary surgeon made a cystotomy or proctotomy before proceeding with the mesh kit, and the mesh eventually wore through the repaired area.

There are also some problems that are inherent to mesh, and that occur even in the

"Repair of major vaginal prolapse is not a simple sling procedure"

SHLOMO RAZ, MD



FIGURE 1 When mesh "erodes" into the urethra





Two images of mesh in the urethra. There is some uncertainty here whether mesh that has penetrated the urethra eroded through vaginal tissue or was placed there inadvertently and overlooked intraoperatively.

best hands and after surgeries that are performed very competently. Some mesh exposures are inevitable, as are some cases of dyspareunia and rare cases of vaginal burning and pain. In addition, I am seeing more de novo SUI [stress urinary incontinence] with anterior mesh kits. Although this is not really a complication, it does lead to dissatisfaction in patients and merits efforts to prevent it.

DR. KARRAM: Yes. With the current state of mesh, I believe pain and dyspareunia are almost inevitable in some cases.

DR. LUCENTE: Another problem that is currently underaddressed is scar plating along the surface of the mesh. Such plating forms more readily in the absence of mechanical movement or distention during the early stages of wound healing. To make a comparison, even the best reconstructive orthopedic surgeons cannot achieve optimal functional outcomes with an implant surgery without intense postoperative physical therapy, which may simply involve range of motion or movement.

Most everyone is familiar with the capsular fibrosis and contraction that develop around a breast implant if there isn't immediate postoperative massaging of the breast tissue and implant during wound repair. I am confident that the rate of dyspareunia will decline over time if specialists in reconstructive pelvic surgery pay closer attention to optimizing vaginal length, preserving the cervix (in women with relatively shorter vaginal length), and ensuring optimal apical attachment (that is, above the ischial spine) in younger, sexually active patients.

DR. RAZ: I think it is the surgeon rather than the surgery who causes most complications. In its effort to sell kits, industry sometimes puts them in the hands of surgeons who are not well prepared for the task. This operation can be quite complex, and you cannot create a pelvic surgeon from a physician who is unfamiliar with the anatomy. If you cannot manage the potential complications, you should not perform this type of surgery.

Should mesh be removed at the time of injury?

DR. KARRAM: As we discuss specific complications, let's start with the most severe, which I would say relate to the inadvertent placement of mesh through important structures "I am confident that the rate of dyspareunia will decline if we pay closer attention to optimizing vaginal length, preserving the cervix, and ensuring optimal apical attachment"

VINCENT LUCENTE, MD, MBA



FIGURE 2 Mesh in the bladder



A segment of tension-free vaginal tape has penetrated into the bladder.

PHOTO: MARK D. WALTERS, MD

such as bowel, bladder, or ureters. If this were to happen and be diagnosed intraoperatively, what would you recommend that the surgeon do—abort the procedure or simply remove the mesh or trocar and attempt to pass it again safely?

DR. LUCENTE: That is a difficult question to answer because so much depends on various intraoperative factors.

I am much more comfortable proceeding with surgery after intraoperative bladder injury than after bowel or rectal injury. We have successfully corrected cystotomies that were small, did not encroach on the ureter, and were easily repaired without tension—and we have seen no fistula formation as a result.

The key is to maintain a high index of suspicion throughout the procedure. We have always diagnosed injuries before mesh is delivered—either during dissection or during passage of the needle or trocar. We have not experienced any ureteral injuries aside from "kinking" of one ureter, which was easily corrected with simple readjustment of the mesh.

If, at any time, we were concerned about potential infection, fistula, or a more severe complication that would be aggravated by proceeding with the operation, we would abort the procedure. However, we would be likely to proceed with an alternative operation to address the pelvic-support defect so that the patient would not awaken with in-

traoperative injury and no surgical treatment for her primary complaint.

We conduct informed consent in such a way as to preserve our flexibility to adapt the surgical plan to execute the reparative work that is necessary despite the development of a non-life-threatening complication during surgery. In the event of any injury to the bowel that would involve gross spillage of fecal material, of course, I would abort placement of synthetic mesh.

DR. WALTERS: If I placed one of the trocars through the bladder or bowel, I would probably remove it, reposition it, and continue with the surgery. With bladder perforation, this approach is generally no problem, but I would usually leave a Foley catheter in place for 1 week of continuous bladder drainage.

If I placed the trocar through the rectum, I would probably oversew the proctotomy, irrigate the space, and continue with the mesh repair. If I had an outright laceration in the bladder or rectum as part of the dissection, I would repair it and consider converting the surgery to prolapse repair without mesh.

The most dreaded complication: the foreshortened vagina

DR. KARRAM: It would seem that the most difficult complication to deal with is the foreshortened, firm, painful vagina. A patient who has these problems may be perceived, at times, as a pelvic "cripple." Is this an accepted, albeit rare, complication? Or can it be avoided?

DR. LUCENTE: This is the most feared complication arising from the use of synthetic mesh. I do believe it can almost always be avoided—but I never say never. The key is to pay full attention to considerations of vaginal length before surgery, including, first, preservation of the cervix, and, second, placing the mesh loosely, properly sized, and attached with optimization of apical support to preserve vaginal length.

I also believe that use of second-generation meshes that are lighter, more elastic, and more flexible helps reduce this complication when the mesh is properly placed by a surgeon well trained in the technique.

When the vagina is foreshortened, the sooner it is revised, the better the chance that

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"I do believe a foreshortened vagina can almost always be avoided but I never say never"

VINCENT LUCENTE, MD, MBA pain will resolve, whether the mesh is removed or released.

DR. RAZ: Mesh infection, capsular formation, dissection of a thin vaginal wall, and excess vaginal-wall excision lead to the short, firm, and painful vagina. The use and abuse of mesh has created a new subspecialty to manage mesh complications. The PFS syndrome (painful, firm, and short vagina) is one of the most difficult complications to treat because, in many cases, it cannot be reversed without major surgery.

DR. WALTERS: Women who have a foreshortened, firm, or painful vagina after mesh augmentation almost always need to have the mesh removed with reconstruction of the vaginal canal. I have never seen a successful outcome in this type of patient without complete or near-complete removal of the mesh. **©**

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