

Augmenting pelvic floor repairs

NEW MATERIALS AND TECHNIQUES

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The use of mesh or grafts to augment surgical repairs is an established technique in many settings. In gynecologic surgery, mesh or grafts help correct paravaginal anterior or posterior compartment defects in patients for whom traditional prolapse repair techniques are inadequate or in patients who are recurrent or complicated cases. Traditional anterior repairs have been marked by failure rates between 25% and 52%.¹⁻⁴

Mesh or graft augmentation corrects both central and site-specific defects and restores correct anatomic support. It may provide additional stability to traditional repair, decreasing recurrence and the need for future procedures. Graft and mesh materials are readily available, but clinicians should be well informed as to the characteristics, safety profile, and clinical outcomes associated with their materials of choice. A "trocar-free" technique, the focus of this publication, minimizes the potential for bowel and vascular injuries associated with blind needle insertion. Thus, the risk for perforation of the gluteal, levator ani, or obturator muscles is avoided. The mesh augmentation procedures themselves are performed quickly and easily through the same incision utilized for traditional colporrhaphy. They may reduce operating-room time or add no more than 10 to 20 minutes to procedures.

Disadvantages include the introduction of foreign material and the potential for complications, such as erosion. Costs are increased as well. While long-term data currently are being collected, short-term results are marked by encouraging rates of success.

This monograph will review currently available materials, surgical technique, preliminary outcomes of clinical trials, and physician preferences.

As surgeons, we need to remember that prolapse results not from failure of the pelvic organs themselves but rather from defects in the vaginal connective tissues and ligaments that support the bladder, rectum, or bowel.

In the anterior compartment, displacement of these organs may occur through distension injuries, such as a central cystocele with attenuation of the midline connective tissues that still remain attached to their fixed side-wall attachment points. Also possible are detachment injuries, such as a paravaginal defect in the anterior compartment, whereby vaginal connective tissues avulse from fixed anchoring points. Some patients can have a combination of both injuries. Displacement or distension injuries may also result from tears in posterior or apical connective tissue structures.

■ **When should augmentation be considered?**

Mesh or graft repairs are not substitutes for traditional colporrhaphy, which depends on adequate tissue for a strong repair. Instead, these techniques replace existing (and typically insufficient) tissue with a stronger material. These repairs are appropriate for patients:

- for whom previous reconstructive surgery has failed; the risk of needing reoperation for recurrent prolapse is 29.2%.¹
- in whom dissection reveals inadequate tissue
- who are elderly and benefit from speedy procedures, which may result from the use of graft/mesh repairs
- who are young and with significant prolapse, suggesting congenital collagen deficiency
- with risk factors for recurrence (obesity, chronic cough, constipation, or Valsalva, or occupational risk factors associated with straining and heavy lifting)

Failures of traditional approaches often are associated with suturing of poor tissue to poor tissue (a fundamentally flawed concept), insufficient support by the levator plate and weak attachments to the pelvic side wall and apex, and the composition of tissues in the anterior compartment (less dense and more elastic). A recent review of the literature and gross/microscopic evaluation of full-thickness bladder and vaginal-wall specimens revealed a complex support structure that maintains the position of important structures.²

■ **Identifying anatomic landmarks for correct graft/mesh placement**

Correct placement of mesh/graft materials depends on accurate identification of anatomic points for suture attachment. Bony structures serve as landmarks and guide the surgeon to the connective tissue and muscles that are the specific repair sites. These landmarks are consistent in every patient, regardless of the soft tissue structure.

Anterior compartment repairs

For cystocele repair, the essential bony landmarks are the sacral promontory, ischial spine, and pubic tubercle. These bones provide a reliable reference to the muscles/ligaments that splay out to each side and which serve as attachment points to anchor grafts. All structures are accessible vaginally.

The sacrospinous ligament (important for apical suspension and for cystocele or rectocele repair) stretches from the ischial spine back to the sacrum. It is located at the front of the coccygeus muscle.

The arcus tendineus fascia pelvis, also known as the white line, is a connective tissue remnant lying on the obturator internus muscle and extends from the ischial spine to the pubic tubercle.

The iliococcygeus muscle lies medial to the arcus tendineus and is a “shelf-like” levator muscle that is utilized for posterior graft augmentation and also as a substitute for the sacrospinous ligament during repair of vaginal vault prolapse.

Posterior compartment repairs

Rectocele repair focuses on repair of the connective tissue layer that separates the rectum from the vaginal epithelium. Essential anatomic boundaries are the vaginal apex (proximal), the superior fascia of the levator ani (lateral), and the perineal body (distal). Unlike anterior compartment repairs, standard posterior colporrhaphy is associated with relatively high success rates, even for large rectoceles, but may be associated with dyspareunia due to levator plication. However, graft/mesh augmented repairs may be of benefit when the tissue layer is insufficient to reunite the fascial edge with its apical attachment or when individuals have had failed surgical repairs. In this type of repair, a rectangular graft is extended from the level of the ischial spine to the perineal body, anchoring laterally to the levator (iliococcygeus) muscle surface. As with the anterior compartment grafts, use of the Capiro® Ligature Carrier (Boston Scientific

Corporation, Natick, Mass) posteriorly allows for fixation rather than perforation of the levator ani muscle and apical fixation point. Apically, the graft is sutured either into the sacrospinous muscle or just distal and lateral to the spine into the iliococcygeus.

■ Practical pearls for performing graft/mesh augmentation

Surgeons who are competently trained in anterior compartment repairs have most of the skills needed to perform mesh/graft augmentation. The procedure requires a standard colporrhaphy incision, palpation of bony landmarks to locate the muscles, use of a device to place sutures, and graft materials. Patients presenting with a grade 3 or 4 prolapse, those with a history of previous surgical failure, or those with risk factors for recurrence are the typical patients selected for possible graft augmentation.

Dissection. The gentle dissection from the pubic tubercle to the ischial spine differs slightly from traditional approaches used for colporrhaphy: the dissection is made 1 cm to 2 cm lateral to the normal cystocele dissection. With blunt dissection, the obturator internus muscle (and in many cases, the overlying arcus tendineus) can be felt, just lateral to the descending pubic ramus on each side.

During fascial dissection, most surgeons are taught to keep the fascia on the bladder side (ie, make the vaginal flaps thinner). Now that surgeons use the mesh to replace the fascia, it is important to place a thicker layer of epithelial and connective tissue over the mesh to avoid erosion.

Palpation. The operator then locates the bony landmarks by tracing a line between the pubic tubercle and ischial spine. If direct visualization is desired, Breisky-Navratil retractors are well suited for exposing the arcus tendineus, coccygeus muscle, and sacrospinous ligament without obstructing the surgical field. Some surgeons use retractors or suction devices mounted with a fiberoptic light source to identify the retropubic anatomy. However, the Capiro suture device allows accurate suture placement by palpation, minimizing the need for extensive dissection or retractor use.

Device selection for suture placement. Various tools can be used for suture placement, including the Deschamps ligature carrier, Miya Hook™ (CooperSurgical, Inc, Trumbull, Conn), and Capiro device. Some surgeons also use a standard long

FIGURE 1

The Capiro® Ligature Device



The long narrow tool catches and passes sutures easily, allowing deep suture throws without excessive dissection.

curved needle holder. The Capiro is ideal for suturing into the sacrospinous ligament (via cystocele or rectocele repair), the arcus tendineus, obturator internus, or iliococcygeus. The long, narrow tool catches and passes the sutures easily, allowing deep suture throws without excessive dissection (**FIGURE 1**). It allows for placement of sutures based on direct visualization or palpation and provides a consistent depth of suture placement. Importantly, the device permits fixation—not perforation—of the suture into musculature and can be used to place both apical and basal stitches; basal stitches may also be placed free-form.

Suture placement. The first sutures are placed at the apex; with the Capiro, a 30-to-45° angle between the needle catch and the ligament provides adequate suture fixation. Additionally, as the ligament lies within the muscle, sutures should not be placed around the sacrospinous ligament. Instead, sutures should be placed into the front side of the coccygeus muscle and sacrospinous ligament to avoid pudendal or major vascular injury.

Mesh characteristics. The nuances of mesh/graft size and specific placement will be described subsequently with respect to various available meshes. In all procedures, however, it is important that the mesh be adjusted loosely (this varies with the type of mesh/graft) and with

TABLE 1

Repair With Synthetic Mesh

AUTHOR	N	MESH	COMPLICATIONS	RESULTS	FOLLOW-UP (mo)
Watson et al, 1996 ⁵	9	Polypropylene Transperineal	11% wound infection	Not stated	29
Dwyer and O'Reilly, 2004 ⁶	67	Polypropylene (Atrium)	12% erosion 1 RVF 2 dyspareunia	0%	24
Salvatore et al, 2002 ⁷	31	Prolene Plus Colpor.	13% erosion Dyspareunia 6 → 69%		
Mercer-Jones et al, 2004 ⁸	22	Prolene	3 infections 2 rectal perforations	75% improved	12

a minimum of folds. Overly tight attachments may result in patient pain and increased possibility of erosions.

Coding and reimbursement. In coding for graft and mesh repairs, surgeons may want to note that graft repairs can be coded for each incision; the use of 2 incisions permits coding for 2 repairs. A recently introduced current procedural terminology (CPT) code 57267 is used as an add-on code to reimburse surgeons for the added work/complexity associated with graft/mesh prolapse augmented repairs.

Follow-up to monitor for erosions. Evidence of erosions should be assessed at 2 weeks and 6 weeks after the procedure and at 6-month intervals for 2 years thereafter. If evidence of erosion is seen, prescription of an estrogen cream, office-based excision, and 6 weeks of pelvic rest generally are effective.

Materials for prolapse repair

Currently available materials include synthetic mesh, allografts, or xenografts. Long-term outcomes data are lacking, although a randomized, case-controlled clinical trial is in progress. At present, however, insufficient data exist regarding terms of functional outcomes and prevalence of dyspareunia. While the ideal material for repair of prolapse has not been identified, new products and refinement of surgical technique offer significant hope for future successes and may improve outcomes for patients.

Use of synthetics in pelvic repair

Bioengineered mesh materials are permanent and feature elasticity, flexibility, and tensile strength. Mesh is readily available and features a consistent manufacturing process, which offers reproducibility

with consistent strength and tissue response. Mesh typically allows tissue in-growth with resulting fixation and continued support. There is a low risk for infection transmission, but erosion can occur and patients with vaginal atrophy or thin vaginal walls, now or in the future, may be at increased risk. Historically, erosion rates as high as 13% have been reported.⁵⁻⁸ Some institutions, however, report erosion rates of less than 5% with a 20% reduction in recurrent prolapse (Kohli, personal communication). **(SEE ONE SURGEON'S TECHNIQUE: USE OF SYNTHETIC MATERIALS, PAGE 7)** The risk for erosion may be minimized by selection of the appropriate mesh material (soft, pliable, macropore meshes) and surgical technique (dissection, fixation, hemostasis, and vaginal packing). Additionally, a surgeon's technique—of ensuring that the mesh attachment is laced without tension—is important to prevent erosions and ensure good outcomes.

Currently available products feature pore sizes sufficient to allow tissue in-growth and to fight infection; therefore, the risk for breakdown of materials is eliminated. New materials offer increased thinness and allow sufficient stretch to accommodate the vagina as a dynamic organ that needs to expand during sexual activity. More rigid materials may not permit vaginal expansion and also may increase the risk for erosion as the vaginal wall thins during the menopause. The results of trials using various forms of mesh⁵⁻⁸ are shown in **TABLE 1**.

A new product, Polyform™ (Boston Scientific Corporation, Natick, Mass), **(FIGURE 2)** offers an important option for clinicians **(TABLE 2)**. It is characteristic of the technical advances in materials that are continually being made.

A recent pre-clinical review compared the in vivo repair processes of Polyform™ and Gynemesh® (GYNECARE WORLDWIDE, Somerville, NJ) in an animal model at 1, 3, 6, and 12 weeks. Collagen deposition and wound-healing properties and processes were evaluated.⁹ Neither product led to encapsulation. Wound healing was characterized by collagen deposition and tissue integration rather than fibrous capsule isolation. Both materials behaved similarly at all time points with respect to the inflammatory and wound-healing response and collagen-deposition characteristics.

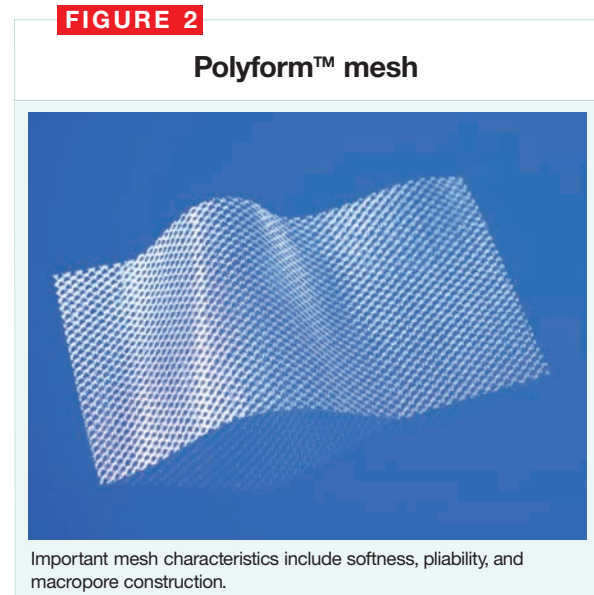
Physician-dependent factors also affect outcomes. These include musculofascial dissection, tension-free application, use of strong attachment points, minimization of folds, good hemostasis, absence of tension on the suture line, and vaginal packing.

Use of allografts in pelvic repair

Repairs using allograft materials avoid many of the problems associated with traditional repairs, including the use of trocars and the risk for muscle perforation. They also avoid the potential for stray mesh arms and thereby reduce the potential for erosion. (SEE ONE SURGEON'S TECHNIQUE: USE OF ALLOGRAFT MATERIALS, PAGE 7)

As is true with synthetic materials, allograft materials are marked by continual innovations in the marketplace. Allograft materials are composed of acellular cadaveric dermis, an extracellular matrix of connective tissue. Tissue is procured from the American Association of Tissue Banks. The graft allows the body to regenerate its own tissue onto the scaffolding provided by the matrix. The transition from graft to functional host tissue mirrors what we see in native tissue: A recent trial with Repliform® (LifeCell Corporation, Branchburg, NJ), demonstrated that, within 12 weeks, typically, graft material can no longer be distinguished from the patient's native skin borders. Histology confirmed robust, vital, and intact collagen with normal cell density at 12 months. Safety has been confirmed: in 12 years of clinical experience, more than 750,000 grafts have been performed, with no reported disease transmissions.¹⁰

Outcomes associated with colporrhaphy plus arcus-to-arcus graft (Repliform) versus colporrhaphy without graft were compared in 84 patients. In the resolution of grades 3 and 4 cystoceles, the results revealed that a 78% reduction of recurrence was associated with the use of graft materials at 12 weeks. Recurrence rates in patients who received grafts were 5% in patients vs



14% in those who received colporrhaphy alone. Equally, if not more important, not a single adverse outcome, erosion, graft exposure, or explant has been associated with the use of Repliform graft augmentation in our cohort to date. No patient reactions to the grafts were seen.¹¹ Currently, a prospective, randomized controlled trial of Repliform augmentation versus traditional colporrhaphy is being conducted at our center in Evanston, Illinois.

Other outcomes data from small short-term, uncontrolled studies demonstrate that posterior allograft repairs are safe and well tolerated and thus represent a promising alternative to colporrhaphy.^{12,13} Oster and colleagues reported a subjective success rate in all 15 patients treated with a dermal allograft; 13% of patients, however, experienced de novo dyspareunia. Kohli and Miklos¹⁴ reported that after site-specific repairs, a dermal allograft was associated with anatomic fixation and permanent sutures. For the 30 or 43 women available for follow-up, a 93% objective cure rate was reported.

Use of xenografts in pelvic repair

These products, harvested from porcine or bovine sources, provide minimal risk for erosion or rejection. The bovine model featured in Xenform™ (Boston Scientific Corporation, Natick, Mass), for example, consists of regenerative tissue matrix derived from a fetal cow that remodels easily into new, native tissues. It consists of a non-denatured, non-crosslinked collagen matrix scaf-

TABLE 2

Polyform™ vs Gynemesh®: Technical Comparison

Within key criteria, compared with Gynemesh PS Mesh, Polyform Mesh is:

- 40% softer (reduction in rigidity/stiffness)
- 55% thinner (reduction in thickness)
- 35% smoother (reduction in coefficient of friction)
- 20% lighter (reduction in basis weight)
- 3x greater stretch (blended reduction in force V displacement)

CHARACTERISTIC	POLYFORM MESH	GYNEMESH PS
Composition	Monofilament, Polypropylene	Monofilament, Polypropylene
Pore Size (microns)	Macroporous–1450	Macroporous–2500
Fiber Diameter (microns)	100	100
Basis Weight (g/m ²)	40	50
Thickness (microns)	205	457
Coefficient of Friction (μ ²)	.67	1.03
Flexural Rigidity/Stiffness (F _{max} N)	2.6	4.3
Ball Burst F _{max} (N)	263	280
Elongation Machine F _{max} (N)	4.0	20
Elongation Transverse F _{max} (N)	6.0	14
Size	10 cm x 15 cm	10 cm x 15 cm

Data on file. Boston Scientific Corporation.

fold. Because this product is not cross-linked, it likely retains important biologic information that aids in the regenerative process. The intrinsic collagen biologic information is not interrupted. The product, as do others in this class, offers biocompatibility as required under FDA guidelines to ensure biocompatibility with the host.

Xenograft materials are processed with effective viral and prion inactivation steps, eliminating the risk for bovine disease transmission. They are available in a wide range of sizes with uniform thickness, providing consistency of graft materials and ensuring that the graft will conform to the site. Material is packaged dry and achieves hydration in a room-temperature saline solution in less than 1 minute. Preparation and packaging provides consistency in terms of hydration, long shelf-life, and ease of use. Techniques are discussed in **ONE SURGEON'S TECHNIQUE: USE OF XENOGRAFT MATERIALS, PAGE 8**.

The repair process has been well documented. In pre-clinical and clinical reviews using a rodent soft-tissue repair model with Xenform, the regenerative tissue matrix has been shown to be populated by host cells and vessels in as little as 3 weeks following the procedure. Within 9 months, the graft has been remodeled into strong host connective tissue and the graft cannot be distinguished from host tissue. At 15 months, there was no

evidence of an elicited foreign body response, no surgical adhesions, and no herniation.¹⁵

Thus, a key benefit of using this modality is the reduced risk of erosion or encapsulation. A 1-year prospective, case-controlled trial is in process and nearing completion to evaluate sexual function and pelvic floor distress in women who have been treated with Xenform. The trial also will assess anatomic outcomes.

Conclusions

Mesh or graft augmentation offers an important resource for surgeons who strive to restore normal pelvic function to their patients. New products and technical advances offer important options with promising initial outcomes. Surgeons interested in these newer techniques should consider the safety and efficacy of the specific graft/mesh material being implanted, as well as the delivery system. The Capio anchoring technique described in this monograph requires a smaller amount of dissection than that of a traditional repair, eliminating the unique risks associated with blind trocar insertion. Currently, large, randomized, prospective, case-controlled clinical trials are underway to assess outcomes associated with currently available products. ■

One surgeon's technique: Use of synthetic materials

We need to remember that the vagina is a dynamic organ and needs to stretch with sexual activity. Bioengineered mesh materials can provide that degree of flexibility. Pore size is an issue, so I select a product that, over time, will allow tissue in-growth and hold the mesh in place. Additionally, I choose the smoothest, thinnest product available. In my mesh repairs, I use the Capiro device and make a transverse or midline incision and dissect underneath, using a very small level of dissection to reduce the amount of incision exposed to the mesh.

For anterior repairs, I use a 4-point attachment, with sutures at the apex (sacrospinous ligament, arcus tendineus, or coccygeus muscle) and pubourethral ligament (for anterior support) or perineal body (for posterior support). I like to attach the mesh to the vaginal apex using a suspension suture. That will fix the vaginal apex underneath the mesh, provide apical support, prevent

enterocele formation, and allow me to code for a vaginal vault suspension. I cut the mesh to size, depending on the specific attachment points required for the individual patient. If I attach the mesh at the arcus or coccygeus, I use a 12-cm piece (not a 10-cm piece) to avoid tension. I use an 8-mm to 10-mm piece for an attachment to the sacrospinous ligament, stopping short of the bladder neck. We have done numerous total vaginal mesh reconstructions using a piece of mesh 15 cm in length, with a 9-cm extension posteriorly and a 6-cm extension. I avoid placing small pieces of mesh that may not extend into important areas.

The procedure can be combined with other procedures, such as suburethral slings.

■ Neeraj Kohli, MD, MBA

One surgeon's technique: Use of allograft materials

I use Repliform for the majority of my graft augmentations at this time, primarily because these grafts have been associated with no adverse patient reactions, while offering promising results to date. Thus, in my view, these procedures conform to the "first do no harm" mandate under which we all need to practice, as we seek to eventually determine the overall "best" material and technique through well-designed studies. I am concerned about the permanence of mesh materials: Traditionally, they have been associated with a risk for erosion. Will mesh contract over time? Or are the traditional rates of erosion associated with surgeon technique, ie, suturing too tightly? What is the risk for dyspareunia?

In assessing outcomes, I am particularly interested in safety and tolerability, in addition to effectiveness. When counseling patients, I always think: is this something I would recommend to my mother? I want to feel completely comfortable with the recommendations I make to my patients, a challenge when I know that, in terms of these materials, we do not have all the answers.

With respect to technique for anterior repairs, I prefer a 6-point suspension to the arcus tendineus and underlying obturator internus muscle, spanning from pubic tubercle to ischial spine. This "arcus-to-arcus" graft addresses both central (distension) and paravaginal (detachment) aspects of a cystocele. The graft supports the entire bladder along its original anatomically correct attachment points. I use a standard midline dissection, about 1 cm to 2 cm to the "east and west" from our normal lateral boundaries of cystocele dissection. I do not rely on being able to see or feel the arcus,

although we find that it is clearly visible and/or palpable about 50% of the time. Whether this connective tissue remnant is present or not, I am confident in placing my sutures because I know that the appropriate span of obturator internus muscle is located between the tubercle and ischial spine.

I use a Capiro device, which allows me to fixate rather than blindly perforate the pelvic floor muscles. In my view, the addition of trocar perforations and stray mesh arms introduce unnecessary risk, with no proven benefit at this stage. The Capiro's placement, very close to the sacrospinous, makes it easy to do a concurrent vault suspension, if indicated. For suturing, I prefer to use a Gore-Tex® #0; I like its feel and find it easy to work with, although no data suggest that any 1 suture material is superior to another.

The Repliform graft is trimmed into a trapezoid shape, 9 cm across at the apex, tapering down to 4 cm. I use a free needle to place the suture ends at appropriate positions along the graft. The Repliform graft will be placed somewhat more tautly than will a synthetic, as no significant scarring or contraction appears to occur, and also because putting the graft on stretch helps to stimulate native tissue growth. Thus, unlike the desired "loose" appearance of a polypropylene mesh insert at the time of closure, the Repliform allograft should have no excessive laxity, but rather should look like a firm, supported sheet.

■ Roger Goldberg, MD, MPH

One surgeon's technique: Use of xenograft materials

As a new product, Xenform provides many of the benefits of products already in the marketplace. However, as is true of all developments in graft/mesh technology, new products have been developed to create materials that are best suited to use in gynecologic surgery. In any graft material, I look for softness and pliability, which aid in restoration of vaginal form and function. I compare the feel of products: some have a stiff, leathery feel. I am concerned that this will translate into lack of flexibility in the vaginal wall, which could result in less-than-ideal function. I want a product that encourages cellular in-growth, and reduces the likelihood of encapsulation. I am concerned that chemically crosslinked products may reduce in-growth and negatively affect a patient's return to normal sexual function.

In follow-up examinations of repairs made with more rigid products, the surgeon may notice a ridge in the mid-to-upper vagina, where it should be softer and more pliable.

I believe that the rate of incorporation of the collagen matrix into the native tissue reduces the risk for wound separation and allows healing of the suture line, the most common site of erosions.

In using Xenform, it is important to hydrate with room-temperature saline: use of hot liquid will denature the collagen.

Our anterior repair technique utilizes an 8 cm x 12 cm piece of Xenform, which is fashioned into a trapezoidal shape that is 12 cm at the base and 7 cm at the apex.

The open-access Capiro needle passer is loaded with 2-0 Gore-Tex suture and aided by Miyazaki lighted

vaginal retractors (Marina Medical, Hollywood, Fla). Four sutures are placed into each arcus from ischial spine to just behind the pubis. This is done under direct vision. The graft edges then are attached to these sutures, and the graft tied into position. Any central defect can be corrected by placcation if desired prior to this step, or it simply can be ignored, as usually is our custom. The graft is anchored in the midline, at the level of the bladder base, with 2 interrupted delayed absorbable sutures to help with enterocele prophylaxis.

Posteriorly, in an effort to protect the vault, we use a graft as well. Again, the approach begins like a standard posterior repair, but dissection continues to both sacrospinous ligaments. The Capiro device, again with Gore-Tex suture, is passed twice into each ligament. An 8 cm x 12 cm graft, 12 cm across and 8 cm front to back, is attached to the medial of the 2 sutures. Two delayed absorbable sutures are placed into the midline of the graft at the uppermost/innermost edge, and attached into the vaginal epithelium, again to help prevent enterocele. Site-specific defects may be corrected at this time, if desired. Often no usable tissue is found. The graft is tied in place, and secured laterally and anteriorly (to levator fascia and perineal body) with a running delayed absorbable suture. The remaining sacrospinous sutures are attached to the vaginal vault to complete a bilateral vault suspension. (A procedural video is available from the American College of Obstetricians and Gynecologists video library.)

■ Joseph Maccarone, MD

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