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This supplement is supported by American Medical Systems, Inc., and has been peer reviewed by the editors of OBG MANAGEMENT.

SUPPLEMENT TO
OBG MANAGEMENT
JANUARY 2010

Innovations in mesh kit technology for vaginal wall prolapse

In this roundtable discussion, 4 prominent urogynecologists and gynecologic surgeons discuss the evolution of techniques used in anterior and posterior prolapse repair

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Dr Bercik reports that he has no financial relationships to disclose.

Innovations in mesh kit technology for vaginal wall prolapse

DR DAVILA: In this roundtable discussion, we will discuss recent advances in prolapse reconstruction, including the use of lightweight, flexible mesh materials and new kits that feature minimally invasive internal fixation approaches to manage advanced prolapse.

I'll start by asking each speaker to describe the process by which he became interested in the use of mesh and kit techniques for prolapse repair.

Kits now offer more standardized and less invasive approaches.

DR MOORE: Over the past 5 years, several prospective randomized trials have evaluated the use of mesh in anterior compartment repairs, demonstrating better cure rates compared with traditional techniques. These reports and others were reviewed in a recent Cochrane Review meta-analysis, which reached the same conclusion.[1]

In the past, clinicians relied on various techniques and attachments for prolapse repair with mesh grafts. Often, complicated dissections were required. The mesh kits now offer more standardized, less invasive approaches and an end result of better—and safer—outcomes for patients than some of the older graft placement techniques.

DR CLARK: Originally, I was taught that the apex was the key to prolapse repair, although colposacral suspension was often associated with cystocele recurrence. I saw the introduction of vaginal mesh via the transobturator approach as an important advance to increase strength and durability of the anterior repair and decrease operative complications.

DR BERCIK: The success of urinary incontinence procedures using lightweight polypropylene was what helped convince me. These techniques demonstrated the safety of using a polypropylene macroporous mesh in the vaginal compartment.

The new kits avoid complicated paravaginal dissection and suturing into that space. The older dissection used previously in the anterior compartment created a false plane between the muscularis and mucosa of the epithelium, resulting in considerable bleeding and weakening of tissue. The kits that use a deeper dissection are much more in keeping with anatomy. By dissecting in a true anatomic plane, there is the potential for lower incidence of bleeding and/or organ damage. While the "deep dissection" was developed to reduce mesh exposure, an additional benefit is an easier and cleaner plane in which to work.

Providing better support for the vaginal apex

DR DAVILA: Dr Clark, could you expand on your comments about the vaginal apex? While we have used various structures for apical support, the current trend seems to favor use of the sacrospinous ligament.

DR CLARK: Three locations are available for use in obtaining apical support:

- The anterior longitudinal ligament of the sacrum
- The sacrospinous ligament
- The uterosacral ligament

The invasiveness of the abdominal colpopexy using the anterior longitudinal ligament has, I think, kept many surgeons from performing such procedures more frequently.

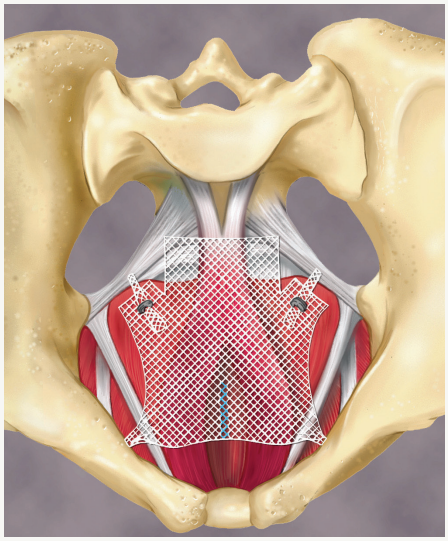
Traditional use of the sacrospinous ligament requires suturing the vagina to the ligament. This shortens the vagina, places it into a posterior pelvic position, and results in an unacceptably high recurrence of cystocele, as noted in a study comparing repairs using the sacrospinous ligament versus traditional colpopexy.[2]

As a result of these issues, gynecologic surgeons began to evaluate the use of the uterosacral ligament for suspension. Unfortunately, prolapse represents a preexisting defect in tissue; these types of repairs are analogous to making a shirt out of old cloth with new thread. We often had results with less than ideal durability.

Recently, with the Elevate Anterior we have a technology that allows for suspension from the sacrospinous ligament in a more effective, less invasive approach. With the self-fixating arms, the vagina is left in a more anatomically correct position and the prior risk of recurrent cystocele is eliminated (**FIGURES 1A AND 1B**).

FIGURE 1A

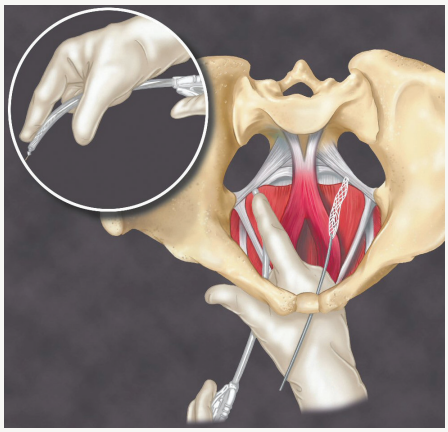
Single-incision mesh placement



The Elevate® Anterior and Apical Prolapse Repair System uses self-fixating tips to place mesh into the sacrospinous ligament through a single vaginal incision.

FIGURE 1B

Delivery and anchoring system



The protective sheath on the Elevate delivery needle allows tactile feedback for safe and accurate placement in the sacrospinous ligament.

Dr Clark: With Elevate we have a technology that allows a more effective, less invasive, and anatomically compatible approach.

Mesh characteristics

DR DAVILA: Dr Moore, what characteristics do you look for in a mesh material for a patient with pelvic prolapse?

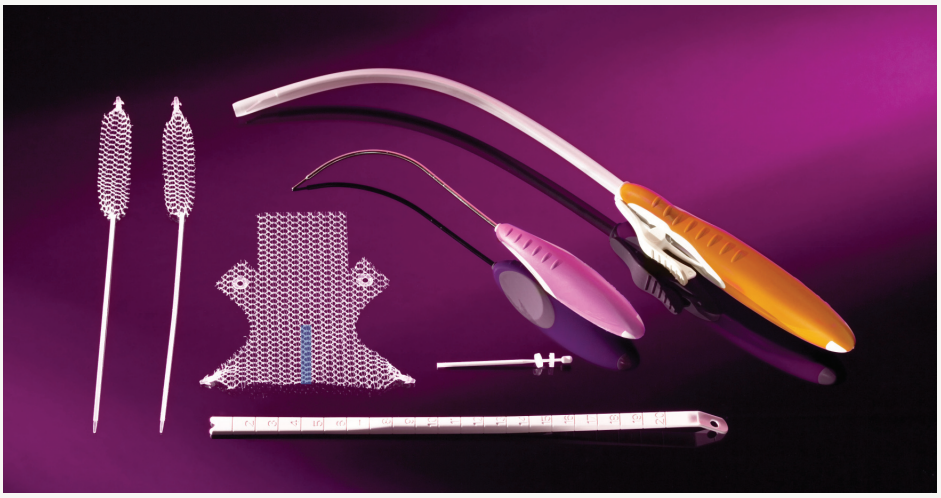
DR MOORE: Among available products, Type 1, macroporous, monofilament polypropylene mesh offers the best option for tissue ingrowth and presents the least risk of complications, including infection, rejection, or extrusion. The most recent improvements have been movements toward even lighter, softer, and less dense Type 1 meshes.

DR DAVILA: Could surgeons use hernia-wall mesh to treat vaginal prolapse?

DR MOORE: No, I would not recommend that, as those meshes are designed for use in different anatomic structures. Heavy, stiff abdominal wall mesh is well suited for use in the abdominal wall, with its thicker layer of adipose tissue. The vaginal epithelium and mucosa are much thinner. As a sexual organ, the vagina must retain flexibility, and a softer, more flexible mesh is better suited.

FIGURE 2

The Elevate Anterior and Apical Prolapse Repair System



Components of the Elevate Anterior and Apical Prolapse Repair System, including fixating arms, apical and anterior needles, adjustment tool, eyelet applicator, and mesh.

Hydrodissection aids in reducing complications.

Issues of mesh placement

DR DAVILA: How does a surgeon obtain the best mesh placement and reduce the risk of complications?

DR BERCIK: To reduce complications, the mesh must be inserted in the proper plane. Hydrodissection—the injection of saline, dilute lidocaine with or without epinephrine, or another local anesthetic into the vesicovaginal space—can aid in doing this.[3] The other thing we need to stop, which we were taught traditionally, is to limit any trimming of excess vaginal tissue.

DR CLARK: I believe that it is important to encourage patients to take either oral or vaginal estrogen preoperatively to minimize the risk of exposure. Of course, you may have to overcome patients' fears and ensure that the patients are appropriate candidates for estrogen use. I also administer a single dose of a second- or third-generation cephalosporin one hour before surgery.

Most patients with uterine prolapse do not need a hysterectomy. By eliminating the hysterectomy, you have decreased operative time and lowered mesh complications.

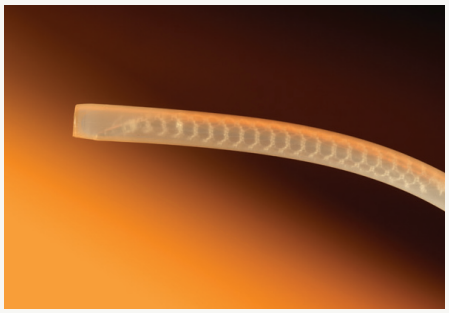
Appreciating the advantages of a new mesh kit

DR DAVILA: Can you describe the benefits of the Elevate® Anterior and Apical Prolapse Repair System (FIGURE 2) (American Medical Systems, Inc. [AMS], Minnetonka, MN) procedure?

DR BERCIK: A key advantage is that Elevate uses small polypropylene fixation tips to affix the mesh to the sacrospinous ligament (FIGURES 3A AND 3B). These tips leave a very small "footprint," preventing them from passing through the ligament and/or into the posterior area. We can access the sacrospinous ligament without going through or behind it, both of which would increase the risk of neurovascular injury.

FIGURE 3A

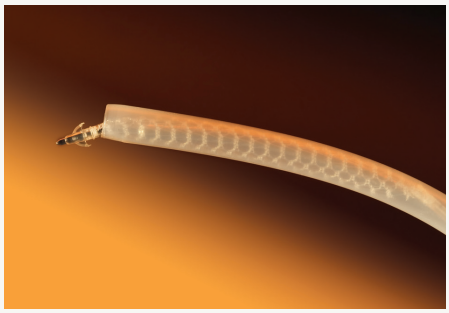
Apical needle: Protective sheath



The depth-limiting feature of the Elevate apical needle allows advancement of about 12 mm of the self-fixating tip into the body of the ligament. In this illustration, the self-fixating tip is retracted.

FIGURE 3B

Fixation tip deployment



The self-fixating tip is deployed for correct placement.

Additionally, Elevate does not utilize external needle passages. The interior fixation arms anchor into the sacrospinous ligament, avoiding the external pulley effect that we have seen with other devices like the Capio, which could put constant tension on key structures, including the obturator internus muscle and the sacrospinous ligament. Elevate provides direct fixation into the supporting structures without that pulley effect, which may translate into less pain.

DR MOORE: I agree that avoiding external needle passages is a key advantage of the Elevate system. Some of the past complications we've seen with mesh kits seem to be secondary to the mesh arms penetrating through the levator muscles. With any of the transobturator kit procedures, if an arm is placed too tight, then there can be some banding and tension that can cause pain or discomfort on a generalized basis or with intercourse.

DR CLARK: For me the major advantage of the Elevate over the prior trocar-based mesh kits is the comprehensive anterior and apical support combined with the lighter density mesh.

How to use the new support system

DR DAVILA: Can you discuss the specific procedural aspects of this new approach?

DR BERCIK: I make a midline incision, no larger than 4 cm, starting at the bladder neck and extending down toward the apex vertically. This allows me to establish the plane and access the fixation-point landmarks.

After making the deep dissection, sweeping the bladder off of the vagina to the apex and developing the paravaginal space, I reach the ischial spine and sacrospinous ligament bilaterally.

Then I measure the anterior-to-posterior distance. After the dissection, I place lightweight absorbable monofilament sutures through the apex, or cervix if the uterus is being preserved, and another stitch midline at the bladder neck to hold the graft in place.

I usually use 2 or 3 stitches proximally and 1 stitch distally. The sutures are held until the mesh is introduced, at which time they are secured to the implant.

Avoiding external needle passages is a key advantage of the Elevate system.

For a complete listing of procedural steps, visit amselevate.com.

Next, I place the distal fixation tips close to the arcus tendineus and ramus. I maintain a relatively flat, almost horizontal, angle to avoid excess elevation of the bladder neck, which could lead to postoperative stress incontinence.

Then I thread my midline stay stitch distally through the blue mark, keeping the mark midline. Placing the distal fixation tips requires a constant forward motion, or the tip may slip off the needle. I like to put my finger onto the tip to stabilize it onto the needle and then use my finger to palpate the ramus.

Once I have the distal portion of the graft fixated at the level of the bladder neck, I measure the vaginal length and trim accordingly. The next step is placement of the apical arms into the sacrospinous ligament 2 to 3 cm medial to the ischial spine to avoid neurovascular injury. The beauty of the needle that is utilized to place the apical arms into the sacrospinous ligament is the sheath, which has a depth-limiting feature and protects the fixation tip until deployed.

While using one finger to mobilize the rectum medially for safety, I place the finger tip on the upper edge of the ligament while bringing the needle tip at the base of the finger, which allows the needle to be positioned near the center of the ligament. This avoids the more cephalad part of the ligament, since that placement may put neurovascular structures at risk.

Following that, the loose eyelets of the mesh are placed over the polypropylene fixation rods until they just engage the mesh part of the self-fixating arm.

Then I use the previously attached sutures to fix the apical part of the mesh either to the cervix or the vaginal apex.

I then adjust the final tension by using the adjustment tool to push each side down a little at a time.

Once the mesh is in the final position, I secure the mesh to the arms with the locking eyelets, taking care to leave at least 1 cm of mesh behind the locking eyelet and to not further tighten the mesh. Then I irrigate with an antibiotic solution.

It is important to ensure that the mesh lays flat and that the edges do not roll out. Three or 4 additional rapidly absorbable tack sutures (size 0) placed along the edges will ensure that the mesh lies flat postoperatively.

Use in conjunction with sling procedures

DR DAVILA: What type of sling would you place in a patient who has an anterior Elevate?

DR BERCIK: For intrinsic sphincter deficiency and in patients with a failed incontinence surgery, I still use a retropubic sling. For anatomic stress incontinence, I use a transobturator sling.

DR MOORE: It's important to fixate the distal area of the mesh either in the midline or to either side of the bladder neck to prevent it from sliding down, as this holds the mesh in position at the bladder neck. However, it has been shown that anterior wall grafts to treat cystoceles do not treat stress urinary incontinence (SUI). I do a separate incision for a suburethral sling after placement of the Elevate.

In my experience, the MiniArc® Single-Incision Sling (American Medical Systems, Inc., Minnetonka, MN), in combination with the anterior Elevate, offers excellent cure rates for cystocele with vault prolapse and SUI at the same time. We have eliminated all external needle passes through the groin with the new fixation system these products utilize, making them safer and less invasive than their predecessors.

Managing more advanced prolapse

DR DAVILA: How would you handle a patient who has complete vaginal eversion or significant uterine vaginal prolapse and exteriorized prolapse of the anterior and posterior vaginal wall?

DR BERCIK: If there is late–stage 3 or stage 4 prolapse—especially in a posthysterectomy patient and there is a large apex—I may do both an anterior and posterior procedure and insert a total of 4 apical arms with their self-fixating tips into the sacrospinous ligament (2 for the anterior system and 2 for the posterior system). I usually place the apical fixation tips of the anterior system more lateral to the posterior tips to stretch out the upper portion of the anterior mesh a bit more. This is especially helpful in elderly patients.

I do the anterior compartment, then the sling, and then finally the posterior compartment, all through separate incisions.

DR DAVILA: Do you have any concerns that these soft tissue anchors may not provide adequate support or have the potential to be inserted too deeply during placement, especially when placing both an anterior and posterior Elevate?

DR MOORE: The Elevate needle is designed with a depth-limiting feature so that only 12 mm of the self-fixating tip can be advanced into the body of the ligament, and the tips are also aligned perpendicular to the fibers of the ligament to ensure optimal fixation. With approximately 8 pounds* of holding force, it gives excellent fixation, much more than a simple mesh arm traversing the ligament. However, if for some reason the tips have not been placed deeply enough and the fixation seems insecure, several options are available.

If the tip is not firmly placed, you may be able to remove it with minimal trauma or bleeding. Grasp it near the tip with a hemostat and gently tug. If it's securely in the ligament and you do not like the location, cut it at its base, leave the tip in place, and place another arm into position; a third arm is provided with each kit. The tips are very small, and we have not had any problems with them during placement of the MiniArc or posterior Elevate system.

DR DAVILA: How would you manage postoperative pain at the placement site?

DR BERCIK: When both posterior and anterior procedures are performed, patients may report some perioperative discomfort deep in the buttocks, which we treat with warm compresses and NSAIDs; however, we have not seen any pain from the tips themselves.

DR MOORE: I agree, we have had over a year's experience with the posterior system and started last April with the anterior system. To date, we have not had any issues with significant pain that has persisted or required any treatment.

New research data on the Elevate system

DR DAVILA: I'd like to briefly review the data being collected on this technique. Dr Moore, as one of the investigators involved in the prospective, multicenter trials on Elevate, can you share any preliminary data?

DR MOORE: We are involved in 2 AMS-sponsored multicenter, prospective trials in US and international sites. The first trial, evaluating the posterior Elevate system for rectocele and enterocele, is collecting intraoperative and postoperative data on

Cure rates were approximately 95%.

efficacy, complications—including buttock pain and bleeding—and overall safety. The initial 6-month preliminary data were presented at the American Urogynecologic Society meeting in Florida in 2009.[4]

Six-month efficacy looks promising, but these are short-term data—patients will be followed for 2 years. Nevertheless, cure rates were approximately 95% for both compartments. Only 2 of 139 patients (1.4%) reported pain or transient discomfort in the buttocks. Median blood loss was 50 cc (range, 5 to 340 cc).[4]

With the posterior system, quality-of-life scores at 6 months had increased significantly over preoperative scores regarding general physical state and sexual function. In a patient-satisfaction survey, 97.7% of patients reported achieving "some" (21.9%) or "a lot of" (75.8%) improvement, and 99.2% reported they would recommend this procedure to a friend.[4]

The trial on the Elevate Anterior and Apical Prolapse Repair System is currently enrolling patients at 23 sites worldwide. We hope to enroll more than 150 patients by the early part of 2010.

DR DAVILA: So to summarize the features of the Elevate procedure: They include the use of a single incision with no external needle passes, the comprehensive support of the anterior and apical compartments, and potentially less trauma to the tissues and sacrospinous ligament. Other advantages include the self-fixation tips, which provide strong, immediate fixation into the tissues for support of the apex, and a tensioning method that avoids horizontal placement through the levators—potentially decreasing the risk of banding, which may lead to dyspareunia. (Dyspareunia is one possible adverse effect of the procedure.)

I'm sending my patients back to work at 10 to 14 days.

Patient satisfaction

DR DAVILA: What has been your impression as to how patients feel about this technique and how they do, relative to techniques you have used in the past for the treatment of vaginal prolapse?

DR. CLARK: The patients are rarely using IV pain medicines, and I'm sending my patients back to work at 10 to 14 days, which is a dramatic improvement over the prior techniques. The vast majority of patients are pleased that their surgery has corrected the problem and they have had such minimal discomfort through the process.

DR. MOORE: We looked back at our first 50 Elevate patients, and in that group we have had no infections and no extrusions to date with the softer, lighter mesh. Patients are extremely happy, with minimal post-op pain and very quick return to normal activities. We have had just one failure, which was apical and resulted from an inadequate dissection and attachment of the mesh to the apex of the vagina. The minimally invasive nature of the procedure and the ability to treat both cystocele and vault in one procedure has been truly advantageous for our patients. n

***Data on file at AMS.**

The information discussed may have been personalized based on the physicians' experience. To the extent that it goes beyond AMS' written materials, it should be recognized as individual medical opinion and does not reflect the opinions or endorsements of the company.

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