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MASTER CLASS

Fad or Future?

As credited to the Ebers papyrus, prolapse was first described in 1500 B.C. Hippocrates described several methods in the treatment of prolapse, including suspending the patient upside down. Another technique championed by Hippocrates included irrigation of the displaced uterus with wine. Once the uterus was reduced, the position was maintained with a pomegranate “pessary.”

Just after the birth of Christ, Soranus of Ephesus placed perfumes at the patient’s head and foul-smelling

substances near the prolapsed portion of the uterus to draw the uterus cephalad.

Needless to say, great advancements have occurred since antiquity in the treatment of pelvic organ prolapse.

Most recently, the use of nonabsorbable polypropylene mesh has become increasingly popular. The latest permutation of this technique is the use of a total pelvic floor repair kit.

I have asked Dr. Dennis P. Miller to discuss the use of total pelvic floor repair kits.

Dr. Miller currently serves as the medical director of urogynecology at Wheaton Franciscan Medical Group, Milwaukee. Since 1995, he has proctored hundreds of surgeons in urogynecologic surgery, in-

cluding laparoscopic and minimally invasive vaginal approaches to incontinence and prolapse.

Currently, Dr. Miller serves on the American Urogynecologic Society Presidential Task Force on graft procedures as well as the International Urogynecologic Association’s graft outcomes committee.

Enjoy reading Dr. Miller’s excellent article, which is the latest addition in the Master Class in Gynecologic Surgery. ■

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Is There a Place for Total Pelvic Floor Repair Kits?

As Dr. Robert Rogers highlighted in the last Master Class in Gynecologic Surgery, traditional transvaginal stitch repairs are associated with unacceptably high failure rates in many patients. In response, the use of nonabsorbable polypropylene mesh has become a growing part of our armamentarium of surgical options for patients with pelvic organ prolapse.

With this change comes a responsibility to ensure that surgeons are well trained and experienced in doing these more highly technical procedures. These are procedures to be performed on patients at higher risk of failure, by the surgeons who regularly treat those patients. Overall, experience with mesh is increasing: A recent survey of American Urogynecologic Society (AUGS) members found that 49% of prolapse specialists use mesh reinforcement.

As expected, there are concerns about mesh reinforcement, and some of these focus specifically on the use of so-called total pelvic floor repair kits. A total repair has previously referred to the simultaneous use of both anterior and posterior grafts, which then integrates true level-one support at the apex. More recent mesh kit modifications, however, introduce the concept of total repair as a purely anterior approach that integrates apical mesh support. Treating the anterior vaginal compartment generally necessitates supporting the apex as well. This has been the main justification for a total repair, along with an inherent reduction in “gap” failure.

The New Case for Mesh

The National Health Service (NHS) of the United Kingdom published guidance on surgical repair of prolapse using mesh last June and made clear that a “rapidly accumulating evidence base” meant the guidance would need to be updated soon.

The NHS went on to suggest that even the evidence to date reveals that surgical repair using mesh may be more ef-

fective than traditional repair without mesh. The NHS reviewers found 10 randomized controlled trials on anterior repair, for instance, and reported that the objective failure rate using mesh was significantly lower (14%) than repair without mesh (30%).

One recently published randomized clinical trial reported by Dr. R. Hiltunen and associates randomized 201 women to undergo anterior colporrhaphy with or without mesh and found a significant difference in the rate of recurrence of anterior wall prolapse when mesh was used. Approximately 39% of women in the no mesh group and 7% in the mesh group had a recurrence at 12 months (Obstet. Gynecol. 2007;110:455-62).

More recently, at last year’s American Urogynecologic Society annual meeting, Dr. J.N. Nguyen and Dr. R.J. Burchette reported similar findings in a well-designed randomized controlled trial. Two years after surgery for anterior vaginal prolapse, recurrent anterior prolapse was seen in 53% of women who were randomized to have anterior colporrhaphy without mesh, compared with 14% of the polypropylene mesh repair group.

Dr. A.A. Sivaslioglu and colleagues similarly randomized patients and found that recurrence rates were reduced from 28% in the no mesh group to 9% in the mesh group (Int. Urogynecol. J. Pelvic Floor Dysfunct. 2008;19:467-71).

These are just several of the recent randomized clinical trials supporting an evidence-based use of mesh.

Case series and other comparative studies can be valuable as well. Despite frequent past assertions, the evidence for the sacral colpopexy is primarily observational, and there may soon be more comparative data available for transvaginal mesh.

Most thought leaders and academic society committees wisely point out that the cost of the new approach stems from mesh-related complications, most no-

tably vaginal mesh exposure. Keeping rates of these complications low requires special training and experience. There are technique tips that can help achieve this goal, but it is also clear that these procedures are not appropriate for all gynecologists, and that we as physicians—not industry—must lead the way in setting credentialing guidelines.

The Place for Total Repair

Many surgeons prefer to use mesh in either the anterior or posterior compartment, but not both. Their concerns about total repair—driven largely by animal data and old literature from hernia studies—focus on the belief that mesh load is associated with increased mesh erosion and more complications involving infection, inflammation, and pain.

These concerns do not entirely apply when mesh is used in two separate compartments, however. In that case, there is not a compelling reason that the mesh in one compartment would affect the erosion or complication rate in the other compartment.

I believe the majority of mesh use should be in the anterior vaginal compartment, where the greater number of vaginal support defects occur—and indeed, there is significantly more agreement about reinforcing the anterior vaginal wall than the posterior. Mesh reinforcement in the posterior compartment is theoretically more likely to contribute to dyspareunia. There is also concern that using a total kit to wrap mesh around the entire vagina may blunt the apex.

Dyspareunia is not restricted, however, to mesh reinforcement in the posterior compartment. Anterior compartment repair also can be associated with dyspareunia, especially if the posterior axis deviation of the vagina is disturbed.

Posteriorly, there actually may be an advantage to mesh reinforcement in that it provides broad support of the upper vagina without the narrowing impact of midline plication.

Posterior mesh reinforcement also enables us to integrate the repair with effective apical support.

The importance of apical support is

central to the case for total repair. The apex has been shown to be involved in the majority of cases of pelvic organ prolapse, and in fact, anterior prolapse is often the secondary consequence of an apical defect.

There is increasing appreciation for the notion that total repair is all about integrating apex repair with coverage of the anterior and posterior compartments, or about reaching the apex through the anterior repair. Unfortunately, only a fraction of prolapse repairs—17%, it has been estimated—has included apical treatment.

In dealing with an anterior defect, the only way to adequately treat the apex using first-generation mesh kits (those that entered the market prior to 2008), therefore, has been to employ mesh in the posterior compartment as well. Through the posterior compartment, the mesh can be attached to the sacrospinous ligament (SSL), enabling true level-one support.

Some surgeons have alternatively modified the anterior kit procedure to be able to place the mesh arms through the sacrospinous ligament.

To understand why some patients experience apical prolapse after anterior vaginal wall mesh kit operations, Dr. J. Delancey’s pelvic floor research group at the University of Michigan used MRI to look at the relationship between anterior mesh kit suspension points along the arcus tendineus fascia and the upper vagina in asymptomatic women with a uterus and normal support. They reported at last year’s annual AUGS meeting that about one-quarter of the anterior vaginal length was uncovered or unsupported during Valsalva when the arcus tendineus is the most cephalad support.

The second generation of mesh kits—those released in 2008, as well as some that are yet to be released—incorporate SSL fixation through the anterior approach. The incorporation of SSL fixation provides greater coverage of the anterior vaginal wall without the need to enter the posterior compartment. This redefines the term total repair and allows a more tailored approach to the posterior-

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or compartment.

In addition to providing apical support, total repair offers an opportunity to prevent gap failure. When one compartment is reinforced and not the other, enough force can be displaced from the stronger compartment to the unreinforced compartment to cause “sequential prolapse” over the ensuing years. (Think of squeezing one end of a balloon.)

In many of the case series on prolapse surgical outcomes, much of what is referred to as failure is really untreated compartment prolapse. Epidemiologic data also suggest that approximately one-third of recurrent operations are due to untreated compartment prolapse (*Am. J. Obstet. Gynecol.* 2003;189:1261-7).

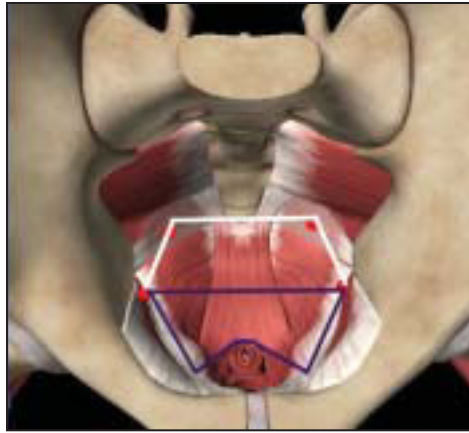
Interestingly, most surgeons acknowledge that the abdominal sacral colpopexy—as it has been performed in recent years, with the evolution of materials and refinement of technique—is a highly successful treatment for pelvic organ prolapse. Yet these surgeons may not fully appreciate why this surgery is successful.

The operation’s success, it can be argued, is due to the fact that the sacral colpopexy is an abdominal delivery system for a grafted repair—in essence, a total mesh procedure. The use of the sacral promontory is a technique choice and not the reason for success. It’s the full graft coverage that really makes the treatment work. Most of us find the procedure is more likely to fail when there is incomplete graft extension.

Tips for Total Repair

The best way to prevent vaginal epithelial complications, most notably mesh exposure and/or stiffening, is to pay strict attention to proper dissection and full-thickness incisions, good tissue handling, and flat and unfolded—but loose—placement of the mesh.

These aspects of total repair are difficult to quantify, and experience thus comes strongly into play. There is a visually recognizable layering to the mus-



Three-dimensional pelvic anatomy simulations based on CT scans demonstrate the greater degree of vaginal support when a total procedure is performed rather than a single compartment repair.

cularis and epithelium, and the dissection plane is in the loosest areolar connective tissue deep to it. You know it when you are there because the dissection is resistance free and bloodless. This is contrary to the methods taught to most of us during residency training on standard colporrhaphy.

Hemostatic dissection also has the advantage of preventing hematomas. Incisional erosion and perhaps also early failure may be affected.

As when you are preparing to hit the ball in golf, the key is how you start. When hydrodissection (generally with a dilute anesthetic) is properly introduced into the space below the vaginal epithelium, the fluid will preferentially flow in the path of least resistance and find this potential space, dissecting it apart.

We can know whether we’re in the proper location for injection by first observing the effect of the injection on the epithelium. When the injection is in the right place, the fluid will not lead to an intraepithelial wheal, nor will we see significant blanching. The injection is followed by a bold full-thickness incision just large enough for two fingers.

One of the main reasons these procedures are not for the busy generalist is that the dissection then needs to be carried fully down to the arcus tendineus

and anteriorly to the SSL. You cannot leave extensive connective tissue covering the fixation point because doing so leads to an increased risk of visceral injury and won’t allow the mesh to spread out over the plane. This is particularly important in a total repair.

Blunting of the apex is prevented by making the mesh traverse an adequate cephalad space.

Mesh will contract by an estimated 10%-20% in the year after surgery, so while it must be placed flat and smooth, it cannot be placed tightly.

I like to make the analogy of the “military-style bed”—straight and tight, with tucked corners—as opposed to a looser, imperfect “guy’s dorm-room bed.” As surgeons, we have to learn to resist any desire for that military-style bed.

Surgeons have taken two approaches specific to a total mesh kit. Some surgeons who are concerned about the need to tunnel around the apex with mesh and potential blunting of the apex will split the system into two pieces, placing mesh in the anterior and posterior compartments separately.

The main disadvantage to this approach, again, is the resultant gap in support and the subsequent risk of sequential prolapse (prolapse of the uncovered portion). In addition, we’ve learned that keeping the mesh intact and wrapping the entire vagina does not result in blunting or shortening of the vagina.

Leaving the mesh intact does necessitate care, however. The bridge must not “bear down” on the apex and is adjusted with clamps or a long retractor to lay in the most cephalad space possible.

We also want to use a certain amount of finesse, taking care not to traumatize the sacrospinous ligament, arcus tendineus, or most importantly, the iliooccygeal, coccygeal, and obturator internus muscles.

The earliest employed techniques for mesh insertion involved multiple stitches encircling the ligaments and muscles. While using these techniques myself, I found that they often traumatized these deep anatomic structures, promoting buttock and vaginal pain.

Some of that trauma may still occur with deep trocar passes, especially in cases where passes are repeated. Securing mesh without either stitches or trocars may be an advantage in avoiding neurovascular structures. Second-generation mesh kits are characterized by their trocar-less delivery systems, in addition to having SSL fixation incorporated into the design for an anterior approach.

Reflections

The so-called total repair has been valuable only in the subset of patients at increased risk in both compartments. The evolution of mesh delivery may change that formula as the apex now can be addressed anteriorly.

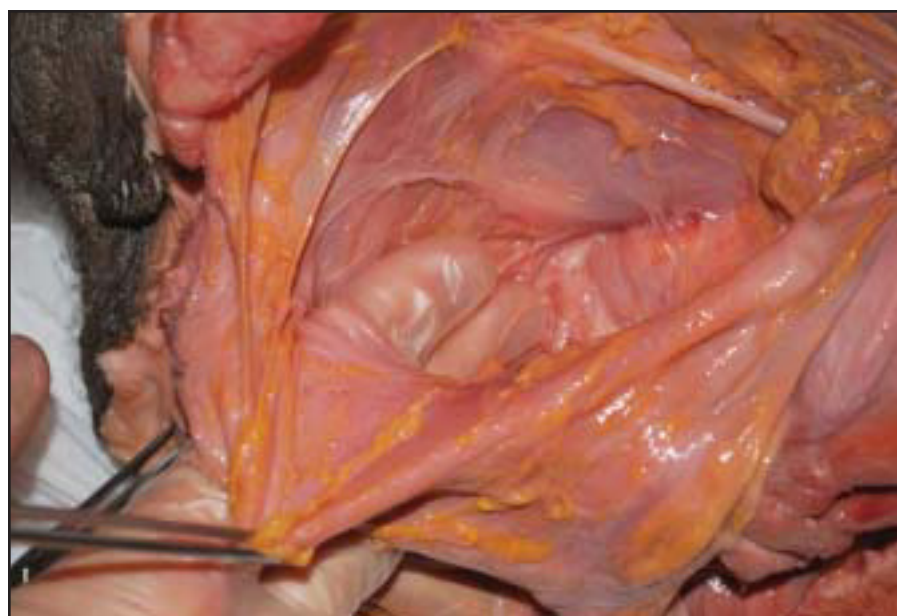
It is clear to me that dogma and ideology are the most potent sources of bias in this time of change for prolapse repair. If we prove greater success rates with one approach, we must then find a way to objectify the differences between the types of complications. How many visceral injuries, for instance, are equivalent to a mesh exposure?

Equally noteworthy is the fact that the data regarding the impact of surgery on sexual function are substandard for all surgical approaches.

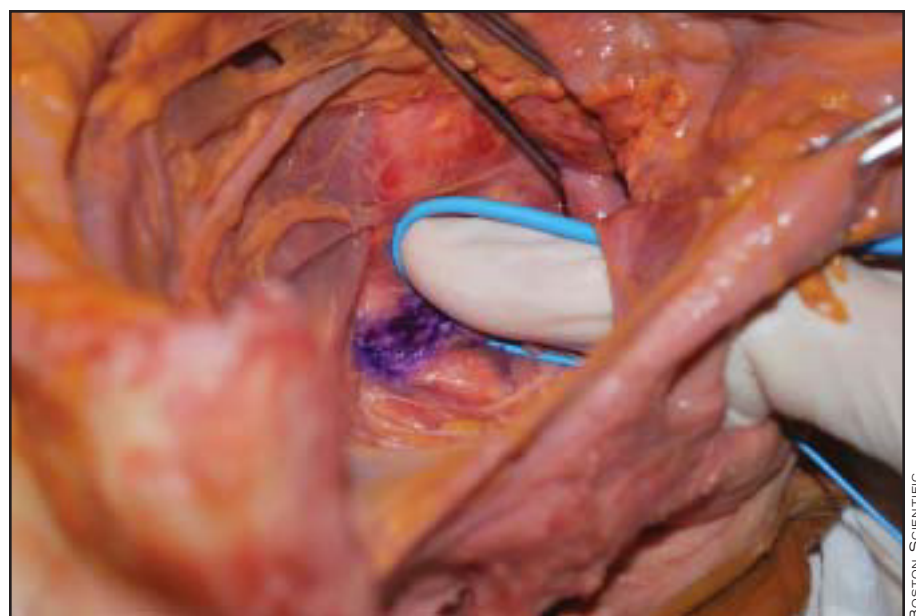
We do not have a validated questionnaire that accounts for the differing causes of pre-op versus post-op dyspareunia. We need qualitative study to find out how patients rate the experience of treating failure versus treating a sexual dysfunction.

There is no gold standard for prolapse repair because there are few standard patients. This complexity is the main reason why pelvic reconstruction is falling more to those who treat it regularly. I believe that if a surgeon is to be able to give the highest standard of care, he or she needs to be facile in open and laparoscopic abdominal approaches as well as transvaginal repairs with and without augmentation. The most successful hunters have multiple arrows in their quiver. ■

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The mid-sagittal hemisected cadaver pelvis improves surgical teaching in these technical and tactile procedures. The obturator internus and obturator vessels are easily viewed in relation to arcus tendineus fascia pelvis and sacrospinous ligament (SSL).



Up to three nerves may traverse ventrally across the surface of the SSL and the radial dilation of a small fixation point provides a smaller area of trauma than seen with trocars yet avoids any encircling sutures. The SSL provides superior support and resistance to displacement for anterior apical support.