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SUPPLEMENT TO

OBG MANAGEMENT

SEPTEMBER 2007

BEST OPTIONS, TECHNIQUES, AND CODING TIPS FOR Pelvic Prolapse Repair

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Options for treatment of pelvic floor prolapse continue to evolve; however, questions regarding the etiology of prolapse remain unanswered. Clearly related to such factors as childbirth and the aging process,^{1,2} prolapse is likely to become of greater concern to clinicians as the population of women aged 60 years and older increases.³ Its incidence is expected to reach or exceed 30% in this age-group.⁴⁻⁷ The demand for gynecologic services likely will increase by more than 45% in the next 10 years.⁸ Prolapse is also associated with defects in collagen and smooth-muscle structure and strength.⁹⁻¹² Tissue may weaken in response to physical activity¹³ or increased intra-abdominal pressure from chronic constipation, chronic cough, chronic obstructive pulmonary disease, or obesity.¹⁴

This roundtable discussion among experts examines the medical evidence regarding the etiology and management of prolapse, evaluates currently available treatments, and describes emerging trends. Tips on coding, provided by Melanie Witt, RN, CPC-OGS, MA, accompany the narrative.

Dr Levy: What evidence supports our current procedures?

Dr Culligan: The best evidence for traditional "suture-based" repairs consists of large case series reported by individual surgeons. These are often marred by poor rates of success, poorly standardized definitions of success and failure, and less-than-ideal follow-up. The failure rate for anterior suture-based repairs approaches 50% or more.¹⁵⁻¹⁷



This publication was developed under a grant from the Pelvic Health Coalition.

Coding issues for clinicians

Clinical question: We report diagnostic codes for patients with varying types of prolapse and symptoms. Denials for services often note that a medically justified reason for the procedure was not provided. Why?

Answer: Increasingly sophisticated payers and claims processing software determine if the primary diagnosis is an approved medically justifiable indication for the surgery billed, based on both the code and its order.

Two ICD9 diagnostic codes cover cystocele: 618.01 (Cystocele, midline) and 618.02 (Cystocele, lateral). A paravaginal defect repair's correct medically justifiable diagnosis is 618.02, not 618.01. Many payers look for codes for existing fascial weakness and why mesh is required to establish medical necessity. To avoid denials, link mesh add-on code 57267 to 618.81 (Incompetence or weakening of pubocervical tissue; anterior compartment) or 618.82 (Incompetence or weakening of rectovaginal tissue; posterior compartment). Code 57267 specifically addresses only the anterior and posterior compartments; only codes 618.81 and 618.82 establish medical necessity.

For colpopexy, ICD9 code 618.5 (Prolapse of vaginal vault after hysterectomy) links to a colpopexy code for vaginal vault for prolapse after hysterectomy. If vaginal vault prolapse is corrected, but the uterus intact, the code is 618.09 (Other prolapse of vaginal walls without mention of uterine prolapse).

Diagnostic code order supports medical necessity. Lists of criteria for procedures may represent actual defects; codes for general symptoms are accepted as secondary clarification. If a patient requires surgery to correct stress urinary incontinence (SUI, 625.6) from intrinsic sphincter deficiency (ISD, 599.82), ISD—not SUI—is the primary diagnosis; the abnormality represents a specific physical defect. Urinary incontinence is viewed as an accompanying symptom. In fact, ICD9 guidelines allow only the diagnosis code 625.6 or other incontinence symptom codes (788.30-788.39) to be reported as a secondary diagnosis when a more definitive diagnosis has been reported. —Melanie Witt, RN, CPC-OGS, MA

Posterior repairs have had better success.¹⁸ Considered in isolation, suture-based apical suspension has a higher rate of success.¹⁹

Dr Miller: Procedures such as sacrospinous vault repair show good clinical outcomes specific to the apex, but they may result in increased vulnerability and failures in the other compartments.²⁰ Integrated repairs using graft materials may offer more overall success without alternate site failures.

Dr Davila: We are seeing the transformation of reconstructive surgery from an art—in which procedures compensate for and repair structural defects—to a

science—in which evaluation of outcomes is most important. Therefore, evaluation of tissue quality is essential. Endogenous tissue may be insufficient or of poor quality; its use will result in a high rate of recurrence. The evolving science has provided good data on the use of graft materials to augment repairs.

The technique for sacral colpopexy is very uniform. Similar standards in newer procedures are evolving, along with improved diagnostic skills to accurately identify defects that require correction.

Repeat procedures: Why do original repairs fail?

Dr Levy: Our maturing patient base allows us to advance the science. A patient may have had a repair at age 50 years and a recurrence at age 70. We are learning about the longevity of our repairs. Women with genetic collagen disorders seem to experience recurrence much earlier than do other women.

Dr Lucente: Certainly, many women outlive the original suture repair. Obesity and its effect on stress loads will also increase the incidence of prolapse.

Dr Culligan: As we develop our discussion, it may be helpful to think about failures occurring at 2 peaks in time: an early peak and a late-term peak. Treatment decisions should be based on the possibility of early failure. Shull's suture-based studies¹⁹ and my study on abdominal sacral colpopexy²¹ had at least 5 years' follow-up. Both investigations showed that roughly 96% of failures occur within 2 years.

Dr Levy: Why do traditional suture-based procedures fail? What about attachments and the forces to which these tissues are subjected? DeLancey is doing a significant amount of work in this area.⁹

Dr Davila: Typical defects involve apical transverse separations of the fascia, both anteriorly and posteriorly. When we reattach the fascia to the apex, and the apex is well supported, the repairs are likely to be successful.

Still, a central issue remains: Even if we repair the anatomy perfectly, weak endogenous tissue (and most defects are very obvious during intraoperative dissection) may deteriorate rapidly, causing recurrent fascial or connective tissue separation from the apex. Both anterior and posterior connective tissue

repairs using good tissue result in good median-term outcomes. The challenge is clinically determining the presence of “good” tissue.

Dr Lucente: No endogenous tissue repair ever returns connective tissue elements to baseline tensile strength. The literature on hernia repair for the abdominal wall suggests that augmentation greatly enhances success rates over time. Graft repairs to compensate for insufficient native tissues have reduced 3-year recurrence rates from 58% to 20%.²² Significantly, in that specialty, surgeons attempt to evaluate tissue quality but still place mesh in almost every patient.

Augmentation: For all patients?

Dr Levy: Can we translate findings from other anatomic locations to the vagina? Are augmented procedures for prolapse appropriate for all patients? Should we augment in initial repairs when existing tissue is of poor quality?

Dr Harris: Not every patient requires augmentation. For instance, I would make different decisions for an older patient with stage 3 or 4 prolapse than for a very symptomatic woman in her 30s with a stage 2 prolapse who is healthy and has tissue that appears to be healthy. This individual will likely live to age 85 or 90 years; augmentation at an early age means that she may have the material in place for 50 to 60 years.

Dr Miller: Still, the evidence in the medical literature does not show complications after 2 decades with materials in place. By contrast, a suture-repair site may endure prolonged chronic stress. In my experience, younger women, more than older women, need augmented repairs because the repair site will be under stress for many years to come.

When to use mesh: Specific patient groups

Dr Levy: Clearly, we use our clinical experience and expertise to make treatment decisions. How do you decide if tissues are of sufficient quality for nonaugmented repairs?

Dr Harris: The degree of prolapse provides important information about tissue strength and quality. In itself, stage 3 or 4 prolapse signals poor tissue and suggests that native tissues may be inappropriate for use in repairs.

Coding issues for clinicians

Clinical question: When performing vaginal hysterectomy, mid-urethral sling, and anterior/posterior repairs with grafts, which coding scenarios apply? Should I be aware of any edits?

- A. 58260 (Vaginal hysterectomy)
57288-51 (Sling operation for SUI)
57260-51 (Cystocele/rectocele repair)
57267 x 2 (Insertion of mesh)
- B. 58260 (Vaginal hysterectomy)
57284 (Paravaginal defect repair)
57250 (Posterior repair)
57267 (Insertion of mesh)

Answer: The coding solution depends on documentation; these coding options imply different procedures. A paravaginal defect repair includes cystocele (anterior) repair and mid-urethral sling, entering the Space of Retzius, and reattaching the lateral vagina to the level of the white line or arcus tendineus fasciae pelvis. If an anterior colporrhaphy is documented (evidenced by plication of the pubocervical fascia) option A is correct. If documentation shows paravaginal defect repair, option B is correct. No edits apply to either coding. —**MW**

Dr Levy: If the patient is 35 years old and has a stage 3 prolapse, would you use mesh?

Dr Miller: The question often boils down to: Which patients should not have surgery performed by the abdominal approach? Abdominal sacral colpopexy, the single best studied and most accepted procedure, is commonly performed with a synthetic graft. Relative contraindications to the use of mesh include patients with significant autoimmune diseases who are at high risk of infection. Some surgeons have reported that patients with such disorders as fibromyalgia and interstitial cystitis tend to have increased rates of complications or poor tolerance to graft use. No absolute contraindications have been documented.

Dr Harris: Mesh represents an excellent solution for many patients, particularly those with apical and anterior prolapse. The latter has an inherently high risk of failure with traditional suture repairs. Additionally, patients who have had a sling or an apical procedure usually also have anterior vaginal defects that can be repaired only by augmentation. I would be more cautious in the use of mesh for posterior compartment repair because of the higher risk of mesh erosion in the posterior wall of the vagina.

Dr Miller: I’ve experienced a higher risk of posterior wall erosion only in relation to abdominal sacral

colpopexy. With vaginally introduced mesh, the great majority of exposure is on the anterior side.²³

Dr Culligan: I use mesh in most patients; however, I would not use mesh in a younger patient with otherwise good tissue and, especially, good muscle strength whose apex just requires better attachment to the uterosacral ligaments. If the rectovaginal tissue has separated from the perineal body after an episiotomy, simple reattachment will correct the defect.

Dr Miller: Still, this procedure is commonly performed with mesh augmentation. I've had excellent success using mesh to correct posterior defects. Mesh provides a flatter and more broad-based support of the posterior vagina and avoids the anatomic narrowing seen in suture repairs. This has a potentially beneficial effect in preventing dyspareunia.

In addition, all of the case series on graft materials introduced vaginally have shown a higher rate of mesh exposure in the anterior vaginal wall than in the posterior region. I believe that we have no reason to limit the use of mesh in the posterior compartment. To avoid mesh exposure, I generally use a full-thickness incision that avoids splitting the vaginal wall, as is traditionally done to open the incision. I also lay the mesh without tension and make sure that it does not fold or bunch up.

Dr Lucente: Degree of prolapse and location are the key issues in my decision-making process. In the anterior apical component, mesh will be advantageous because of the higher risk of failure associated with

traditional procedures. Rapid progression often indicates tissue weakness.

What about other aspects of the patient history? We know that smoking destroys healthy connective tissue. Excessive stretch marks during pregnancy signal low-quality connective tissue.

We face challenges in counseling young patients who must decide: Should I have a procedure using currently available graft material or choose a suture-based repair? Wait for advances in material science or new treatments? Tolerate symptoms? Use a pessary? What is the risk for failure or complications for procedures currently available?

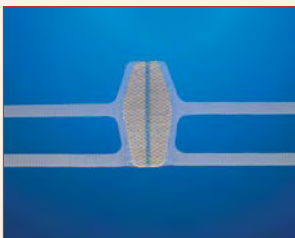
Pre- and perioperative patient assessment for mesh use

Dr Davila: My evaluation algorithm and decision-making tree begin with the preoperative exam. I first look at the vaginal apex. Most women with advanced prolapse have apical prolapse. Isolated apical prolapse may be resolved by suspending the apex, correcting both the anterior and posterior defects.

I then look for obvious fascial defects. If I find an area of the anterior or posterior vaginal wall where rugation stops and the smooth mucosa begins, a large fascial tear is present; in most patients, I am able to find it.

I make a functional assessment of the pelvic floor to evaluate muscular strength and determine the patient's ability to perform Kegel exercises (all patients are instructed on Kegel exercises postoperatively to

COMMONLY USED MESH PRODUCTS AND PROPERTIES



▶ **The Anterior Avaulta Plus Biosynthetic Support System** (C.R. Bard, Inc, Covington, GA) utilizes a nonabsorbable monofilament, polypropylene mesh; a porous, acellular, ultra-thin sheet of crosslinked collagen attached to the polypropylene mesh establishes a protective barrier between mucosal tissue and the polypropylene mesh and contains apertures uniformly sized to allow the ingrowth of host tissue and capillary vessels.



▶ **The Perigee** (American Medical Systems, Minnetonka, MN) system for transobturator cystocele repair includes the graft and needles used for anterior wall repair. The graft (large-pore polypropylene or a biologic porcine) has a tail that can be cut to fit the length of the patient's vagina and 4 arms that are attached to the pelvic sidewall using the needles passed through the transobturator space.

maintain repair integrity). If patients are not well estrogenized, I will prescribe appropriate agents, especially if I may use a graft.

Preoperatively, I discuss the use of graft materials with all patients. For a primary repair, endogenous tissues are often of good quality and can therefore be used. In repeat surgery, graft materials have greater applicability. I counsel these patients that, because they have had a recurrence, it is likely that endogenous tissue is insufficient for repair.

I evaluate the quality of the endopelvic fascia and connective tissue in the anterior and posterior walls. If the tissue is of good quality, reattachment to the apex will often correct the defect satisfactorily. If the endopelvic fascia is of poor quality and the patient is relatively young, I might select a biologic graft for the anterior or posterior walls. For a well-estrogenized patient who is more physically active or a little older, I might use a synthetic graft.

Dr Miller: I consider the potential impact of a single repair on another compartment. For example, an anterior-compartment repair may increase the vulnerability of the apex and vaginal wall to future prolapse. An advantage of a grafted repair is that it provides integrated support for all 3 compartments.

Dr Levy: I also evaluate tissue by exploring the patient history. Women with tissue defects and collagen genetic abnormalities often have had umbilical or inguinal hernias. In addition to the factors discussed, I look for external signs of poor tissue quality: For instance, is her face aging?

Coding issues for clinicians

Clinical question: The nomenclature of CPT 57284 (Paravaginal defect repair [including repair of cystocele, SUI, and/or incomplete vaginal prolapse]) includes repair of cystocele. If I perform a cystocele repair with mesh, can I bill either:

- A. 57240 (Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele) with 57267 (Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site [anterior, posterior compartment], vaginal approach)
- B. 57284

Answer: Neither code supports the procedure documented. If a lateral cystocele is corrected by paravaginal repair, it is incorrect to report a 57240 and 57267. Additionally, this code combination pays more than 57284. Upcoding a procedure without documentation to obtain higher reimbursement is considered fraud by Medicare and most private payers. —MW

Clinical outcomes and surgical technique

Dr Levy: Let's review the clinical outcomes of these procedures: What do we know about the science of these repairs? How much data do we have with which to evaluate and counsel our patients?

Dr Lucente: There is now a large body of level III evidence. Well over 1000 patients have been followed for 6 months or longer in clinical study settings with well-described outcome variables. Oral and poster presentations delivered at specialty and subspecialty international congresses also enhance the published literature. Overall, the data for patients



► **The GYNEMESH PS Nonabsorbable PROLENE Soft Mesh Implant** (Gynecare, Somerville, NJ) is a lightweight, soft, and supple knitted monofilament mesh with a large pore size. It is used here in the Gynecare Prolift Complete Pelvic Floor Repair System.



► **The Xenform Soft Tissue Repair Matrix** (Boston Scientific, Natick, MA) is an acellular, non-crosslinked, bovine dermal matrix which promotes revascularization and regeneration as opposed to scarring and encapsulation.

Coding issues for clinicians

Clinical question: Patient is a 43 y/o diagnosed with midline cystocele, rectocele, vaginal vault prolapse, and weak pubocervical and rectovaginal tissue. Repairs (cystocele, rectocele, and vaginal vault prolapse) are performed transvaginally utilizing mesh for all procedures. Are the following CPT codes correct?

- A. 57282 (Extraperitoneal colpopexy)
- B. 57260-51 (Cystocele/rectocele repair)
- C. 57267 x 2 (Insertion of mesh for anterior/posterior repairs) noting that CPT 57267 is exempt from the multiple-procedure rule.

If urethral hypermobility causes SUI and is treated by a sling procedure performed during the same session, is it appropriate to also bill CPT 57288 (Sling operation for SUI)?

Answer: Yes, provided documentation clearly indicates that the vaginal vault was attached to either the sacrospinous ligament or the iliococcygeus muscle. The code order is incorrect: Always list the most extensive or highest valued procedure code first; this will be paid at 100% of the payer allowable. Subsequent listed codes will be reduced by some percentage; payment will only cover intraoperative work for additional procedures. The correct code order is 57260, 57282-51, 57267 x 2. The code for the mesh insertion does not require a modifier; as a CPT “add-on” code, it has already been valued only on intraoperative work.

Code 57288 can be billed in addition to the above 3 procedure codes, assuming documentation for both urethral hypermobility (ICD9 code 599.81) and SUI (625.6). If all 4 procedures are billed, the code order is 57288, 57260-51, 57282-51, 57267 x 2. —MW

who have received augmented graft repairs—particularly using monofilament macroporous polypropylene materials—over time have become increasingly favorable.^{20,21,23-26}

Surgeons must appreciate the learning curve associated with transvaginal surgical implantation, particularly in terms of depth of placement. In transvaginal delivery (just as with abdominal procedures), we place the graft material behind all of the separate histological layers of the vaginal wall—the epithelium, the muscularis, and the fibrous connective tissue that we loosely refer to as fascia.

This requires a specific dissection technique: full thickness dissection, midline incisions, and preservation of the uterus to help preserve the blood supply to the upper third of the vagina. Within these parameters, the data are impressive: Our recent

patient series, accepted as a poster at the annual Society of Gynecologic Surgeons meeting, followed 350 patients over 6 months using validated outcomes study tools. We demonstrated only a 1.1% erosion rate and a 91% success rate as measured by the Pelvic Organ Prolapse Quantitative (POP-Q) system for describing, quantifying, and staging pelvic support.²⁷ This preliminary study demonstrates the importance of carefully evaluating outcomes related to materials, methodology, and—most importantly—surgical technique.

Placement within layers of the vaginal wall results in high erosion rates. A recent study posted a 16% to 24% erosion rate with a polypropylene macroporous material.²⁴ The surgeons used a traditional splitting technique for vaginal wall dissection, peeling the epithelium from muscularis and laying the graft between muscularis and epithelium. This technique may lead to a poor outcome, as the mesh is not properly placed behind the full thickness of the vaginal wall.

Dr Davila: As clinicians become more comfortable with the required dissection technique, tissue preparation, etc, the use of mesh has been associated with decreasing rates of healing abnormalities, or erosions.

As the literature evolves, 2 ways of using graft materials emerge: In the first, the graft functions as a prosthesis, replacing the fascial layer. In the second, the graft augments fascial strength after a plication repair. These different uses affect surgical technique: A fascial replacement requires less specific dissection of the vaginal wall since the fascia will be replaced.

When the graft is used to augment a plication repair, it is placed between the plicated fascia and mucosa, increasing the risk for erosion. Therefore, a more meticulous vaginal wall dissection and plication technique are needed; a biologic graft may be the best option in this setting.

Dr Levy: Could you describe a patient for whom augmentation is appropriate as opposed to one who needs fascial replacement?

Dr Davila: Let’s consider a 50-year-old woman who has had a previous repair for a cystocele. We open the vaginal wall, intending to perform a traditional plication and reattach the fascia to the vaginal apex. However, the fascia is of poor quality: When we place a suture, the tissue tears slightly. So we decide to plicate and place a graft on top of the tissue,

securing the graft apically and laterally, and then closing the mucosa.

Similarly, an anterior enterocele may exhibit minimal fascia, with nothing of substance to plicate, thus requiring a facial replacement technique, likely with a synthetic graft.

Quality-of-life issues and outcomes

Dr Levy: What about quality of life associated with outcomes from these procedures, particularly in comparison with standard procedures?

Dr Davila: Gynecologic surgeons have conscientiously collected and reported data for primary and recurrent cases. The French group has reported 6-year outcomes with synthetic grafts.²³ Advances in surgery differ from those in pharmaceutical therapy. Rather than emphasize prospective randomized placebo-controlled trials to describe outcomes, advances in surgery stem from published reports by expert surgeons using new approaches that may improve on outcomes.

Dr Lucente: The most relevant quality-of-life issue centers on vaginal and sexual function, including not only an evaluation of dyspareunia but also sexual identity and libido. Our data compared women who had polypropylene mesh delivered transvaginally with controls (women who have not had prolapse). Both groups have similar scores using the POP-Q/Urinary Incontinence Sexual Questionnaire. We have seen no significant negative impact on overall sexual function in our patients. We see about a 6.3% incidence of new-onset dyspareunia,²⁵ which is manageable and will sometimes spontaneously resolve over time.

Regarding postoperative outcomes measurement tools, I am most interested in those that evaluate long-term overall functional status. These women have good lower urinary tract function, and rectal and evacuation function. I am particularly concerned, especially in younger patients, about vaginal function with intercourse. The data we have collected thus far are extremely favorable. The CARE trial showed that, even with the gold-standard nonaugmented procedures, dyspareunia rates are high.²⁸

Dr Miller: This is an important point. We have increased our standards for data concerning new procedures, but we often forget that historical procedures were not subjected to similar levels of scru-

Coding issues for clinicians

Clinical question: Is it ever appropriate to bill modifier 50 on CPT 57282 for a bilateral procedure?

Answer: No. The clinical vignette submitted by ACOG in support of revising code 57282 in CPT 2005 states "Available ligamentous structures in the pelvis, which are accessible via the extraperitoneal approach through the vagina, include the sacrospinous ligament(s) and the iliococcygeus ligament(s).... To complete the vaginal colpopexy, permanent sutures are placed through these pelvic ligaments..." The code revision and valuation under RBRVS assumes this procedure to be bilateral. Therefore, no modifier -50 may be reported. Medicare will not accept a modifier -50. —MW

tiny nor did they incorporate patient self-reported outcomes. Posterior suture repair is supported by very little data concerning the rate of dyspareunia; however, in the studies that provide data on sexual function, the dyspareunia rates are often quite high. While we apply high standards to new repairs, we do not subject traditional repairs to the same scrutiny and hold them to a lower standard.

Evaluating subjective outcomes

Dr Levy: How do you compare these procedures with the standard suture repair? We know our procedures are not ideal, but we seek to make life better for our patients, avoid reoperation, and improve on what currently is available. How can we compare quality-of-life measures in standard repair procedures with sutures versus those augmented with biologics or mesh?

Dr Culligan: Such reports are emerging, but we have had the tools to make these assessments for only a few years. Particular repairs have become popular based on objective anatomic outcomes. Assessment of patient expectations is also critical. Important questions include: What specific activities can the patient no longer pursue but wants to resume? How can you help her achieve her goals and follow up so that she achieves the quality of life she desires? Still, it is exciting that we can evaluate more formalized subjective outcomes measures, which I find more interesting than the POP-Q objective anatomic outcomes.

Dr Harris: The only true randomized study that evaluated such outcomes compared a site-specific posterior-compartment repair with a porcine submucosal graft. Outcomes were measured by the Pelvic Floor

Coding issues for clinicians

Clinical question: In performing a transvaginal hysterectomy, anterior and posterior repair, and vault suspension (intra-peritoneal approach) with mesh, which are appropriate CPT codes?

- A. 58260 (Vaginal hysterectomy)
- B. 57284-51 (Paravaginal defect repair)
- C. 57283-51 (Colpopexy, intraperitoneal approach)
- D. 57250-51 (Posterior colporrhaphy)
- E. 57267 x 2 (Insertion of mesh)

Answer: Paravaginal defect repair code 57284 may be used only if this procedure—not anterior colporrhaphy—is described; mesh may not be billed. The add-on mesh code 57267 may be used only with codes 45560 or 57240 to 57265. For an enterocele repair with the vaginal hysterectomy (code 58263), intraperitoneal-approach colpopexy, considered an integral part of the repair, cannot be coded in addition. Correct coding (if a paravaginal defect repair is documented) is 58260, 57284-51, 58283-51, 57250-51, 57267 x 1. For an anterior colporrhaphy, coding changes to 58260, 57260-51 (combined anteroposterior repair), 57283-51, 57267 x 2. —**MW**

Distress Inventory short form and POP-Q. Both groups showed significant improvements.²⁰

Dr Culligan: I published the objective anatomic outcomes of mesh versus fascia lata for sacral colpopexy.²⁹ We hope to publish the subjective results such as prolapse-specific quality of life, effects on defecation, and sexual satisfaction.

Dr Levy: This is a key point: the literature has traditionally not reported quality-of-life outcomes of standard repairs made without augmentation. My experience reveals that standard procedures are accompanied by a much higher rate of dyspareunia than are the recently introduced site-specific or anatomic repairs, possibly because of our clinical experience: We have learned not to remove vaginal epithelium and that postoperative scarring is painful and difficult to manage. We still need more outcomes research for new and emerging procedures.

Higher safety standards for prolapse mesh procedures

Dr Lucente: As surgeons, our challenge is to raise the bar higher in the research we demand. But the general physician community also must become more receptive to early level III evidence. Procedures must be validated through case descriptions and case-controlled trials followed by randomized clinical trials.

The outcomes of well-designed level III clinical studies are worth sharing. It is not absolutely necessary to wait for level I studies to be completed.

Dr Miller: Documentation of safety is the key feature to making a procedure acceptable in a clinical nonexperimental setting. A well-designed case series effectively records the number of adverse events associated with a procedure. Randomized clinical trials compare outcomes associated with one procedure versus another and do not provide significant data regarding the safety of a given procedure.

Dr Levy: Level I studies in surgery are extremely difficult to perform; it is challenging to obtain Institutional Review Board (IRB) approval. We need to make clinical decisions based on the best evidence available, with basic science and training in physiology as our background and, indeed, the backbone of our endeavors. We can evaluate new technology and employ solid judgment to develop strategies that will be beneficial for our patients.

Dr Davila: Still, reading papers or even performing studies may be insufficient to understand outcomes. For example, Paul Hilton's elegant tension-free vaginal tape (TVT) versus the Burch colposuspension study reported a success rate lower than desired. Interpretations of these results differed, as he discussed in his subsequent editorial.^{30,31}

Dr Miller: Certainly, the history of the TVT procedure provides a sound basis and a model for other technologies. These investigators initially gathered case series, safety data, and medium-term postoperative adverse events and outcomes data. These findings from level II and III studies allowed the TVT procedure to be utilized clinically without being classified as experimental. More rigorous studies and comparison trials followed almost immediately. This progression makes sense: it starts with the collection of observational data and progresses rapidly to comparative trials.³¹

I wish that the “standard” suture repairs faced the same rigorous requirements. This has become an excellent model for evaluation of graft repairs. Currently, at least 9 case series are in various stages of completion; several thousand patients are being monitored under study conditions. The more difficult and costly randomized comparison trials are being planned; many are underway.

Potential complications with augmentation

Dr Levy: We can agree that there are fascial and tissue issues in patients who have prolapse and that there is often a need for augmenting these repairs. What are the potential complications? How do you counsel a patient about expectations?

Dr Harris: I find it helpful to stratify complications. A minor complication commonly consists of a slight extrusion of mesh into the vagina that can be managed conservatively. A major complication requires reoperation. I counsel my patients about 2 serious complications: the significant buttock pain that may result from passing materials—from sutures to trocars—through the sacrospinous ligament. This condition may prove debilitating and be very difficult to resolve, even after removal of materials and attempts to obliterate the coccygeal nerve. True erosion of mesh into the rectum also is a major complication.

It is essential that the patient be comfortable with the possibility of these complications, particularly when a posterior repair is required.

I also discuss the risk of dyspareunia, which I believe is probably comparable in these newer repairs and more traditional ones.

Dr Lucente: I have an open discussion to educate the patients about the procedures under consideration, based on the long-term data and information we have compiled. We provide relative reassurance by extrapolating from our TVT experience and data that approach 10 years and show no long-term sequelae.³²

Dr Davila: To quote Dr Miller, “the most dreaded complication is failure.” Our failure rates are clearly lower with augmented repairs compared with traditional repairs, even though level I evidence does not yet demonstrate this conclusively. Our use of graft materials is based on experience and our own personal outcomes. When we combine all of our data, they are convincing.

I discuss the risk of erosion. Because I primarily use biologic grafts, the graft material will, in time, be replaced by endogenous fascia. Therefore, the erosion rate is almost nonexistent. I also discuss dyspareunia, noting that this is usually temporary. I advise atrophic patients to use estrogen cream and have intercourse regularly to enable tissue to adapt to sexual activity.

Coding issues for clinicians

Clinical question: How should a physician code a vault suspension, cystocele, rectocele, and sling operation using mesh?

- A. A sling with anterior/posterior repair (CPT 57288) (Sling operation for SUI [eg, fascia or synthetic] and 57260 and 57267)
- B. Or bill a sling with a colpexy (CPT 57288 and 57282)

I think I can bill the colporrhaphy procedures with the vault suspension; however, the 2007 Ingenix OB/GYN Coding Companion states that transvaginal colporrhaphy often accompanies CPT 57282 (Colpexy, vaginal; extaperitoneal approach [sacrospinous, iliococcygeus]) and should not be reported separately. National Correct Coding Initiative edits do not prohibit those codes from being billed together. Please confirm the correct coding of this procedure.

Answer: You are correct. The National Correct Coding Initiative (NCCI) does not bundle the colporrhaphy codes with either sling procedures for SUI or vaginal vault suspension; per the ACOG Procedural Coding Manual, colporrhaphy codes are reported in addition. The Ingenix OB/GYN Coding Companion, however, is a guide; some payers may bundle colporrhaphy codes when a vaginal vault suspension is performed. This information may relate to the clinical vignette submitted in 2005 to the CPT Editorial Panel for revision to code 57282, describing presence of cystocele, rectocele, and enterocele with a suspension of the vaginal apex and repair of the cystocele, rectocele, and enterocele. Since the colporrhaphy codes are not bundled under NCCI rules and CPT does not prohibit this code combination, I advise reporting all procedures performed, unless the payer specifically includes them. Document clearly: Did mesh accompany the sling procedure? Did it augment posterior and anterior compartment defects? If the former, correct coding is 57288, 57260-51, 57282-51. If the latter, add 57267 x 2. —MW

My referral patients typically present with small mesh erosions at the suture line that occur relatively early in the postoperative course. Complex erosions occur in more remote locations and are associated with an inflammatory response and result in granulated tissue.

With the currently used graft materials—large pore monofilament polypropylene graft—erosions are easier to manage than those that occurred with previous generations of materials. As we have improved in our skills and approaches, the science of graft materials also has improved.

Dr Miller: Unprovoked vaginal pain is the most serious complication of grafted procedures, followed by dyspareunia. The former is more serious because it is difficult to correct when it occurs. Fortunately,

Coding issues for clinicians

Clinical question: How should a rectocele, enterocele, and sacrospinous ligament fixation be coded?

Answer: Coding for the rectocele repair depends on procedure documentation. The typical repair via posterior colporrhaphy is represented by code 57250. Code 45560 (Repair of rectocele [separate procedure]), is listed in “Digestive System, Rectum, Repair” and may have bundling issues. It represents a procedure commonly performed by general surgeons for fecal incontinence and should not be used by urogynecologists and gynecologic surgeons to report rectocele repair via colporrhaphy.

Two codes for an enterocele repair are: 57268 (Repair of enterocele, vaginal approach [separate procedure]) and 57270 (Repair of enterocele, abdominal approach [separate procedure]). Either can be billed in combination with a posterior colporrhaphy (57250). Sacrospinous ligament fixation (57282) creates a complication. Enterocele repair is considered integral to extraperitoneal colpexy; as such, either code will be denied as included. Therefore, the only coding option is 57250, 57282-51. If mesh is used, the coding solution is 57250, 57282-51, 57267 x 1. Mesh is reported only once for the posterior compartment repair, whether it is placed for a rectocele or rectocele and enterocele repair. —MW

Coding issues for clinicians

Clinical question: Which CPT code should be used to report revision of a vaginal graft?

Answer: Two codes address this situation: 57295 (Revision [including removal] of prosthetic vaginal graft, vaginal approach) added to CPT in 2006, and 57296 (Revision [including removal] of prosthetic vaginal graft; open abdominal approach) added to CPT in 2007. These codes are reported whether the graft is revised, for instance because of infection or erosion of the material, or the entire graft is removed. —MW

within the available case series, the rates of these complications are low. Hematomas are uncommon, and they can occur as with any pelvic surgical procedure.

Mesh exposure is overdiscussed, primarily because it is easily addressed. Surgeons become highly sensitized to the possibility of mesh erosion, in large part because they fear they will be blamed for the condition.

Dr Levy: It might be appropriate to use 2 different terms for these complications: minor erosion of graft material at the suture line versus true erosion into the bladder or rectum.

Dr Miller: Perhaps the term extrusion should be avoided because it implies a known mechanism of action. The term vaginal exposure of graft materials accurately describes what we observe. The term erosion can be accurately applied to more serious visceral penetration.

Dr Davila: We are validating a classification system through the International Urogynecological Association, in which we separate types of healing abnormalities into simple and complex. The system defines a “simple” healing abnormality as one that occurs at the suture line within 12 weeks after surgery, without granulation tissue and limited to the vagina. “Complex” healing abnormalities (there is no accepted definition for extrusion, erosion, etc) are associated with granulation tissue that may not be at the suture line and may present at locations more remote from the surgical site, after more than 12 weeks and may involve tissues adjacent to the vagina (eg, the bladder and rectum).³³

Infection prevention and management

Dr Culligan: Reports from other specialties that implant permanent material—cardiothoracic and general surgery, for instance—suggest that early complications may be related to subclinical infections. Late complications (after 12 weeks) are often mechanical. We operate in a clean contaminated space. Surgical scrubs and prophylactic antibiotics may contribute to our low complication rates.

Dr Miller: We rarely see signs of even low-grade infection; therefore, it is likely that these incisional exposures are biomechanical or related to simple wound breakdown. Little histological evidence suggests an infectious origin for vaginal mesh exposure.

Dr Levy: When we implant semipermanent materials, what rules for antibiotic prophylaxis should we follow?

Dr Culligan: The literature suggests that 1 dose of a cephalosporin within 24 hours prior to surgery is sufficient. Additional administration may increase surgical site infection rate as much as 10-fold. Further, scrubbing with chlorhexidine seems to create a cleaner surgical field.

Dr Lucente: Betadine is ineffective when wet, it cannot sterilize the vagina. For that reason, we prefer to use diluted chlorhexidine as a prep. Strategies for

reduction of infection risk include making the smallest possible incision and irrigating copiously, effectively debriding the surgical site. We have enjoyed an extremely low rate of healing abnormalities in our series of mesh-augmented patients. The French group also demonstrated the importance of uterine preservation, which preserves blood supply to the upper third of the vagina.²³

Reports from MAUDE

Dr Miller: The MAUDE [Manufacturer and User Facility Device Experience] database skews toward the reporting of technology-related complications. Most important, it completely lacks a usable denominator. The reason we panel members do not report any hemorrhage is that it is really a very uncommon complication and rarely occurs within the typical size case series with which we work. It should also be noted that rates of hemorrhage associated with such common gynecologic procedures such as hysterectomy (either vaginal or abdominal), cesarean delivery, or dilation and curettage, are typically not reported. If they were reported in the MAUDE database, their incidence would exponentially surpass that seen in mesh repair procedures. Also, newer procedures receive more reporting. As the procedure “ages,” the tendency to report declines.

Dr Davila: In the MAUDE database, hemorrhage is the most commonly reported complication. Interestingly, the participants in this panel report no significant increased risk of hemorrhage.

Physician education

Dr Levy: What are the concerns related to physician training or the learning curve that we should address?

Dr Davila: That’s been an issue. The top-tier surgeons have been trained. What should be required for physicians who want to learn these procedures? First, they must be very comfortable with both the anatomy and traditional repairs. While it is tempting to perform these procedures, I caution surgeons that they should perform these procedures only if they intend to focus their practices around them.

Dr Lucente: It is a constant challenge to identify the surgical skill set needed to perform these procedures safely and effectively. While industry is to be commended for giving us training sessions, cadaver labs,

Coding issues for clinicians

Clinical question: Does the code 57284, paravaginal defect repair, apply to the laparoscopic approach? Since a cystocele is being repaired, can we also use the mesh add-on code?

Answer: The paravaginal defect repair is commonly performed through an abdominal incision, but it can also be performed vaginally. Code 57284 represents either approach. However, when a procedure is performed laparoscopically, under CPT rules, it cannot be reported with a procedure code representing an open or vaginal procedure. There is no specific code for a laparoscopic approach; an unlisted code must be billed for this procedure. The closest unlisted code is 49329, unlisted laparoscopic procedure, abdomen, peritoneum, omentum. While sutures are most often used to repair a paravaginal defect, some surgeons use mesh to augment this repair. The add-on mesh—with any approach—may not be separately billed with a paravaginal defect repair. ACOG and AUGS have recently requested the addition of a laparoscopic paravaginal repair code to CPT. Revisions of the paravaginal repair codes have been published for 2008. —**MW**

proctorships, and preceptorships, the buck stops with us. I’m disappointed in the due diligence of our specialty in policing our credentialing privileges. Ideally, the physician leaders, the chairpersons, division chiefs, and directors of medical staffs will refocus, reenergize, and recommit to this venture. Only these individuals can guide the process of identifying the physicians who should perform these procedures, although this is not an easy task.

Data collection and reporting by surgeons

Dr Levy: How much data are being collected? What do we see in terms of long-term registries? Industry-sponsored registries?

Dr Davila: There are a number of registries, and I participate in several of them. We also maintain our own database.

Dr Lucente: At our center we have a database of over 750 patients.

Dr Harris: AUGS [American Urogynecologic Society] has developed a self-reporting registry that may be a very reasonable way for gynecologists to report outcomes in a central registry.

These interventions represent positive options for patients, and we expect continued improvements, both in the procedures themselves and in the development of kits that bring convenience to the surgeons.

Dr Miller: I am a member of the new AUGS presiden-

tial task force on graft usage. Our primary mission is to develop an Internet-based registry for the evaluation of graft complications. Our biggest challenge is to make the registry sufficiently large to capture uncommon complications, yet maintain the integrity of the denominator, so that we know the total number of patients who have undergone procedures in enrolled institutions.

Dr Davila: The volume of mesh repairs speaks for itself in terms of its utility and success and its association with better outcomes.

Conclusions

Graft materials have proven beneficial to augment weakened tissue, particularly in patients who experience recurrence. As the population ages and the demand for pelvic floor repairs increases, the use of

graft materials will continue to develop and play an important role in the repair of pelvic floor prolapse.

Clearly, the specialty continues to evolve, with an emphasis on quality-of-life outcomes and advances to meet the needs of an aging, but highly active, population of women who want to maintain their desired lifestyles. ■

Dr Levy is a consultant to American Medical Systems, Conceptus, and GyneCare, and is on the speakers' bureau of American Medical Systems. **Dr Culligan** receives grants and research support from CR Bard Inc, Ethicon Women's Health and Urology, Novasys Medical Inc, and Solace, and is a consultant to CR Bard Inc, Intuitive Surgical, and Mediflex. **Dr Davila** receives grants and research support from Adamed Inc, American Medical Systems, Astellas Pharma US Inc, and Synovis Life Technologies Inc; is a consultant to Adamed Inc and American Medical Systems; and is on the speakers' bureaus of Adamed Inc, American Medical Systems, and Astellas Pharma US Inc. **Dr Harris** reports no financial relationships. **Dr Lucente** receives grants and research support from American Medical Systems, CR Bard Inc, and Ethicon Women's Health and Urology, and is a consultant to CR Bard Inc and Ethicon Women's Health and Urology. **Dr Miller** receives grants and research support from and is a consultant to Boston Scientific Corporation and Ethicon Women's Health and Urology. **Ms Witt** is affiliated with Boston Scientific Corporation.

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