

IN THIS ARTICLE

- What is the best operation for advanced prolapse? Page 77
- Are unaugmented repairs doomed to fail?

Page 78

- Are kits the new standard? Page 80
- The Golden Rule of surgery Page 84

CONTROVERSIES IN PELVIC SURGERY

Pelvic organ prolapse: Which operation for which patient?

The stream of new technologies seems never-ending. That's part of the problem.

he more numerous the choices of surgical techniques for pelvic organ prolapse, the less agreement there is on which operation is best. Further complicating the picture is the industry's push to consider augmentation with synthetic or biologic materials on an almost routine basis.

Few scientific comparisons of the various approaches have been performed, however. To help shed some light on surgical decision-making, we convened an expert panel to review published data and explore our experience with selected procedures.

What to consider before choosing a procedure

- A woman's desires regarding sexual activity are a critical piece of information, just as are her general health and history of pelvic surgery.
- It also helps to know which symptoms of her prolapse and related pelvic floor disorders she finds most bothersome.

KARRAM: When a woman with symptomatic Employer pelvic organ prolapse desires surgical correction, what factors do you explore before deciding which procedure to use?

BRUBAKER: I make an effort to determine the woman's readiness to undergo surgery and her expectations for it, as well as any concomitant pelvic floor or medical/surgical conditions.

Other important factors that I consider include her pelvic surgical history—specifically, whether she has undergone earlier continence and/or prolapse repairs—and the presence of any materials in the proposed surgical site, especially foreign bodies that may limit dissection planes or have eroded into pelvic viscera.

I also consider her desire (or lack of it) for sexual activity, and her preferred route of surgical access.

Patient's lifestyle should sway surgical decision

PARAISO: I take into account her age and stage of prolapse; vaginal length; innervation of the pelvic floor; hormonal status; desire for uterine preservation and coitus; symptoms of sexual, urinary, or bowel dysfunction; and any comorbidities that influence her eligibility for anesthesia or chronically increase intra-abdominal pressure. Connective tissue disorders are also important, as are any coexisting medical conditions that impede healing.

Lifestyle has an impact, too, especially if she regularly performs heavy manual labor.

After assessing the patient's history and performing an examination, I target the prolapse and functional symptoms and correlating anatomic defects that exacerbate her quality of life. I tailor her surgical therapy in order to correct her symptoms and minimize compensatory defects and de novo dysfunction.

Ask her to prioritize her complaints

SHULL: I have the patient list her complaints in order of their severity and impact on her lifestyle.

Next, I complete a detailed pelvic exam, including use of a mirror to demonstrate the findings to her. If appropriate, I test bladder or bowel function.

At that point, we discuss what I think

are appropriate options, although in some situations I may not be able to treat all her complaints with equal success.

KARRAM: I think prioritizing the patient's complaints is a good idea. My foremost aim is to determine what the woman is most bothered by. If it is prolapse symptoms such as pressure and tissue protrusion, with no functional derangements, I try to ensure that my surgical repair provides durable support but does not create de novo derangements such as stress incontinence. So, for example, I try to determine whether she has preexisting stress incontinence that is masked by the prolapse.

Correlation between prolapse and dysfunction can be weak

Obviously, if the patient has many functional derangements associated with the prolapse symptoms, the preoperative consultation becomes much more complicated. Although the complexity may not change my surgical approach, I think it is important for the patient to understand that the correlation between anatomic

OUR EXPERT PANELISTS

- Moderator Mickey Karram, MD, Director of Urogynecology, Good Samaritan Hospital, Cincinnati, and Professor of Obstetrics and Gynecology, University of Cincinnati.
- I Linda Brubaker, MD, MS, Assistant Dean of Clinical and Translational Research, and Professor and Director, Division of Female Pelvic Medicine and Reconstructive Pelvic Surgery, Departments of Obstetrics & Gynecology and Urology, Loyola University Health System, Chicago.
- Marie Fidela Paraiso, MD, Co-Director of Female Pelvic Medicine and Reconstructive Surgery, Department of Obstetrics and Gynecology and the Urological Institute, The Cleveland Clinic, Cleveland, Ohio.
- Bob L. Shull, MD, Vice Chairman, Department of Obstetrics and Gynecology, and Chief, Section of Female Pelvic Medicine and Pelvic Reconstructive Surgery, Scott & White Health Care System, Temple, Tex.

FAST TRACK

"My foremost aim is to determine what the woman is most bothered by"

-Mickey Karram, MD

descent and the functional derangement may not be very good.

As previously mentioned, I make a point to ask about sexual function. If the woman is elderly and has no intention of being sexually active again, I may consider a very tight or obliterative repair because these are much less invasive than conventional repairs.

Is one surgical route superior?

 There is no consensus among experts as to the preferred route of surgery for advanced pelvic organ prolapse.

KARRAM: Numerous vaginal, abdominal, and laparoscopic procedures have been described. Which route do you prefer?

BRUBAKER: I don't prefer any laparoscopic procedures, but I am flexible about vaginal or abdominal approaches.

Among vaginal procedures, I prefer uterosacral suspension at the time of hysterectomy, or the Michigan modification of sacrospinous ligament suspension when the patient has already undergone hysterectomy.

As for abdominal procedures, I prefer sacrocolpopexy with Mersilene mesh.

In my hands, these reconstructive procedures give predictable results that allow me to appropriately counsel patients preoperatively.

KARRAM: Why do you dislike the laparoscopic approach?

BRUBAKER: It is not a matter of "dislike," but a matter of getting the most reliable result for my patient. When scientific evidence from well-done clinical trials demonstrates the equivalency of laparoscopic procedures, I fully anticipate incorporating them into my practice. Similarly, the novel use of the robot may be useful in reconstructive pelvic surgery.

Laparoscopic repair can produce good results in the right hands

PARAISO: I prefer the laparoscopic and vaginal routes. In fact, I have converted

most abdominal procedures to laparoscopic access. I have nearly 10 years of experience with laparoscopic sacrocolpopexy, with excellent success.

My colleagues and I did a cohort study that showed equal cure rates for this procedure, compared with open sacro-colpopexy. I also have had great success with the vaginal route when performing uterosacral vaginal vault suspensions.

Patients are referred to me or seek me out specifically for minimally invasive procedures, so the majority of operations I perform are laparoscopic procedures with or without vaginal procedures, or vaginal procedures alone.

Vaginal approach is possible in high percentage of cases

SHULL: I probably perform 98% of reconstructive cases transvaginally. If the woman has urinary incontinence as well as prolapse, I usually perform a midurethral sling procedure along with the repair.

KARRAM: I do roughly 90% of prolapse repairs transvaginally. For the last 6 to 8 years, my colleagues and I have utilized a high uterosacral vaginal vault suspension to support the vaginal cuff. We do so in conjunction with a modified internal McCall-type procedure to obliterate the cul-de-sac. We also do site-specific anterior and posterior colporrhaphy as needed, and a synthetic midurethral sling if the patient has stress incontinence.

In very young patients (under 35 years of age) or those who have substantial recurrent prolapse or a prolapsed foreshortened vagina, we consider abdominal sacrocolpopexy with synthetic mesh as our primary operation. In such cases, we commonly perform retropubic repair for incontinence and paravaginal defects, as well as posterior repair and perineorrhaphy.

I have very little experience with laparoscopic prolapse repairs.

Abdominal sacrocolpopexy is anatomically superior

KARRAM: Dr. Brubaker, you just chaired a consensus panel on pelvic organ prolapse

FAST TRACK

"I probably perform 98% of reconstructive cases transvaginally"

-Bob L. Shull, MD

for the International Consultation on Incontinence. This panel reviewed all the published literature on the topic. What conclusions did it reach about the various surgical procedures for pelvic organ prolapse? BRUBAKER: The "big picture" findings were that abdominal sacrocolpopexy is anatomically superior to the other procedures, but carries a higher rate of shortterm morbidity than transvaginal procedures. Since that panel, a review on sacrocolpopexy by Nygaard et al² highlighted the strengths, weaknesses, and uncertainties of this procedure.

We found no indications for routine use of ancillary materials when performing primary transvaginal repairs.

What is the best operation for advanced prolapse?

• The best procedure depends on the patient's health, type and extent of prolapse, and sexual activity. Surgical history also is key.

KARRAM: Let's say a 60-year-old woman with advanced, symptomatic, primary pelvic organ prolapse presents to you for surgical treatment. The findings include posthysterectomy vaginal vault prolapse with a large cystocele, large rectocele, and an enterocele. What operation would you perform?

SHULL: I would probably elect a transvaginal approach using the uterosacral ligaments to suspend the cuff and reapproximate the connective tissue of the anterior and posterior compartments. My colleagues and I described this technique.3 **PARAISO:** If the patient is physically and sexually active and willing to undergo synthetic graft implantation, I would perform laparoscopic sacrocolpopexy, especially if previous transvaginal apical suspension has failed, if she has a foreshortened vagina, or

Check for defecatory dysfunction

if she has denervation of her pelvic floor.

If it is necessary for her to manually digi-

tate her vagina or splint her perineum to defecate, I would perform a rectocele repair and perineorrhaphy.

If she is not a candidate for laparoscopic or abdominal surgery because of a history of multiple procedures for inflammatory bowel disease or severe adhesions, has not had a previous transvaginal apical suspension, and has intact pelvic floor innervation, I would perform either uterosacral vaginal vault suspension or sacrospinous ligament suspension with concomitant anterior and posterior repair.

I would consider offering this patient a tension-free vaginal mesh "kit" procedure (with synthetic mesh) if she:

- has failed previous vaginal procedures,
- has multiple comorbidities,
- is not a candidate for laparoscopic or abdominal surgery,
- desires to remain sexually active, and
- is willing to use and has no contraindications to intravaginal estrogen therapy. If she does not wish to remain sexual-

ly active and is not a good operative candidate, I would offer colpectomy and colpocleisis with perineorrhaphy.

Which circumstances pose special challenges?

 Apical suspension is a critical factor in success and durability of the surgery.

KARRAM: Which segment of the pelvic floor do you find most challenging when correcting advanced pelvic organ prolapse? SHULL: My colleagues and I have reported our experience with several techniques of vaginal repair for prolapse, including sacrospinous ligament suspension, iliococcygeus fascial suspension, uterosacral ligament suspension. When we analyzed specific sites in the vagina, the anterior compartment always had the greatest percentage of persistent or recurrent loss of support.

Our best success has been with uterosacral ligament suspension.

CONTINUED

FAST TRACK

"If you get the apex up solidly, you're usually home free"

-Linda Brubaker, MD



▶ Pelvic organ prolapse: Which operation for which patient?

Vaginal apex is key to success

PARAISO: I also find the anterior segment challenging. However, if I am able to suspend the vaginal apex well, management of the anterior vaginal wall is less challenging. The anterior wall fails because treatment of high transverse cystoceles and anterior enteroceles (less commonly seen) depends on the apical suspension. Many of these defects go untreated because they are often not detected.

BRUBAKER: I agree with Dr. Paraiso. If you get the apex up solidly, you're usually home free. **KARRAM:** Yes. If one can get good, high, durable support to the apex, the other segments of the pelvic floor are much more likely to endure.

Are unaugmented repairs doomed to fail?

- Despite claims to the contrary, reoperation rates are low for most conventional repairs.
- Surgeons may be tempted to adopt graft augmentation techniques to keep up with "Dr. Jones."

KARRAM: As you know, there has been a recent push to consider augmenting most pelvic organ prolapse repairs with either biologic or synthetic mesh. This approach is based on a perception that conventional repairs without augmentation inevitably will fail. Do you agree with this perception? SHULL: Not based on my own experience. Mesh has been effectively and safely used for midurethral slings and abdominal sacrocolpopexies, but there are not enough data on the use of allografts, xenografts, or meshes to be able to counsel a patient properly about their safety, efficacy, or long-term effects.

PARAISO: I agree that this perception is being promoted, prompting many physicians to adopt graft augmentation techniques to keep up with "Dr. Jones" or to offer their patients "cutting-edge" treatment. Despite the fact that conventional procedures are often described as having high failure rates, the reoperation rates in most series are low. Nevertheless, augmen-

Putting Research into Practice. www.hormonecme.org tation with biologic grafts has been widely adopted without prior investigation or data.

Traditional and site-specific repairs versus graft augmentation

My colleagues and I just presented a manuscript on traditional posterior colporrhaphy, site-specific rectocele repair, and site-specific repair with graft augmentation using a porcine small intestinal submucosa bioengineered collagen matrix.

The anatomic cure rate was substantially higher in the traditional and site-specific groups when compared with the graft augmentation arm, with cure rates of 86% and 78% versus 54%, respectively (P=.02).⁴

Currently, my indications for a meshaugmented prolapse repair are:

- Nonexistent or suboptimal autologous tissue
- Need to augment weak or absent endopelvic tissue
- Connective tissue disorder
- Unavoidable stress on the repair (eg, chronic lifting, chronic obstructive pulmonary disease, chronic straining to defecate, obesity)
- Need to bridge a space such as sacral colpopexy
- Concern about vaginal length or caliber
- Denervated pelvic floor
- Recurrent prolapse

Surgeons should not believe that graft augmentation compensates for surgical mediocrity or patient risk factors for pelvic organ prolapse.

—Mickey Karram, MD

The key to success: Maintain the vaginal axis

KARRAM: I don't believe all traditional repairs are bound to fail. Many factors play into recurrent prolapse. I think most people overlook the fact that the vagina is very sensitive to its axis. Any operation that alters the vaginal axis will seriously weaken the vagina opposite the distorted axis.

For example, we know that sacrospinous ligament suspension retroverts the vagina and sets women up for recurrence or development of anterior vaginal wall prolapse. Another example is a Burch colposuspension that anteverts a portion of the vagina and sets patients up for posterior vaginal wall defects in the form of a rectocele and enterocele.

Too much simplification

I also think surgeons and device manufacturers have attempted to simplify what, in reality, is a very complicated clinical picture. So many factors are involved in the identification and appropriate utilization of support structures for a durable prolapse repair.

Since Dr. Shull's popularization of a high uterosacral suspension, we have had very good long-term success with transvaginal vault repair. Also, over time I have realized that it is possible to mobilize a substantial amount of durable fascial tissue—which is nothing more than the muscular lining of the vagina—to appropriately support the anterior and posterior vaginal walls.

That said, the results are far from perfect. I would estimate our anatomic failure rate at 15% to 20% over the long term.

Does augmentation add complications?

When it comes to mesh, we have to ask: Is it truly going to increase durability? If it is, is that going to be at the expense of a new set of complications such as mesh erosion or extrusion and dyspareunia?

The only way to answer these questions is with a randomized trial with long-term follow-up. At this time, such data are not available.

Are tension-free repair kits the wave of the future?

 It's not yet time to make these kits the standard, although preliminary data are promising.

KARRAM: Do you think the synthetic mesh repairs now being promoted as tension-free repairs utilizing numerous industry-

CONTINUED

FAST TRACK

"Any operation

that alters the

vaginal axis will

seriously weaken

the vagina opposite

the distorted axis"

created "kits" will be the future of prolapse repair?

BRUBAKER: I hope not.

KARRAM: At present, I would say the answer to that question is "no." However, I was very reluctant to accept synthetic midurethral slings, and they have turned out to be the standard of care.

SHULL: These products are the future for surgeons who allow industry to dictate their practice styles. For those of us who are more skeptical, we will change only after there is adequate scientific information to do so.

Though unproven, kits do have advantages

PARAISO: I agree. Even so, in many ways, these kits make sense. Operative time is greatly reduced and incisions are small, thus offering the advantage of minimally invasive procedures. Preliminary data at 6 months show excellent anatomic outcomes. However, the graft extrusion rate is high with the kit procedures, compared with existing evidence on synthetic mesh erosion associated with abdominal and laparoscopic sacral colpopexy.

In addition, current synthetic materials are not ideal. Long-term sequelae of transvaginal implantation of these meshes are not known. Nor do we have long-term data on sexual function.

By and large, these procedures are blind and involve the transobturator and transgluteal (ischiorectal fossa) spaces—uncharted waters for many gynecologic surgeons. Further, many gynecologic surgeons lack extensive training or experience in sacrospinous ligament suspension, iliococcygeus fascia suspension, and vaginal paravaginal defect repair, which are prerequisites for the kit procedures.

Matching the kit procedure to the patient

As for patient selection, women for whom previous anterior repair (with or without biologic graft), paravaginal defect repair, and apical suspension have failed, and who continue to have asymptomatic anterior vaginal wall prolapse are the best candidates for anterior kit procedures. The best candidates for posterior and apical segment kit procedures are women in whom transvaginal apical suspension has failed, and who are not suited for laparoscopic or abdominal procedures.

The only impediments to widespread adoption of these procedures for years to come will be adverse events or technology so advanced it makes gene modification possible, rendering surgery obsolete.

KARRAM: I think we need better and longer follow-up. Most of the surgeons currently using these procedures are proponents of the repairs, in my opinion, but until results from comparative trials become available, we won't really know how they compare to conventional repairs.

Bringing up the next generation

 Residents need as much hands-on experience as possible, including cadaveric dissections, urodynamic labs, and urogynecologic clinics even virtual-reality models.

KARRAM: How do we best train residents in the appropriate evaluation and surgical management of these very common pelvic floor disorders?

BRUBAKER: Carefully and ethically. Encourage them to be good consumers of surgical literature and to resist the urge to constantly demonstrate the "latest and greatest" until we have solid evidence.

PARAISO: Residents can learn from discussions of surgical indications prior to pelvic reconstructive procedures in which they are involved, attendance at urogynecologic clinics, urodynamic lab rotations, and study of urogynecologic learning modules and current clinical textbooks that focus on these surgeries.

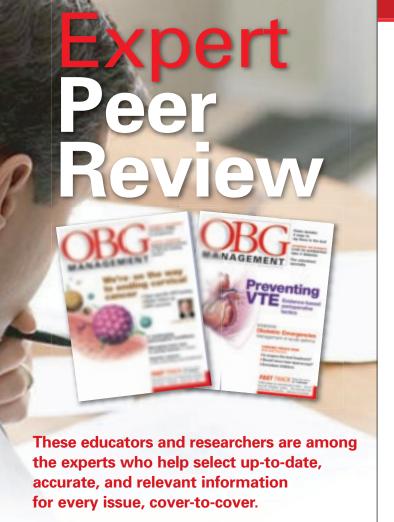
Given the decrease in resident work hours, which translates to fewer cases, cadaver labs are also helpful.

CONTINUED

FAST TRACK

"Until trials are done, we won't really know how the kits with synthetic mesh compare with conventional repairs"

—Mickey Karram, MD



Harold Bivins, MD

Savannah, Ga

Andrew I. Brill, MD Chicago, III

Brian C. Brost, MD

Rochester, Minn

Haywood Brown, MD

Durham, NC

James Burke II, MD

Savannah, Ga

David Byck, MD

Savannah, Ga

Frank Chervenak, MD

New York, NY

William A. Cliby, MD

Rochester, Minn

Alan H. DeCherney, MD

Bethesda, Md

Philip J. DiSaia, MD

Orange, Calif

Patrick Duff, MD

Gainesville, Fla

Abimbola O. Famuyide, MD

Rochester, Minn

Sebastian Faro, MD, PhD

Houston, Tex

John Gebhart, MD

Rochester, Minn

Martin L. Gimovsky, MD Newark, NJ

Mark H. Glasser, MD

San Rafael, Calif

Amos Grunebaum, MD

New York, NY

Steven Hockstein, MD

New York, NY

Thomas M. Julian, MD

Madison, Wis

Christopher Klingele, MD

Rochester, Minn

Robert Kovac, MD

Atlanta, Ga

Franklin Loffer, MD Tucson, Ariz

Anthony A. Luciano, MD

New Britain, Conn

Dev Maulik, MD, PhD

Mineola, NY

Ramon V. Meguiar, MD

Savannah, Ga

William H. Parker, MD

Santa Monica, Calif

JoAnn Rosenfeld, MD

Odenton, Md

Amy Rosenman, MD

Santa Monica, Calif

Gerard Roy, MD

New Britain, Conn

Hyagriv Simhan, MD

Pittsburgh, Pa

Anthony R. Scialli, MD

Alexandria, Va

Stephen B. Young, MD

Worcester, Mass

Carl W. Zimmerman, MD

Nashville, Tenn

▶ Pelvic organ prolapse: Which operation for which patient?

Virtual-reality models are being developed and will be available this decade.

Golden rule of surgery: Do unto others...

SHULL: I would advise residents to treat every woman as you would your wife, mother, sister, daughter, or yourself. That may mean using a consultant for some of your patients.

Those of us who are teachers must use all available resources, including didactic instruction, video clips, cadaver dissection, simulators, and hands-on supervision in the operating room.

Those who are learning new procedures must be willing to accept constructive comments and critically evaluate their own skills.

KARRAM: I think it is important to continue training residents in the basics of pelvic floor support and anatomy. If the future involves passing needles into blind spaces, the outcomes will be disastrous if the surgeon is not comfortable with the relevant anatomy.

Secondly, surgeons should maintain their skills in proven operations such as abdominal sacrocolpopexy and sacrospinous ligament suspension. As we gain experience and long-term data, other procedures can be added more easily if we have a good understanding of the conventional repairs. ■

REFERENCES

- 1. Paraiso MFR, Walters MD, Rackley RR, Melek S, Hugney C. Laparoscopic and open sacral colpopexies: a cohort study. Am J Obstet Gynecol. 2005;192:1752-1758.
- 2. Nygaard IE, McCreery R, Brubaker L, et al. Abdominal sacrocolpopexy: a comprehensive review. Obstet Gynecol. 2004;104:805–823.
- 3. Shull BL, Bachofen CG, Coates KW, Kuehl TJ. A transvaginal approach to repair of apical and other associated sites of pelvic organ prolapse using uterosacral ligaments. Am J Obstet Gynecol. 2000;183:1365-1374.
- 4. Paraiso MFR, Barber MD, Muir TW, Walters MD, Rectocele repair: a randomized trial of three surgical techniques including graft augmentation. Am J Obstet Gynecol. 2006 [in press].

Dr. Karram receives grant/research support from American Medical Systems, Carbon Medical, Gynecare, and Pfizer; is a consultant to Gynecare; and is a speaker for Gynecare, Indevus, and Ortho-McNeil. Dr. Paraiso has received grant/research support from American Medical Systems and Organogenesis Inc.; and is a consultant to American Medical Systems, and Ethicon Women's Health and Urology. Dr. Brubaker and Dr. Shull report no financial relationships relevant to this article.