

“SYNTHETIC FULL-LENGTH MIDURETHRAL SLINGS REMAIN THE STANDARD OF CARE FOR SUI SURGERY”

CHARLES W. NAGER, MD (GUEST EDITORIAL; NOVEMBER 2012)

Why patients no longer trust urogynecologists

When it comes to the surgical use of mesh, a few things weigh heavily on my mind and heart. The issue is not mesh itself—it is trust. Our patients have lost faith in us, and it is our fault. One surgeon who has experience in the treatment of pelvic organ prolapse and incontinence has been humbled by failures associated with inherent weakness in some patients’ supporting connective tissue. It is these failures that led to the use of grafts.

It is our responsibility to evaluate the treatments we offer our patients to ensure the best outcomes. Instead, we have relied on the Food and Drug Administration (FDA) to be the gatekeeper. That agency has failed us as well as our patients. Since the 2004 approval of vaginal mesh for use in reconstructive pelvic surgery, the FDA’s 501(k) predicate device loophole has led to the approval of dozens of products based solely on their similarity to already-approved devices. The lack of a requirement for device-specific safety and efficacy data, along with aggressive promotion by industry, have led to widespread, indiscriminate use of mesh—and to poor outcomes. The FDA safety communication of 2011 was too little, too late.

Now the furor over vaginal mesh procedures in the media and the legal arena has led to understandable fear among patients, who worry that we may not necessarily perform procedures of benefit to them. Our patients also worry that the surgeries we perform will leave them with potentially



NOVEMBER 2012

permanent problems that impair their daily activities and their ability to be intimate with their partner. The scope of this fear was brought home to me recently when a continent woman who had undergone placement of a tension-free pubovaginal sling 9 years earlier requested that her sling be removed for fear that it would cause cancer.

I offered this patient my best evidence-based opinion, explaining that midurethral slings are different from the vaginal mesh featured in legal recruitment commercials and that mesh has no association with cancer. I also informed her that complete removal of her sling would be difficult—if not impossible—and carry a significant risk of complications. I concluded by telling her that I believed it would be unethical to put her through such an ordeal.

The woman was unhappy with my counseling and left when I offered to refer her to another provider. It was then that I realized that, for the first time in my career, I was unable to effectively counsel a patient referred to me for prolapse repair, thanks to a barrage of contradictory information on the airwaves.

Although it is obvious to urogynecologists that the use of mesh in pubovaginal slings and abdominal sacrocolpopexies is fundamentally safe, according to substantial, reliable data, that fact doesn’t matter. To our patients, mesh is mesh.

James P. Theofrastous, MD
Asheville, North Carolina

How I counsel patients about surgical mesh

I offer comprehensive educational information on the options, from native tissue repair and use of biologic grafts to the placement of synthetic mesh. I draw from Cochrane data in my counseling, and I provide patients with information from the American Urogynecologic Society and the Institute of Aesthetic Plastic and Reconstructive Surgery—and I give them time to peruse the materials before they come back to finalize scheduling.

Michael Makii, MD
Macon, Georgia

FDA’s “13 questions” form the basis of my counseling

When I talk to patients about vaginal mesh, I answer in detail the 13 questions the FDA has recommended that patients ask their doctors.¹ I also provide them with a document that contains these questions and my answers as part of my surgical informed consent, and I have them sign that consent and a copy of the FDA communication as well.

Drew Cassidenti, MD
Laguna Niguel, California

Reference

1. US Food and Drug Administration. FDA Safety Communication: Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse. July 13, 2011.



“UPDATE: OSTEOPOROSIS”

STEVEN R. GOLDSTEIN, MD
(NOVEMBER 2012)

FRAX, too, has limitations

Dr. Goldstein recommended annual use of the FRAX tool (WHO fracture risk assessment tool) in patients with osteopenia to determine when pharmacologic intervention is warranted, suggesting that it should be the “standard of care.” He also advised against follow-up dual-energy x-ray absorptiometry (DXA) imaging at any arbitrary interval, but urged that the interval be based on FRAX findings.

I am unaware of any randomized, controlled trial demonstrating that women who have low bone mass (femoral neck T-score above -2.5 without vertebral fracture) and a high FRAX score benefit from anti-resorptive agents. A recent post-hoc analysis demonstrated that women who have such characteristics do not benefit from alendronate for the reduction of nonvertebral, clinical, or major radiographic fractures.¹ The results of this analysis suggest that alendronate benefits only patients with a femoral neck T-score of -2.5 or below (compared with patients with a femoral neck T-score above -2.5).

For this reason, I do not believe that we can rely on annual FRAX assessment alone in women with low bone mass to determine who would benefit from therapy. For menopausal patients with osteopenia, if a follow-up DXA scan after several years demonstrates a loss in bone density that exceeds the least significant change, one might consider a workup for secondary causes of bone loss and consider medical therapy.

Frank Bonura, MD
Smithtown, New York

Reference

1. Donaldson MG, Palermo L, Ensrud KE, Hochberg MC, Schousboe JT, Cummings SR. Effect of alendronate for reducing fracture by FRAX

score and femoral neck bone mineral density: the Fracture Intervention Trial. *J Bone Miner Res.* 2012;27(8):1804-1810.

“YOUR AGE-BASED GUIDE TO COMPREHENSIVE WELL-WOMAN CARE”

ROBERT L. BARBIERI, MD (OCTOBER 2012)

Seeking clarification of Pap test interval

I believe that recommendations regarding the Pap test interval have changed, requiring testing every 5 years rather than every 3 years in low-risk women. Also, aren't we supposed to give patients the option of a clinical breast exam rather than perform it routinely?

Jerome Klobutcher, MD
Ashland, Ohio

Well-woman guide is an excellent resource

Thank you for the excellent article! It will greatly aid me in providing standard-of-care necessities for each age group.

Kelly Shrum, DO
Monticello, Arkansas

» Dr. Barbieri responds

I thank Dr. Klobutcher and Dr. Shrum for taking time from their busy schedules to share their perspectives. I am pleased that Dr. Shrum will use the well-woman guide in her practice.

Dr. Klobutcher raised the issue of which cervical cancer screening interval to use. For women 21 to 30 years of age, the recommendation is to perform cytology screening for cervical cancer every 3 years. After 30 years of age, either cytology screening every 3 years or cytology screening plus HPV testing every 5 years is acceptable.

Dr. Klobutcher also wondered about the role of clinical breast examination (CBE) in screening for breast cancer. It is difficult to provide definitive advice regarding CBE because

the quality of data from clinical trials is suboptimal. Many experts recommend that CBE be performed at a regular interval, such as every 1 or 2 years if mammography screening is being recommended.

CBE occasionally finds lesions not detected by mammography. In one clinical trial of breast cancer screening, with breast cancer mortality as an endpoint, CBE alone and mammography plus CBE were equally effective in reducing mortality.¹

Reference

1. Miller AB, To T, Baines CJ, Wall C. Canadian National Breast Screening Study-2: 13-year results of a randomized trial in women aged 50-59 years. *J Natl Cancer Inst.* 2000;92:1490-1499.

“UPDATE: PELVIC FLOOR DYSFUNCTION”

AUTUMN L. EDENFIELD, MD, AND CINDY L. AMUNDSEN, MD (OCTOBER 2012)

Atrophic vulvar tissue is sensitive to irritant agents

When patients report dysuria or irritative voiding or vulvar symptoms, I always ask what soap they use for bathing. They often respond with the name of a harsh deodorant soap, assuming such a product is good for hygiene. Many patients also scrub the perineum with a washcloth.

I advise all postmenopausal patients—as well as premenopausal patients who have symptoms—to use plain baby bath (no added aloe or other ingredients) and to wash gently and rinse well. Atrophic vulvar tissue is much more sensitive to contact irritants than normal tissue is, and soaps often contribute to dysuria, vulvar irritation, and other problems.

As for probiotics, it is my experience that they are more helpful for chronic vaginitis than for urinary tract infections.

Lisa Rogers, MD
Jackson, Tennessee