

MEditorial October 2012

“Vaginal Mesh”

Sitting in the surgeons' lounge at the hospital, watching one of several cable news stations, I am amazed at the number of commercials exhorting patients to call law firms to explore liability compensation for environmental exposures such as asbestos (linked to a type of lung tumor called mesothelioma); as well as “defective” medical products. Among the latter, at least as viewed from the legal perspective, are certain hip prostheses and various kinds of synthetic mesh used in female reconstructive surgery.

Synthetic mesh for groin (inguinal) hernia repairs (mainly in men) has been used for years with a very low complication rate and increased success compared to non-mesh repairs, especially as regards faster recovery and lower chance of hernia recurrence. Although the mesh material is similar to that used in vaginal reconstructive surgery, it seems that “purpose” and mesh location make for great variance in outcomes.

Two women I saw recently bring the vaginal mesh subject into focus. One, seen as a 2nd opinion, had a robot-assisted hysterectomy and sacrocolpopexy—a surgery to keep the prolapsing vagina from turning inward on itself (literally inverting), by tacking the top of the vagina upwards and posteriorly to the sacral (bony) area at the bottom of the spine. Synthetic mesh, most often made of a safe substance called polypropylene, is used to bridge the gap between the top of vagina and sacrum, since the distance involved is too great in most to allow direct suturing. A piece of mesh, in this case, eroded through the top of the vagina but was causing minimal symptoms to her; and since she was not sexually active, there was not an issue of male partner coital (penile) trauma. One issue that arose was whether to use synthetic or biologic material, at the time of removal of the eroded sacrocolpopexy mesh, for a suburethral sling needed for, unfortunately, the “new onset” of urinary leakage after the hysterectomy/prolapse repair. The implication, as seen by this patient, was erosion at one site would lead to concern of this

happening again (were synthetic mesh used) at another site below the vaginal wall.

A second case was a woman with a large cystocele, a type of prolapse [or hernia] of part of the back of the bladder into the space usually separating the vagina from the more anterior bladder. The cystocele (or anterior pelvic organ prolapse abbreviated as “POP”) caused symptoms of vaginal pressure and sense of something “falling out” as well as frequent/urgent/small volume urinations.

POP is a common female urologic/gynecologic problem seen usually with aging--but sometimes observed in younger women presumably due to childbirth or aberrant genetic tissue quality. This 70-year-old [second] patient had several legitimate concerns. If the cystocele were fixed, would repair of the cystocele, simply by bringing together the, by definition, weak, tissues suffice, or would some additional material be needed to insure a better/more durable repair? Would that material be synthetic or biological? Were it biological, what would be the tissue source? Since larger cystoceles serve, in a sense, as pressure regulators, would any POP repair increase the risk of new onset stress incontinence (leakage with laughing, coughing, sneezing, exercise)?; if likely, should a pre-emptive suburethral sling be placed and if so, how about using synthetic material? Note: it is known that up to 50% of women, especially with larger cystocele repairs, will develop leakage when they had none or minimal before the POP reconstructive operation.

Most of the controversy around using synthetic mesh for female reconstruction, centers on problems seen with POP repair, and far less so with suburethral slings. Complications from synthetic mesh for POP repairs, cited below, have led the FDA to raise the standard for “proof of safety” to the many producers of these POP “kits”; some manufacturers due to decreasing demand/revenues or the potential/actuality of legal actions, have dropped out of this market. Issues of concern include erosion of the synthetic material through the vaginal suture line; extrusion or migration of the mesh through the vaginal wall or worse, into the bladder or urethra; rare fistulae (holes between lower urinary tract and vagina); “blind” needle passage injury to pelvic organs or blood vessels and nerves; mesh

infections very difficult to sure with antibiotics alone; and stiffening of the vaginal area with or without nerve injury--causing pain, more so with intercourse.

Repairing the above problems (which granted, occur in a minority of women) can be as easy as application of topical estrogen creams and watchful waiting; to excising a small piece of mesh from the vagina in the office; to a major surgery under anesthesia to remove most or all of the problematic mesh with precise closure of (if available) healthy vaginal wall tissues. Most, but not all, will have as successful outcome. In my practice, the few such cases I have seen lent themselves to simple excision of extruded mesh.

Women who are older and especially those who have thinned out (atrophic) vaginal tissue; and/or who are diabetic or otherwise prone medically to poor healing, or have had prior vaginal reconstructive attempts should be more "on guard" to their doctor's suggestions of repair using synthetic materials for POP surgery. Biological materials (including patient's own tissues harvested from elsewhere; or cadaveric and porcine/bovine issues treated to prevent any risk of infection or "rejection" by the body) are a reasonable alternative--with perhaps lesser strength but lower chance of serious complications.

I am not as concerned with using synthetic kits for suburethral slings (i.e., to treat stress incontinence) since these had a great track record BEFORE we started using similar materials for POP repairs. In the many years I have been in practice, there has been an evolution toward these easy-to-use kits, and away from open surgery (good results but a major operation with a few days in the hospital and not suitable to all of the several different mechanisms of stress incontinence); and transvaginal surgery requiring suturing, more bleeding, more pain, and a higher long-term failure rate than simple slings. In the 20 or so year international experience with synthetic anti-incontinence slings, the success rate has exceeded 90%--and may be higher if women are carefully selected so that the operation is "right" for the presenting symptoms and findings. For the woman not wanting a mesh sling or whose complicated history increases risks of synthetic material near her urethra (e.g., need to repair a urethral outpouching or diverticulum), a so-called "PVS" or pubovaginal sling using her own/ "autologous" tissues [harvested

form the fascia covering muscles in the lower abdominal wall] and polypropylene sutures and can be substituted. Results are good--but this is a slightly bigger operation than using a synthetic sling kit; healing takes longer; and one could argue that autologous tissue repair will not hold up, in the long run, for the same reasons the incontinence began, i.e., the woman's tissues involved in support of the mid-urethra are genetically or developmentally defective.

By the way, in the example of 1st patient of mine mentioned above, I did not see a problem in her undergoing a mesh suburethral sling at the same time the sacrocolpopexy mesh was being removed. The sacrocolpopexy mesh erosion does not imply she would have trouble, in general, from mesh. In the 2nd woman, we satisfied her legitimate concerns and did a nice repair using biological material of a porcine origin to reinforce the cystocele closure; and a synthetic suburethral sling to try to avoid new onset stress incontinence.

As in all surgeries, vaginal reconstruction patients deserve appropriate consent about the benefits versus risks of the various options. I, as well as most who delve in these procedures, will do what the woman wants as long as it is within the "wide" range of reasonable options and she feels an "invested partner" in the decision process.

Dr. Alan Freedman
401 Old Newport Blvd., Suite 101
Newport Beach, CA 92663
Phone: (949) 645-3434
FAX: (949) 645-0277