

Surgical mesh for pelvic organ prolapse repair the subject of FDA warning



In a Health Notification issued in October 2008 and updated in July 2011, the U.S. Food and Drug Administration (FDA) warned of serious complications associated with transvaginal placement of surgical mesh for the repair of prolapsed bladder, rectum, uterus or vaginal vault after hysterectomy. The procedure may expose patients to more risk than other surgical options without providing added benefits. Mesh urethral slings used to treat urinary incontinence were not included in the FDA warning and have a long track record of safety and efficacy.

After conducting a systematic review of the published scientific literature from 1996 to 2011, the FDA concluded that transvaginal pelvic organ prolapse repair with surgical mesh does not improve symptomatic results or quality of life over traditional repair procedures that do not use mesh.

The FDA has categorized surgical mesh as a Class III medical device when used to treat pelvic organ prolapse. Class III is the FDA's most stringent classification, requiring premarket approval of the device.

Emphasis on quality of life

While surgical mesh can provide a very good anatomical result in pelvic organ prolapse repair, "treating complications of mesh procedures is very difficult and some patients are permanently disabled as a result of mesh complications," explains Shlomo Raz, M.D., Chief of Urologic Pelvic Medicine and Reconstructive Surgery at UCLA. Even removal of the surgical mesh does not reverse complications in all patients.

Research has shown, however, that quality of life and patient satisfaction are not dependent on achieving the best possible anatomical repair. "If you cure the symptoms, the patient is very satisfied with the surgery," states Dr. Raz. At UCLA, pelvic-floor reconstructive surgeons are pioneering new procedures to repair prolapse without the use of surgical mesh.

"Physicians should discuss the pros and cons of reconstructive procedures with their patients," says Dr. Raz. "They should be made aware of the potential complications of mesh procedures and the fact that satisfaction with pelvic organ prolapse surgery does not correlate with anatomical results."

Complications of prolapse repair using mesh

For the past 10 years, surgical mesh has been widely used to reconstruct the pelvic floor, treating conditions including cystocele (bladder prolapse) and rectocele (posterior vaginal wall weakening). Surgical mesh grew in popularity on hopes that it would provide a more durable repair than traditional procedures. It is also relatively easy to implant and provides a good anatomical result.

Outcomes data revealed that, though serious complications were rare, they were difficult to treat and often caused permanent disability, even after removal of the mesh. Complications include diffuse vaginal and pelvic pain; leg, inguinal and gluteal pain; dyspareunia (pain with sexual intercourse) and the inability to walk. Some complications are due to damage done when the mesh is initially introduced using trocars (needles) that pierce the muscles of the pelvis. Other complications can develop years later as age-related atrophy of the vaginal tissue increases the likelihood of ulcerations that lead to exposure of the mesh through the vaginal wall. Mesh erosion occurs when mesh enters the urinary tract or bowel.

Pelvic floor reconstruction at UCLA

UCLA pelvic-floor reconstructive surgeons have developed alternative procedures to provide durable repair of pelvic organ prolapse without the use of surgical mesh and without the high rate of prolapse recurrence experienced with the traditional repair surgeries. For example, they are using nonabsorbable sutures to repair central and lateral defects of the bladder to treat cystocele. Another innovative procedure performed at UCLA to avoid the use of surgical mesh in pelvic organ prolapse is the transvaginal repair of vaginal vault prolapse — prolapse of the roof of the vagina — usually following hysterectomy.

UCLA is a leader in laparoscopic abdominal pelvic floor reconstruction, including robotically assisted laparoscopic techniques, which have proven to be among the best, safest and most durable methods of correcting pelvic organ prolapse.

Mesh removal is a difficult and complex procedure requiring the surgeon to enter the muscular complex in the inner thigh, the space lateral to the rectum or the retropubic space. At UCLA, pelvic floor reconstruction procedures are performed by highly trained pelvic floor reconstructive surgeons with specialized training and considerable experience. UCLA has performed more than 400 mesh removals for complications in our center in the past five years.

Surgical mesh and stress incontinence

Surgical mesh has also been widely used to treat female stress incontinence using a sling that supports the bladder neck and urethra. UCLA surgeons have performed hundreds of sling procedures with good clinical results and minimal complications.

While FDA warnings on surgical mesh have not changed the status of sling procedures, UCLA surgeons are now performing more sling procedures using the patient's own tissue (a small strip of fascia from the lower abdomen) and bladder neck suspensions using nonabsorbable sutures, both of which avoid the use of surgical mesh.

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