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July 13, 2011 FDA recommended questions to ask your surgeon about transvaginal mesh surgery and Dr. Cassidenti's answers

Are you planning to use mesh in my surgery?

I have been using mesh in my pelvic reconstructive procedures to repair pelvic organ prolapse (prolapse of bladder, rectum, uterus and vaginal cuff) since 2009 and have achieved very favorable results. Many studies comparing mesh to non-mesh repairs have demonstrated lower recurrence rates when mesh is utilized. This has been my experience as well. The FDA review of these studies acknowledges the anatomical benefit of mesh use, but unfortunately “dismisses” it because measurement scales of “quality of life” were no different. The fact is that these studies are not long term (only one year), and my many years of experience tell me that patients with anatomical failure (when the prolapse recurs) will eventually suffer symptoms and quality of life deterioration. If I am planning to use mesh, I ALWAYS discuss the benefits as well as risks with you. Remember, the use of mesh is my recommendation only; it will only be used with your informed consent.

Why do you think I am a good candidate for surgical mesh?

Many women are good candidates for surgical mesh. Women who have weak or compromised tissue such as older patients, tobacco users, women with known collagen deficiencies, large prolapses, and those who have undergone prior reconstructive surgery that has failed are especially good patients for mesh placement. Research has shown that relatively “poor” candidates for mesh are those who have had prior pelvic surgery utilizing any permanent material (suture or mesh) and now have chronic pelvic pain.

Why is surgical mesh being chosen for my repair?

Mesh placement is being recommended for your repair in order to improve the durability of your surgery (by decreasing the risk of prolapse recurrence). Several studies have demonstrated superior anatomical repair when mesh is used vs. when it is not used.

What are the alternatives to transvaginal surgical mesh repair for POP, including non-surgical options?

For a non-surgical option, you could use an intra-vaginal support device called a ‘pessary’. The other surgical alternatives include transvaginal suture (or “traditional”) repair of your own native tissue, a biologic graft augmented repair using human cadaveric fascia lata or dermis (skin) which both carry higher failure rates, or trans-abdominal delivery of the mesh to the

pelvis. Trans-abdominal (which may be laparoscopic) placement is another good option, but exposes patients to other potential complications such as bowel injury or obstruction. Laparoscopic delivery may result in lower rates of mesh erosion, but other factors, such as age, body habitus, and prior abdominal surgery will influence the decision as to which type of operation is best for you.

What are the pros and cons of using surgical mesh in my particular case? How likely is it that my repair could be successfully performed without using surgical mesh?

Many studies consistently demonstrate a 30-40% failure rate in anatomical correction of prolapse when a traditional native tissue suture repair is performed and no mesh is involved. Data from my practice demonstrated that biologic graft augmentation has a 20% failure rate for bladder prolapse (cystocele) repair and a 10% failure rate for rectal prolapse (rectocele) repair after five years. This experience has been confirmed by other pelvic floor surgeons. The benefit (“pros”) of using mesh is to lower the failure rate to less than 10%. The “cons” of using mesh are the risks associated with its use, namely exposure of the material into the vaginal cavity (approximately 1-5% of the time) and pain during intercourse (2-3% of patients). These complications can be treated and resolved in most all patients with office based or outpatient surgery interventions or vaginal wall physical therapy. A complication of not using mesh and performing a traditional suture repair of your own tissue is a 30-40% failure rate requiring another more difficult (because of scar tissue from the first failed surgery) prolapse surgery and pelvic reconstruction.

One of the keys to optimal mesh placement and results is to perform a full thickness vaginal wall dissection and place the mesh as a cradle of support directly under the bladder. In performing this full thickness dissection, there is a 2% incidence of dissecting through the bladder wall (called a cystotomy). The bladder entry is repaired, the mesh can still be placed in the vast majority of cases and you would need catheter drainage of your bladder for 7-10 days to let the bladder heal.

Will my partner be able to feel the surgical mesh during sexual intercourse? What if the surgical mesh erodes through my vaginal wall?

Your sexual partner should not be able to feel the mesh during intimacy as the mesh lies deep behind the vaginal wall. Newer material properties of the mesh (light weight and increased elasticity) have contributed to the material being essentially undetectable by your partner or even your gynecologist. If there is an exposure of the mesh, however, your partner might feel a “scratchy sensation” with penetration. This happens in only 1% of the cases when I have performed the mesh placement. These exposures also tend to be small and easily repaired, often in the office, or as an outpatient in an ambulatory surgery center. In addition, a small percentage (2-3%) of women experience mesh contracture over time and can have vaginal pain and pain with intercourse. Mesh contracture often responds to vaginal wall physical therapy and local injections of pain medication. If these treatments fail, an outpatient surgery to release and possibly remove the area of the contracted mesh could be performed. Mesh exposure and pain can occur years after initial mesh placement.

If surgical mesh is to be used, how often have you implanted this particular product?

I have implanted hundreds polypropylene meshes since 2009.

What results have your other patients had with this product?

In order to feel confident about counseling my patients on the success I've had with vaginal mesh, I have been following patients and collecting data since my initial use of mesh in 2009. Some of the patients have had transvaginal mesh implanted over two years ago. The most common risks of mesh placement include exposure of mesh material (about 1% of the time to date in my practice), and/or pain with intercourse (in about 2-3% of patients). Although complications can occur with any surgery, the overwhelming majority of my patients have reported that they are very satisfied with the results.

What can I expect to feel after surgery and for how long?

You can expect to "feel" relief from pressure-like discomfort within your lower pelvis or vagina, the resolution of fullness or any protrusion of vaginal tissue you may have had prior to your surgery. I also anticipate you will experience improvement in function of your lower urinary tract (voiding and/or urinary control) as well as your rectum (with defecation) depending on the type and location of your prolapse preoperatively.

Which specific side effects should I report to you after the surgery?

As I discuss with all patients peri-operatively and at our pre-op visit, I ask all patients to notify me if after surgery you have any fever or bleeding more than a menstrual period. Other symptoms in the future I would want you to report would be vaginal discharge, spotting, pain or irritative symptoms you or your partner may experience during intercourse.

What if the mesh surgery doesn't correct my problem?

If the surgery doesn't "correct" your symptoms, we will continue to evaluate you to determine "why". Functional improvement in the lower urinary tract or rectum does not always occur after anatomical correction of prolapse (surgery). Occasionally, additional medical or behavioral therapies will be necessary in addition to the corrective surgery for your prolapsed condition. Unfortunately, these interventions rarely ever significantly help without first surgically correcting the prolapse.

If I develop a complication, will you treat it or will I be referred to a specialist experienced with surgical mesh complications?

I am one of the most experienced surgeons in mesh surgery for pelvic organ prolapse in the region. I will treat any complications you may have. I do care for women referred to me from other doctors with mesh complications. I have a greater than 90% success rate in resolving complications.

If I have a complication related to the surgical mesh, how likely is it that the surgical mesh could be removed and what could be the consequences?

I occasionally have to “revise” a surgical mesh by either releasing the tension or excising a small exposed area. I have never had to “remove” an entire mesh that I have placed. I do have experience in removing the entire mesh in patients referred to me by other physicians. Removal of a small piece of mesh that was exposed rarely has any significant consequences as the area is small and the chance of re-prolapse through such a small area is rare. Having to remove an entire mesh would increase the chances of recurrent prolapse.

If a surgical mesh is to be used, is there patient information that comes with the product, and can I have a copy?

Yes, I routinely provide the product information to all patients at the time of consultation and/or consent for surgery.

We discussed at length the 2011 FDA safety notification regarding transvaginal mesh to treat prolapse, and it's relevance to the proposed surgery. Specifically, we discussed the fact that transvaginal mesh placement for prolapse repair has been associated with certain risks not present with traditional non-mesh surgery for prolapse, including mesh exposure and erosion, but that other risks, including pain, dyspareunia, infection, bleeding and injury to adjacent organs, can be seen with any surgery for prolapse, whether mesh or other grafts are used or not. I explained that the reason we use synthetic mesh in certain cases (including advanced or recurrent prolapse) is because of the excellent long term success rates compared with traditional surgery

Patient signature

Date

Witness

Date

Andrew Cassidenti, MD

Date