VAGINAL MESH IN GYNECOLOGICAL SURGERY <u>Frequently Asked Questions</u>

By Hugo D. Ribot, Jr., MD

What is vaginal mesh?

Vaginal mesh is an artificial or biologic material used in the surgical repair of women who have prolapse, or loss of support, of their pelvic organs. It is mainly used when the uterus or upper vagina is part of the prolapse.

Why would vaginal mesh be used?

The primary reason for using vaginal mesh is to increase the chances that the procedure, or prolapse repair, will work. Another major advantage is that mesh procedures do not require hysterectomy – and thus, require much less surgery.

Research has shown that women with pelvic organ prolapse often have a weakness in the strength of the tissues that support the vagina and uterus. These tissues are often injured during pregnancy and delivery, and the damage increases over time. Surgery does not make the tissues stronger, and "tacking" these weak tissues together often fails. Hernias also occur due to a similar weakness in the abdominal wall tissues, and using the patient's own tissue to fix the problem also often fails. Surgeons have been successfully using mesh to repair hernias for decades.

What problems can occur after a vaginal mesh procedure?

The main problem with any procedure using mesh is the chance that the skin over the mesh will not heal and that the mesh will become exposed. If this happens in the vagina, it can cause discharge, spotting and pain with intercourse. The latter is more common in younger women. Recent research also shows that mesh can make the vagina stiffer and less flexible, particularly when it is used between the bladder and vagina. It is difficult to say how often this happens, as many cases are unreported.

There have been more than 250,000 mesh procedures performed in the United States, with some 2,500 reported cases of complications. Many studies have shown that surgical experience significantly impacts the rate of complications, with higher-volume surgeons reporting problem rates of 2%-4%, and less-experienced surgeons reporting rates of 16% or higher.

There also are biological meshes or grafts, which are used vaginally, but many studies have shown that these, too, can cause problems with healing or scarring.

Do we use vaginal mesh?

No. Our practice no longer uses vaginal mesh for the treatment of vaginal prolapse. We are proud to say that complications among our patients with mesh have been *extremely* rare.

This notwithstanding, we made the decision to stop using vaginal mesh based on the recent barrage of negative advertising on the product in the media and Internet, as well as the huge number of class-action lawsuits that have been filed against its manufacturers. This has, understandably, frightened many women about its use.

Have vaginal meshes been recalled?

No. In June of 2011, the FDA issued a warning that complications after vaginal mesh were "not rare," and that patients should be counseled about the possibility of potential complications. The FDA now requires manufacturers of vaginal mesh to perform three-year studies on their product to demonstrate its safety and effectiveness. Our practice believes that those studies should have been done years ago, and that the FDA has been too lax in allowing such products on the market. Some mesh manufacturers, however, have chosen not to undergo the new testing requirements, and have taken their products off the market.

What are the alternatives to vaginal mesh?

There are many procedures which use the patient's own tissues to repair prolapse. We have successfully performed hundreds of these procedures over the last 25 years.

Is a bladder sling the same as vaginal mesh?

No. Although much of the advertising of legal suits against vaginal mesh uses the word "sling," the bladder (or vaginal) sling used to treat urinary leakage is completely different from the vaginal mesh used for prolapse repair, and is not the focus of the FDA concerns. Recent medical research has concluded that synthetic slings are safe and effective, and they remain the standard of care in the treatment of women suffering from stress urinary incontinence. Millions of bladder slings have been performed worldwide over the last 15 years, with very low complication rates. Our practice has successfully performed hundreds of these procedures over the past 10 years.

What about abdominal mesh?

Like bladder or vaginal slings, synthetic mesh used in the abdominal repair of prolapse is completely different from vaginal mesh, and is not the subject of FDA concerns. The use of abdominal mesh for the treatment of upper vaginal prolapse – or sacral colpopexy – was introduced in the 1970s. It remains the "gold standard" of treatment for this condition in both safety and effectiveness. This procedure is much more complicated than a vaginal mesh procedure because it is performed abdominally. The risk of the mesh becoming exposed vaginally is extremely rare (less than 1%).

Our practice has successfully performed many of these procedures. We are one of a very small number of surgeons statewide who perform the procedure laparoscopically without robotic assistance.

What is the best procedure for my prolapse?

Our goal is to provide you with the safest, least invasive and most effective procedure to repair your prolapse, and to provide you with the quickest recovery possible. The choice of procedures depends on your age, activity level, health and severity of your prolapse. If your prolapse does not involve your uterus or upper vagina, we would repair it using your own tissues. If your uterus or upper vagina are part of your prolapse, we would determine whether a vaginal or abdominal approach would be best, as well as if a hysterectomy or abdominal mesh would be useful.

All of our procedures for repairing prolapse problems are performed laparoscopically – that is, using tiny keyhole incisions – *and* as outpatient surgery, providing you with the fastest, least painless recovery possible. We are highly experienced in all of the options available to you. Ultimately, it will be your decision as to which procedure you are most comfortable with.

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