

Surgical mesh: not as bad as you think

Modern forms of surgical mesh have been in use for over 60 years. Mesh has been used in the treatment of many conditions including hernia repair, pelvic organ prolapse (POP), stress urinary incontinence (SUI) and in a variety of reconstructive procedures. While beneficial in many of these surgically treated conditions, some patients have suffered significant complications. Issues surrounding the use of trans vaginal synthetic mesh for the repair of POP were first raised in 2011 by the FDA. In April of 2019, the FDA suspended the use of surgical mesh for the vaginal repair of POP and ordered that all products be withdrawn. Several countries such as Australia and New Zealand have completely banned vaginal meshes for any indication. It is critical in this discussion of surgical mesh to note this FDA ban is specifically on the use of transvaginal mesh for POP. This does not include mesh used in trans-abdominal sacrocolpopexy for the correction of POP or the use of mesh in mid urethral slings for stress urinary incontinence (SUI).

Mangir and associates have a recent review of the development of surgical meshes and mesh use for the treatment of POP and SUI.¹ When used for SUI in females as a mesh tape for mid urethral slings, cure rates are reported as high as 93% with about 4% mesh related complications. However, the use of trans-vaginal mesh for POP repair has strikingly different results with high rates of mesh erosion, pain, infection, and dyspareunia. One study demonstrated erosion rates of 42% over 7 years.

Using mesh for groin and ventral hernia repairs have shown the superiority of mesh-based treatments in terms of recurrence and complications compared to standard techniques. A Cochrane review of groin hernia repair with and without mesh demonstrated the clear superiority of mesh-based repair. Preventing parastomal hernias, a common problem with ileal conduits, is a troubling complication causing quality of life issues and often requiring extensive surgical revision. Prophylactic use of mesh in a clinical trial decreased the risk of parastomal hernia when creating an ileal conduit with no increased risk of mesh related complications.

There have been consequences due to the use of transvaginal mesh in POP. One change was in the approval process for mesh products. In the late 1990s the FDA approved the use in mid-urethral slings for SUI, the first transvaginal mesh approval. This success led to an explosion in other mesh products to treat conditions such as POP. Many of these early products were subsequently withdrawn from the market due to complications. These withdrawals resulted in the 2016 FDA reclassification of vaginal mesh from class II to a class III (high risk) medical device. A class III device poses the most risk to patients and requires pre-market studies and scientific review for efficacy and safety. As a result of mesh injuries, many individual and class action lawsuits have been filed against manufacturers with many including treating physicians.² Lastly, with the negative association of mesh with POP, the internet is now full of legal solicitations for patients with any mesh related complication from any procedure to seek compensation.

Today, surgeons must advise patients of the risks and benefits of using FDA approved mesh products in their informed consent and be aware of the specific use guidelines for each product. It is unfortunate that the recognized benefits of surgical mesh have resulted in litigation for a wide variety of approved indications such as hernia repair. While hundreds of surgical mesh products have been developed with many subsequently withdrawn, non-absorbable synthetic polymers such as polypropylene based surgical mesh are commonly used today. Recognizing that alternatives such as autologous fascial tissue for urethral slings are potential solutions, research continues on the development of improved surgical mesh. This new mesh would ideally integrate with the native tissue, promote healing, and reduce the risk of erosion and infection. New biomaterials such as absorbable and natural polymers, integrated drugs, and advanced manufacturing technologies, are under development to further reduce the limitations of surgical mesh.³ Until these new products are available and prove to be more effective than our currently approved mesh products, the existing FDA approved products will continue to benefit many patients. Recognizing its limitations, the use of surgical mesh does not always result in a bad outcome.

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References

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