

Review of Recent Advances in Vaginal Mesh Tissue Interaction



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Abstract

Pelvic Organ Prolapse (POP) is a critical deformity of the female pelvic floor suffered by over millions of women in the US. POP leads to prolapse of pelvic organs onto the vaginal canal causing discomfort, pain, strain and sexual dysfunction. Vaginal meshes are traditionally implanted surgically to rectify the herniation of the pelvic organs and correct patient-specific POP conditions. However, the bio incompatibility of such meshes within the female pelvic system have been recognized to be deleterious to the surrounding tissues due to mesh erosion, organ perforation and tissue slicing, leading to severe complications. In literature, several studies have been conducted to understand vaginal mesh mechanical properties and mesh tissue interactions. The current article reviews these recent advances, which will not only be valuable to understand the state of the art in the mesh tissue interaction characterization and the directions in which further work needs to be conducted, but would also be indispensable for understanding the challenges associated with vaginal mesh failure and the corrective strategies in terms of design and implementation moving forward.

Keywords: Transvaginal mesh; Pelvic organ prolapse (POP); Female pelvic system

Introduction

A vaginal mesh is a net-like woven material which is surgically implanted through the vaginal opening to treat Pelvic Organ Prolapse (POP) condition. In POP, the female pelvic organs such as the urinary bladder, rectum, or the uterus prolapses onto the vaginal wall (Figure 1) causing vaginal discomfort, sexual dysfunction and strained urination and defecation [1]. The mesh creates a hammock-

like structure under the drooping pelvic organs to fix them in place. However, traumatic mechanical failure of most such standard meshes within few months of implantation, accompanied with mesh induced complications such as organ perforation, tissue erosion and slicing, and prolapse relapse, have led to their discontinuation by the Food and Drug Administration (FDA) [2].

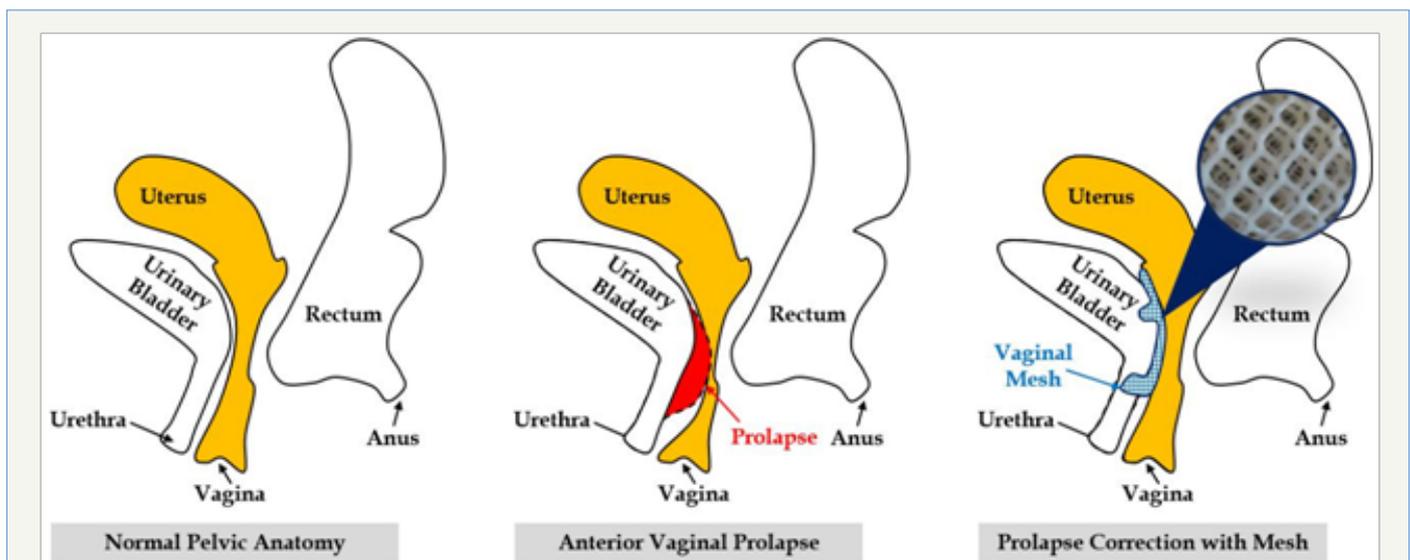


Figure 1: Schematic of normal pelvic anatomy, POP and mesh.

Also, thousands of lawsuits have been filed against major mesh manufacturers namely Ethicon, Coloplast, Boston Scientific and American Medical Systems, not allowing patients to trust and avail vaginal meshes, and leading to major monetary losses. To improve the biofidelity of vaginal meshes, studies have been conducted to understand mesh mechanical properties, and its interaction with animal tissues. The upcoming sections will briefly cover these topics, and will be followed with conclusions and future directions of the vaginal mesh technology.

Mechanical testing and characterization of vaginal meshes is important for distinguishing the structural properties and material behaviour of the various mesh products available in the market. Extensive uni-axial, bi-axial and cyclic load testing's have been conducted on dry and wet meshes under different loads and boundary conditions. Rohrbauer et al. [3,4] in 2014 studied the mechanical behaviour of prosthetic mesh at different length scales. A global mechanical testing framework was developed along with a methodology to estimate local deformation and kinematics. From the study, the global mechanical response of the mesh was found to depend on its anisotropic structure, non-linear force response, hysteresis and preconditioning effects. The local deformation analysis helped identify mesh mechanics at the unit cell level. Both the global and local kinematic responses of the mesh were observed to have direct relation with clinical observations such as mesh wrinkling, erosion and dislocation. Based on the study, various protocols were generated to characterize range of the mesh products available in the market.

Maurer et al. [3] in 2014 studied the mechanical biocompatibility of meshes using a robust experimental framework. It was found from the study that mesh porosity doesn't predict stiffness and mesh stiffness was observed to have a weak correlation with permanent deformation. Excessive biaxial stresses were found to lead to intense mesh shrinkage. Special emphasis was placed on carefully matching the mesh and underlying tissue stiffness to minimize discomfort. A very stiff mesh compared to the tissue was found to lead to stress shielding and shrinkage. On the other hand, a very compliant mesh was observed to lose their supportive function and affect mesh handling properties. To control the mechanical stiffness of an implanted mesh, embedding the mesh into a polymer matrix with preconditioning effect was suggested.

Mechanical Tests on Meshes Explanted in Animal Models

Mesh implantation was found by Morch et al. [5] to lead to the development of scar tissue and the formation of a new composite made of native tissue, the mesh implant and scar tissues. The influence of healing and healing time on the mechanical response under uniaxial tension of the new composite was studied in detail with various animal models [6-8]. Under small deformations, healing was found to have minimal influence on the composite mechanical properties. However, under large deformations, the composite was observed to stiffen at the last stage of healing (3-6 month span). It was concluded that the minimum time required

to observe complete healing and a stable mechanical property for the composite was two months. In future, 3-6 month long mesh tissue interaction studies on animal models would be suitable to appropriately understand biocompatibility of vaginal meshes.

Conclusion and Future Directions

In the current brief review, the criticality of understanding vaginal mesh tissue interaction ultimately aimed at improving mesh implantation outcomes for POP correction was discussed. The types of mechanical tests which have been conducted to date to understand mesh mechanical properties under varying loading conditions and at different scales were presented. One important observation mentioned based on the test results was the importance of improving the mesh material system by altering and matching its stiffness closer to the vaginal tissues.

Also, recent studies involving the mechanical interaction of meshes implanted into different animal models through various phases of healing was discussed. In future, further work needs to be conducted mainly in three areas to improve vaginal mesh biocompatibility. First, vaginal tissue surrogate materials [9-13] will have to be used along with additive manufacturing techniques to construct meshes [14]. Second, various bioactive and nano particle based coatings [15] have to be investigated for enhancement of mesh-tissue biocompatibility. Third, short and long term vaginal tissue erosion due to its mechanical interactions with meshes will have to be studied. Patient studies can follow only after such detailed investigations into the vaginal mesh technology.

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