GYNECOLOGY

Textile properties of synthetic prolapse mesh in response to uniaxial loading

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BACKGROUND: Although synthetic mesh is associated with superior anatomic outcomes for the repair of pelvic organ prolapse, the benefits of mesh have been questioned because of the relatively high complication rates. To date, the mechanisms that result in such complications are poorly understood, yet the textile characteristics of mesh products are believed to play an important role. Interestingly, the pore diameter of synthetic mesh has been shown to impact the host response after hernia repair greatly, and such findings have served as design criteria for prolapse meshes, with larger pores viewed as more favorable. Although pore size and porosity are well-characterized before implantation, the changes in these textile properties after implantation are unclear; the application of mechanical forces has the potential to greatly alter pore geometries in vivo. Understanding the impact of mechanical loading on the textile properties of mesh is essential for the development of more effective devices for prolapse repair.

OBJECTIVE: The objective of this study was to determine the effect of tensile loading and pore orientation on mesh porosity and pore dimensions.

STUDY DESIGN: In this study, the porosity and pore diameter of 4 currently available prolapse meshes were examined in response to uniaxial tensile loads of 0.1, 5, and 10 N while mimicking clinical loading conditions. The textile properties were compared with those observed for the unloaded mesh. Meshes included Gynemesh PS (Ethicon, Somerville, NJ), UltraPro (Artisyn; Ethicon), Restorelle (Coloplast, Minneapolis, MN), and Alyte Y-mesh (Bard, Covington, GA). In addition to the various pore geometries, 3 orientations of Restorelle (0-, 5-, 45-degree offset) and 2 orientations of UltraPro (0-, 90-degree offset) were examined.

RESULTS: In response to uniaxial loading, both porosity and pore diameter dramatically decreased for most mesh products. The application of 5 N led to reductions in porosity for nearly all groups, with values decreasing by as much as 87% ($P < .05$). On loading to 10 N of force, nearly all mesh products that were tested were found to have porosities that approached 0% and 0 pores with diameters >1 mm.

CONCLUSION: In this study, it was shown that the pore size of current prolapse meshes dramatically decreases in response to mechanical loading. These findings suggest that prolapse meshes, which are more likely to experience tensile forces in vivo relative to hernia repair meshes, have pores that are unfavorable for tissue integration after surgical tensioning and/or loading in urogynecologic surgeries. Such decreases in pore geometry support the hypothesis that regional increases in the concentration of mesh leads to an enhanced local foreign body response. Although pore deformation in transvaginal meshes requires further characterization, the findings presented here provide a mechanical understanding that can be used to recognize potential areas of concern for complex mesh geometries. Understanding mesh mechanics in response to surgical and in vivo loading conditions may provide improved design criteria for mesh and a refinement of surgical techniques, ultimately leading to better patient outcomes.

Key words: prolapse, pore diameter, porosity, synthetic mesh

Synthetic mesh use in the surgical repair of pelvic organ prolapse is widespread, with approximately one-third of all surgical repairs using mesh.[1] Ideally, synthetic mesh provides structural support to the vagina to eliminate the symptoms of prolapse, restore vaginal function, and relieve the psychosocial issues that result from this disorder. [2,3] Although synthetic mesh–augmented prolapse repairs boast superior anatomic outcomes relative to repairs that use native tissues, the benefit of mesh has been questioned because of complication rates that are as high as 20%, with notable rates of pain and mesh exposure (Figure 1, a).[4-5]

In an attempt to define the mechanism of complications,[6,7] significant focus has been placed on the textile properties of mesh. Specifically, the geometry and dimensions of the mesh pores have been found to impact the biologic response to mesh directly.[8-11] Indeed, greater pore sizes were found to yield mesh-tissue composites of greater strength and increased collagen deposition; smaller pores restricted vascular growth and contained less mature collagen.[10,11] Notably, it has been shown that effective tissue in-growth, which is characterized by the quality of the tissue that forms between mesh fibers, occurs in mesh pores with a diameter of ≥1 mm for polypropylene mesh.[12] Importantly, pore diameters of <1 mm are associated with an enhanced inflammatory response that accompany poor tissue in-growth and fibrotic encapsulation.[13,14] Thus, it is not surprising that nearly all contemporary vaginal mesh products are constructed with initial pore diameters of >1 mm. Yet, despite this design feature, it is not uncommon for mesh to appear bunched after implantation, particularly in areas of complications (Figure 1, b).

The apparent deformation of prolapse meshes highlights the need to consider the mechanical environment in which mesh is placed. Specifically, both abdominal sacrocolpopexy and transvaginal procedures anchor mesh (or mesh arms) at 2 distinct locations (vagina and sacrum or vagina and pelvic sidewall, respectively). Thus, when surgically tensioned to remove the presence

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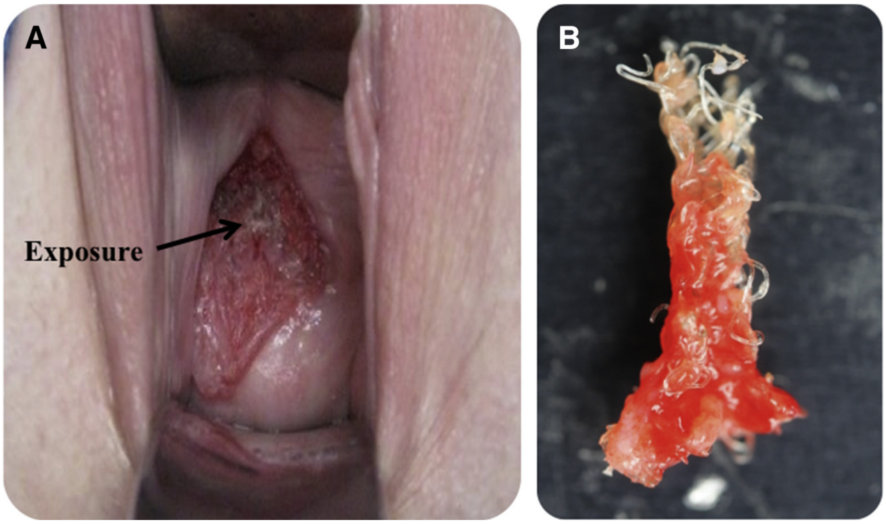
FIGURE 1
Example of mesh exposure



A, Mesh exposure characterized by visualization and palpation of mesh in the vaginal lumen. **B,** To treat exposure, mesh is often surgically removed. On removal, it is not uncommon for mesh to appear bunched, with noticeably altered pore geometries.

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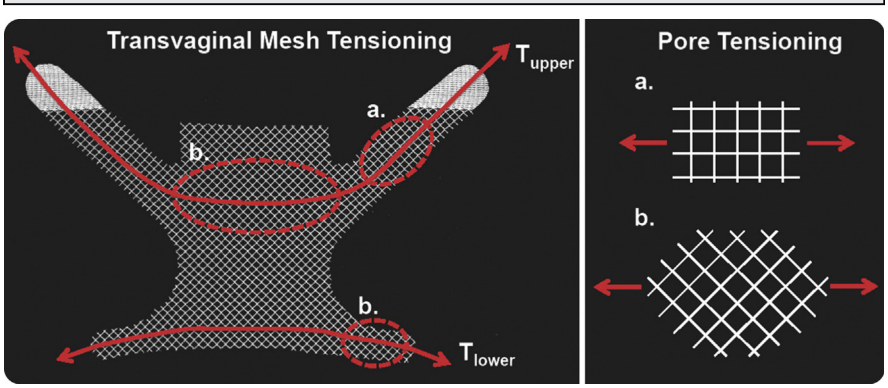
of a vaginal bulge or loaded by other pelvic organs and/or abdominal pressure, the mesh largely experiences unidirectional (uniaxial) tensile loads along significant regions of the device (Figure 2). In response to this loading condition, one would anticipate pore geometries to deform readily as the load is increased. Such loading previously has been shown to reduce mesh porosity.[15] Therefore, surgical tensioning and/or in vivo mechanical loading may provide a potential mechanism to explain clinical observations, often described as "mesh shrinkage."[16,17]

Although previous studies have performed mechanical testing of synthetic mesh, many of these report data that are related to mesh failure (ie, begins tearing apart).[18,19] However, mechanical failure of synthetic mesh products is extremely rare clinically, because the typical failure properties of mesh far exceed in vivo loads and deformations. Rather, this study aims to characterize pore deformation at levels of force that occur in vivo and during surgical implantation, while considering the impact of initial pore orientation. We hypothesize that, regardless of initial pore geometry, mesh pores will become unsuitable for effective tissue ingrowth (dimensions, <1 mm) with decreased porosity on tensile loading.

Materials and Methods

Four synthetic mesh products with distinct pore geometries were considered: Gynemesh PS (Ethicon, Somerville, NJ), UltraPro (aka Artisyn; Ethicon), Restorelle (Coloplast, Minneapolis, MN), and Alyte Y-mesh (Bard, Covington, GA; Table 1). Each product was cut to 90×15 mm strips along their recommended implantation direction. Multiple orientations were considered for several mesh products based on pore geometry and anticipated loading conditions for current sacrocolpopexy and transvaginal meshes. Specifically, UltraPro was loaded with mesh cut at 0- and 90-degree offset from the recommended direction (labeled herein as UltraPro and UltraPro$_{Opp}$, respectively). Because the initial pore geometry of Restorelle is square, porosity was not expected to change significantly in response to loading along this implantation direction. However, loading the mesh along an axis 45-degree offset to the square configuration (ie, tensioning a diamond shape pore) was expected to result in significant deformation. Therefore, Restorelle samples were cut in 3 orientations: pores offset at 0-, 5-, and 45-degrees from the horizontal axis. The 0- and 45-degree orientations were chosen based on geometry but were

FIGURE 2
Transvaginal prolapse mesh



Transvaginal prolapse mesh is tensioned to remove the presence of a vaginal bulge. Tension applied to the upper (T_{upper}) and lower (T_{lower}) arms of a transvaginal mesh results in transmission of force throughout the entire device. Along the path of force transmission, the pore structure is loaded in various orientations. Shown here, Restorelle's square pores are loaded at approximately 0-degree offset in the upper mesh arms; pores at the center of the mesh and in the lower arms are likely tensioned at approximately 45-degrees offset.

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