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The impact of boundary conditions on surface curvature of polypropylene mesh in response to uniaxial loading

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ABSTRACT

Exposure following pelvic organ prolapse repair has been observationally associated with wrinkling of the implanted mesh. The purpose of this study was to quantify the impact of variable boundary conditions on the out-of-plane deformations of mesh subjected to tensile loading. Using photogrammetry and surface curvature analyses, deformed geometries were accessed for two commercially available products. Relative to standard clamping methods, the amount of out-of-plane deformation significantly increased when point loads were introduced to simulate suture fixation in-vivo. These data support the hypothesis that regional increases in the concentration of mesh potentially enhance the host's foreign body response, leading to exposure.

1. Introduction

As of 2011, approximately one-third of all surgical repairs for pelvic organ prolapse were utilizing synthetic mesh products, yet up to 20% of those who undergo surgery with mesh require repeat operations for recurrent symptoms or complications (US Food and Drug Administration, 2011; Bako and Dhar, 2008). One of the most devastating and most common complications is mesh exposure (Diwadkar et al., 2009; Iglesia et al., 2010; Deffieux et al., 2007). Exposure is characterized by the degeneration of native vaginal tissue in contact with the mesh, often allowing visualization and palpation of the mesh in the vaginal lumen. Recent findings have shown that mesh exposure through the vaginal wall occurs in up to 15% of transvaginal repairs and 10.5% of sacrolcolpopexy repairs (Nygaard, 2012). In addition, surgeons have commonly noted this complication to correspond with the appearance of mesh “contraction”, “buckling”, “wrinkling”, and/or “bunching” in the area of exposure (Fig. 1a).

Though the mechanisms that lead to mesh exposure remain unclear, much focus has been drawn to the properties of the mesh products in an attempt to minimize complications (Shepherd et al., 2012; Feola et al., 2013a, 2013b) . Often mesh manufacturers report on the structural properties of mesh, in addition to in-vivo histological data following implantation, in order to demonstrate the mechanical integrity of their products. Given that most prolapse meshes are constructed from the same material (type I polypropylene), the wide range of mechanical behavior observed in previous studies primarily arises from variations in knit pattern between products (Shepherd et al., 2012; Moalli et al., 2008; Jones et al., 2009). While load–elongation behavior is required to understand the functional behavior of mesh, several findings in the hernia mesh literature suggest that deformation of mesh upon loading is crucial for predicting the host response. In the abdominal wall, it was determined that mesh pores with diameters less than 1 mm elicit an enhanced immune response, with poor mesh incorporation into the host tissue. Recent studies, including our own preliminary work, have found that application of tensile loads drastically reduces mesh porosity and yields pore dimensions which are unfavorable for host integration (Otto et al., 2013; Muhl et al., 2007). This intensified immune response is attributed to increases in mesh burden, where mesh burden is defined as the

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Nomenclature

Z	Cartesian co-ordinate which was fit
N_i^{jk}	Shape functions
(ξ, η)	Local co-ordinate system for finite elements
g_i , g^i	Covariant and contravariant basis (in-surface curvilinear co-ordinate system)
g_{ij}	Surface metric (metric tensor)
B_{ij}	Curvature tensor
k_1, k_2	1st and 2nd principal curvatures (eigenvalues of the curvature tensor)
I_B, II_B	1st and 2nd principal invariants of the curvature tensor (B_{ij})
k_{max}	Maximum curvature, defined here as the maximum of the absolute values of the principal curvatures

amount of mesh material per unit volume of tissue. While tensile loading clearly leads to pore collapse at some level of force, additional deformations, such as wrinkling and folding, may provide an alternative or concomitant mechanism to increase mesh burden.

Boundary conditions greatly impact the mechanical behavior of mesh, as observed when comparing results from standard uniaxial tensile and ball burst tests (Shepherd et al., 2012; Feola et al., 2013a). In addition, the mesh deformations observed during these tests are quite dissimilar (Fig. 2). During uniaxial testing mesh is allowed to contract in the direction perpendicular to loading (similar to Poisson's effect for continuum solids), while fixing the mesh along the entire boundary, per a standard ball burst protocol, prevents the collapse of pores. Although both testing methods assume a planar geometry (i.e. no buckling or wrinkling), the method in which mesh is fixed noticeably alters changes in mesh burden under mechanical loading.

Indeed many previous studies have employed standard testing protocols to access the properties of mesh, yet these standards do not employ boundary conditions that mimic the in-vivo boundary conditions a mesh product experiences. As such, important features of mesh mechanical behavior may have been overlooked. Specifically, when a surgeon places a mesh to restore vaginal support, sutures are used to attach the material to the vagina as well as the anchoring surfaces. This method of attachment subjects the mesh to various point loads, as opposed to the uniform application of load or displacement to an entire boundary. Further, the number of point loads and their positions are variable, as surgeons do not necessarily use the same number of sutures or exactly the same suture placements from patient to patient (anatomical variations, patient size, etc). Without constraining an entire edge, point loading of mesh is more likely to create out-of-plane deformations, resulting in a bending or wrinkling phenomenon along the lines through which force is transmitted, due to the constraint effects of pore deformation. Describing surface deformations, such as bending, has been well characterized in several fields of research, including neurological development (Filas et al., 2008; Batchelor et al., 2002) and cardiology (Lee et al., 2013; Sacks et al., 2002; Smith et al., 2000). Following from these studies, out-of-plane surface deformations for a thin body can be characterized via surface curvature, as the geometric transformation of a flat surface to a curved one implies some local surface deformation.

Understanding the surface deformation of mesh products will provide valuable insight into the local deformation and mesh burden throughout a mesh device, which may greatly impact the manner in which the surrounding tissues interact and integrate with mesh. Therefore the aim of this study was two-fold: (1) develop an experimental and theoretical approach by which the surface curvature of polypropylene mesh could be quantified and compared and (2) use this approach to examine the impact of variable boundary conditions on the surface curvature polypropylene mesh products used in repair of pelvic organ prolapse. We hypothesize that boundary conditions more representative of in-vivo loading will result in significantly greater surface curvature compared to those deformations resulting from traditional tensile testing.

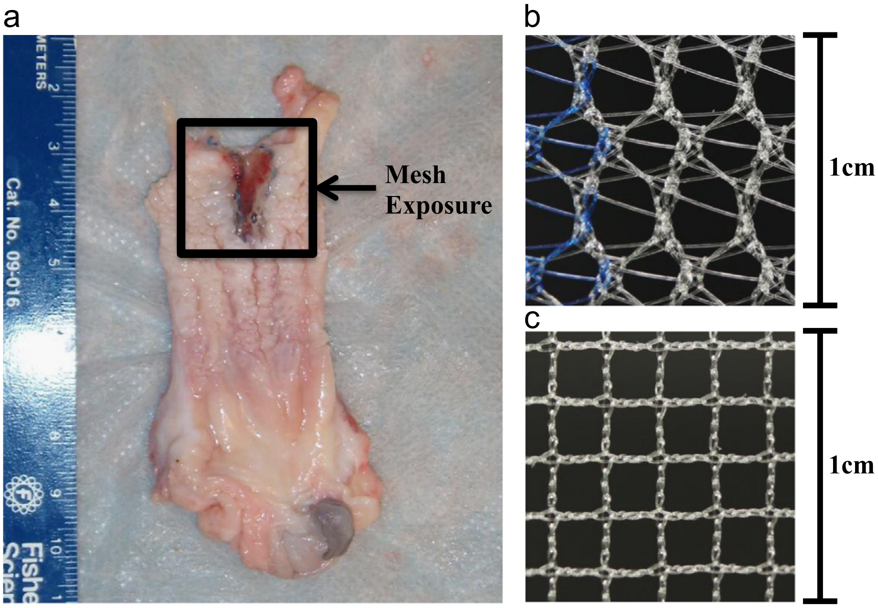

Fig. 1. Evidence of mesh exposure through the anterior vaginal wall of a primate vagina upon explantation (a). The mesh appears folded, with a ridge in the center of the degenerated vaginal tissue. The distinct pore geometries of Gynemesh (b) and Restorelle (c) have been shown to elicit differing structural mechanical behavior, though both are comprised of type 1 polypropylene.