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Varying degrees of nonlinear mechanical behavior arising from geometric differences of urogynecological meshes

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ABSTRACT

Synthetic polypropylene meshes were designed to restore pelvic organ support for women suffering from pelvic organ prolapse; however, the FDA released two notifications regarding potential complications associated with mesh implantation. Our aim was to characterize the structural properties of Restorelle and UltraPro subjected to uniaxial tension along perpendicular directions, and then model the tensile behavior of these meshes utilizing a co-rotational finite element model, with an imbedded linear or fiber-recruitment local stress–strain relationship. Both meshes exhibited a highly nonlinear stress–strain behavior; Restorelle had no significant differences between the two perpendicular directions, while UltraPro had a 93% difference in the low (initial) stiffness ($p=0.009$) between loading directions. Our model predicted that early alignment of the mesh segments in the loading direction and subsequent stretching could explain the observed nonlinear tensile behavior. However, a nonlinear stress–strain response in the stretching regime, that may be inherent to the mesh segment, was required to better capture experimental results. Utilizing a nonlinear fiber recruitment model with two parameters A and B, we observed improved agreement between the simulations and the experimental results. An inverse analysis found $A=120$ MPa and $B=1.75$ for Restorelle (RMSE=0.36). This approach yielded $A=30$ MPa and $B=3.5$ for UltraPro along one direction (RMSE=0.652), while the perpendicular orientation resulted in $A=130$ MPa and $B=4.75$ (RMSE=4.36). From the uniaxial protocol, Restorelle was found to have little variance in structural properties along these two perpendicular directions; however, UltraPro was found to behave anisotropically.

1. Introduction

In the field of urogynecology, synthetic polypropylene meshes saw a dramatic increase in use over the last decade. It had been estimated that these devices were implanted in over 200,000 women annually when their use peaked. They are designed to restore pelvic organ support for women suffering from pelvic organ prolapse (Olsen et al., 1997). Because they are essentially modified abdominal hernia meshes, their use in the field of urogynecology has undergone little oversight. Evidence had suggested that the number of patients experiencing post-surgical morbidity had been grossly underreported, which lead to the Food and Drug Administration to release two Public Health Notifications about the potential complications associated with urogynecological mesh implantation (FDA Public Health Notification, 2008, 2011). These complications often include scarring, pain, mesh exposure and dyspareunia and can greatly reduce the quality of life for women (Chen et al., 2007; Fenner, 2000). Recent data from our laboratory suggest that the mechanics of the mesh plays a significant role in dictating the host response following implantation (Feola et al., 2013a, 2013b; Liang et al., 2013). However, other than some fundamental mechanical testing experiments, little has been done to more rigorously analyze the mechanical response of these meshes.

The latest generations of meshes are all made of polypropylene; yet, their knit patterns, quantity of material, and geometry can yield a wide array of mechanical behavior. A study by Saberski et al. found that several polypropylene meshes were anisotropic in response to uniaxial tensile testing protocols in perpendicular directions, while others were not (Saberski et al., 2011). Since the material used to create many of these different mesh products is the same (polypropylene), it is the different textile properties that gives rise to the large variations in mechanical behavior observed in previous studies (Feola et al., 2013a, 2013b; Shepherd et al., 2012). Understanding the relationship between mesh textile properties and its mechanical behavior is critical to improve mesh design.

The textile field has a deep history of utilizing constitutive and finite element modeling techniques to understand the mechanics of various products (Kaiser, 2008; Yeoman et al., 2010). However,

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the application of these approaches to the field of urogynecology and the commonly used synthetic meshes utilized in prolapse repair is relatively new. In this study, we propose to employ a co-rotational finite element technique that allows for large rotations and displacements, but small material strains to model mesh mechanical behavior (Battini 2002; Battini and Pacoste, 2002a, 2002b; Crisfield, 1997). A constitutive law can then be described independently as a linear or nonlinear function using this method. This approach may be better suited for prolapse meshes that are macroporous and undergo large-scale segment rotations and realignment in response to uniaxial extension (Shepherd et al., 2012).

We hypothesized that much of the difference in mechanical behavior between two different mesh designs could be attributed to the overall geometry of the mesh. Thus, we aimed to characterize the ex vivo structural properties of a bidirectionally isotropic mesh [Restorelle™ (marketed as Minimesh™ by Mpathy Inc. at the time of this study) and an anisotropic mesh [UltraPro™ (marketed as Prolift +M™ by Gynecare Inc.)] subjected to uniaxial tension along two perpendicular directions. Next, we utilized the co-rotational finite element model to determine if their differences in structural behavior can be solely attributed to the different geometries of these meshes. We first employed a linear stress–strain law for the mesh fibers to evaluate the contribution of segment rotation and alignment to the nonlinear structural response of the mesh. Using an inverse approach to fit the model to experimental data, allowed the contribution of geometry to the mechanical nonlinearity to be assessed. A nonlinear fiber recruitment constitutive model was used to simulate the mesh structural response. We found that this model was necessary for better agreement of model predictions and experimental observations, pointing to the inherent nonlinearity of the mesh segments due to the presence of knits and crimps. We finally utilized our model to study the origin of direction-dependence of the mesh structural response, and found that it may depend on the architecture of the mesh.

2. Methods

2.1. Uniaxial testing

Manufacturers provided sterile sheets of the Restorelle and UltraPro for uniaxial tensile testing. The methods for tensile testing have previously been described (Jones et al., 2009; Shepherd et al., 2012). Mesh samples were attached to a custom set of clamps to form a clamp–mesh–clamp construct. Clamp to clamp distances were measured. To ensure that samples were tested consistently, an aspect ratio (length to width ratio) of five was maintained for all samples. To determine the ex vivo structural properties of each mesh, samples of clinically relevant size (75×15 mm^2) of Restorelle ($n=5$) and UltraPro ($n=4$) were tested in response to uniaxial extension along orientation 1 (O1) and orientation 2 (O2) as shown in Fig. 1. Orientation 1 indicates the direction implanted along the longitudinal axis of the vagina during placement for an abdominal sacral colpopexy procedure.

After each mesh sample was cut and placed within the custom designed clamps, the constructs were placed into a 37 °C saline bath fixed to the base of the Instron™ testing machine (Instron[5565], Norwood, MA) screw driven testing apparatus (Shepherd et al., 2012). Samples were allowed 15–20 min to equilibrate prior to testing. Samples were preloaded (0.1 N) at a rate of 10 mm/min, and the final clamp-to-clamp distance was recorded as the reference length. Next, each mesh was loaded to failure at a rate of 50 mm/min.

The load–elongation curves yielded a nonlinear response that can be approximated as bilinear, which is commonly seen with prolapse meshes (Shepherd et al., 2012). The failure load (N) and corresponding relative elongation (%), defined as the elongation divided by the reference length $*$ 100, were recorded. The slope in the toe region of the curve was defined as the low stiffness (N/mm), while the slope in the linear region of the curve was defined as the high stiffness (N/mm). These values were determined by assuming the response is bi-linear and fitting lines to each region. The inflection point was defined as the intercept of these two lines.

2.2. Finite element modeling

Prior to the simulation, the geometry of each mesh was approximated using a custom made Matlab script (MathWorks Version 7.11, 2010). In short, two populations of fibers, with a similar diameter, were assumed for each of these meshes to create a computer representation of the mesh based on the actual micrographs.

All generated mesh renderings were standardized to the average size of each mesh tested experimentally (75×15 mm^2). The number of finite element nodes along each mesh segment was set to 10, as changes in the simulated load–elongation response after increasing the node number to 20 was negligible. Individual segments between each node were modeled as Timoshenko beam elements, which account for the first-order shear deformation. Constitutive relationships, both linear and nonlinear, were prescribed to these beam elements. In addition to implementing a unique local stress–strain relationship, this co-rotational and finite element approach accounts for the fiber geometry and nodal interaction. Interaction between mesh segments can affect the degree to which overlapping nodes, or joints, can transfer bending moments generated during rotation of the mesh. Since these meshes are not rigidly locked at the overlapping knits, it is important that simulations consider the interaction of these joints. Therefore, we implemented a 'hinge' parameter that can range from 0, or no moment transferred, to 1, indicating the entire moment is transferred. Although it is unclear how much of the moment is transferred between nodes, it is known that these are not rigid interactions. Subsequently, this parameter was set to 0.5 to allow 50% of the moment forces to be transferred at the joints.

Lastly, the cross-sectional area of each segment was estimated based on the width and number of individual fibers within each of the mesh strands. Reexamining Fig. 1, it is evident that each strand of the Restorelle and UltraPro meshes consist of multiple fibers of polypropylene. A single representative fiber diameter was calculated from these multiple fibers. In short, the number and diameter of the individual fibers was determined and the cumulative area of those fibers was utilized as the representative area. The areas for Restorelle and UltraPro were calculated to be 0.11 mm and 0.19 mm, respectively.

For the first simulation, the local stress–strain relationship was assumed to be linear according to

$$\sigma = E\varepsilon \tag{1}$$

where E is the elastic modulus relating stress and strain. Using this model, any degree of nonlinearity or anisotropy described by the model in terms of the force–displacement relationship would be strictly a function of mesh geometry. In the second set of simulations, the local stress–strain relationship was assumed to be

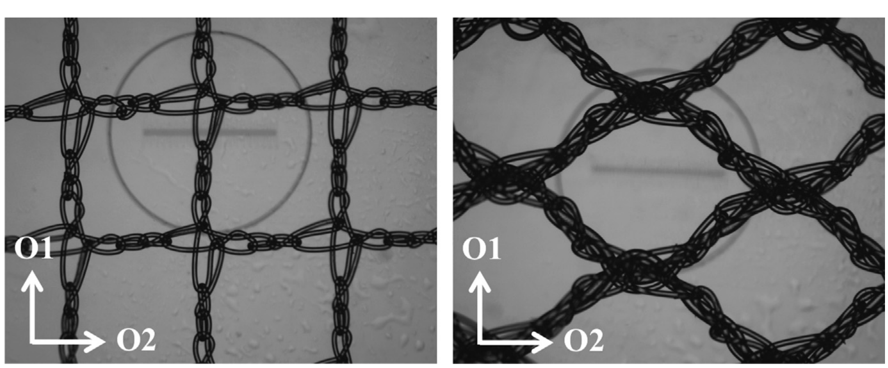

Fig. 1. Macroscopic images of Restorelle (left) and UltraPro (right) meshes illustrating orientation 1 (O1 or warp) and orientation 2 (O2 or weft).