Biomechanics and Bioresorbable Material Study toward Pelvic Organ Prolapse Corrective Mesh Design

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Statement of Purpose: Corrective meshes, used in treatment of pelvic organ prolapse, have come under much scrutiny, being the focus of several current class action lawsuits. These meshes are not bioresorbable and do not match the mechanical properties of the surrounding tissue, causing a range of maladies. This study aims to resolve these issues by studying the mechanical properties of freshly harvested vaginal tissue and initiating the development of replacement bioresorbable materials for corrective meshes. To achieve these goals biaxial modulus data was collected from freshly harvested vaginal tissue samples depicting the anisotropy of tissue. Bioresorbable Poly-lactic acid (PLA) was synthesized in different molecular weights (M_n), in order to gain control over the bioresorption of the material.

Methods: *Polymer:* PLA polymers were synthesized using previously described methods from our group.[1] Mns were determined using Gel Permeation Chromatography (Shimadzu).
Tissue Testing: After attaining IRB approval, fresh HAVW tissue was harvested from postmenopausal women with advanced stage III and IV anterior wall vaginal prolapse undergoing surgical treatment. In order to avoid a compromise in the tissue during biomechanical testing cauterization, indentation or small side cuts in the strip edges were avoided during excision. In order to maintain equivalency, all samples were approximately 1 cm in width and 3 cm in length and were harvested in the same orientation, noted using a suture placed at the distal end of the sample. The samples were wrapped in moist gauze and transported in a cooler (and maintained at 25°C) with a data logger to track humidity and temperature. Biopsy punches of 4mm diameter were used to cut out two discs of the tissue to be tested using Dynamic Mechanical Analysis (DMA-Mettler Toledo). The orientation of the tissue was noted using ink marks along the longitudinal axis. Frequency sweeps were run on samples in longitudinal and transversal orientations from 100-0.1 Hz at a constant temperature of 37°C in order to obtain biaxial data from the tissue.

Results: It is understood that polymer M_n dictates the rate of degradation *in vivo* of a polymer, thus a systematic study was done to understand the effect of catalyst concentration on the PLA M_n. Our results show that optimal molecular weight conditions are obtained under low catalyst loading and dilute conditions.

Table 1. Control of PLA M_n as a function of catalyst.

PLA Sample	Conditions	Catalyst	Solvent	Mn	Mw	Mw/Mn
1	Round bottom method, under N2, 0.036 drops catalyst, 5mL toluene solvent	0.036g	5mL	7087	12356	1.743473966
2	Round bottom method, under N2, 0.012 drop catalyst	0.012g	no solvent	9584	**18795**	1.961080968
3	**Round bottom method, under N2, 0.012g catalyst, 5mL toluene solvent**	**0.012g**	**5mL**	**27068**	**74285**	**2.744384513**
4	Round bottom method, under N2, 0.024g drops catalyst	0.024g	no solvent	7970	15398	1.931994981
5	Round bottom method, under N2, 0.024 drops catalyst, 5mL toluene solvent	0.024g	5mL	16886	**31736**	1.879426744

Biaxial DMA results clearly show anisotropy in the tissue. The longitudinal and transversal orientations show different storage moduli. Fig 1 depicts the variation between the different orientations.

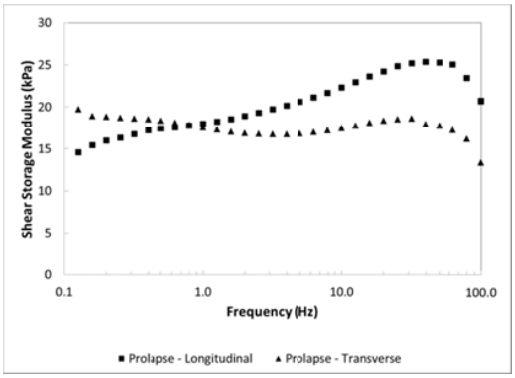

Figure 1. Storage moduli with orientation.

Conclusions: Tensile tests using Instron were previously performed at UTSW [2], however attaining large samples for the runs was found to be difficult and the non-physiologic break point tests unreliable. DMA requires minimal sample size, and can reach lower frequencies that mimic physiological strains. Biaxial data is important in understanding tissue mechanical properties. To our knowledge we are the first to perform such tests. Also, different Mns of PLA were successfully synthesized by varying catalyst concentrations. Novel bioresorbable material design must mimic, to the best of its ability, the surrounding tissue characteristics.

References:

[1] Haynes, D. Macromol. 2007:40:9354-9360
[2] Zimmern, P. Neuro&Urody. 2009:28:325-329