Mechanical Properties of Polypropylene-ePTFE Surgical Mesh Explanted After in vivo Function

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Statement of Purpose: The purpose of this study is to characterize properties of surgical mesh that have been exposed to physiological conditions in patients and explanted after in vivo function.

Surgical meshes are woven or polymer-based materials commonly used to augment surgical repair of abdominal hernias. While hernia repair with surgical mesh is highly sucessful in the majority of cases, some patients experience pain and discomfort that can require mesh removal. Some studies suggest that changes in mesh properties during in vivo function, such as increased stiffness or altered pore size, may negatively impact patient comfort and the success of the surgical repair. From a biomaterials perspective, it is important to document such unanticipated changes in material properties that occur in the physiological environment.

Surgical mesh that has been explanted (surgically removed) from patients provide unique evidence for characterizing the effect of the physiological environment on mesh materials. This project establishes and reports necessary cleaning procedures prior to the testing of mechanical properties. The tensile stiffness and compliance of the cleaned, explanted mesh are measured and compared to unused mesh (control).

Methods: This IRB approved study established a registry of explanted surgical meshes containing 102 explanted meshes surgically removed by our clinical collaborators. The mesh used for this initial study is COMPOSIX™ EX (C.R. Bard/Davol, Inc., Warwick, R.I.), which consists of a polypropylene mesh layer attached to an extended polytetraflouroethylene barrier layer. Prior to testing, the explanted meshes were stored in formalin and then underwent a bleach tissue digestion method to remove adherent tissue. The two explanted COMPOSIX™ EX meshes were submerged in 8.025% bleach for two hours at 37°C and subsequently sonicated in distilled water for five minutes and dried with compressed air. This tissue digestion method had previously been shown to not significantly affect mesh properties. Control mesh and explanted meshs were cut into strips (25mm x 75mm for tensile stiffness and 25mm x 25mm for compliance testing) and the control mesh were soaked in PBS for 18 hours at 37°C before testing. To assess tensile stiffness, the mesh strips were uniformly aligned into a jig attached to an MTS load frame and loaded at a rate of 25 mm/min with a gauge length of 25 mm (ASTM D5035). To assess compliance, the mesh squares were placed over an open slit jig and the force required to push the specimen through the slot using a rounded blade was measured (ASTM D6828). For tensile testing, the control mesh had 12 samples, while the explants had five samples each. For compliance testing, the control mesh had 12 samples, Explant 1 had 11 samples, and Explant 2 had 9 samples. Mesh stiffness was calculated as the slope of the linear portion of the stress-strain curve.

Results: The mean tensile stiffness and compliance for the control mesh was significantly lower than the explanted mesh (Table 1).

Mesh	Duration [months]	Tensile Stiffness [N/mm]	Work to Peak Load [J]
Control	N/A	11.0390±0.6440	0.0015±0.4990
Explant 1	37	12.2750*±0.5439	0.0025*±0.4840
Explant 2	12	11.8378*±0.4878	0.0033*±0.5380

Table 1. Stiffness values for control and explanted surgical mesh.
*Indicates significant difference between the explanted meshes and the control.

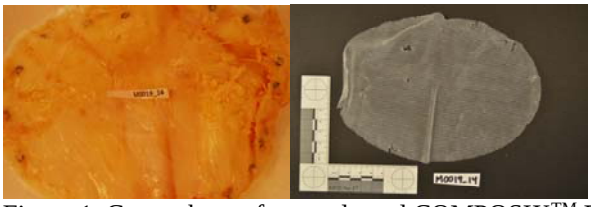

Figure 1. Gross photo of an explanted COMPOSIX™ EX mesh before (L) and after (R) tissue digestion.

Conclusions: These preliminary results indicate that COMPOSIX™ EX meshes are stiffer after relatively short duration of exposure to the physiological environment. Previous studies have noted similar stiffening after in vivo function. Costello found between a 4 and 30 fold decrease in the compliance of explanted meshes. The underlying cause of such increased stiffness and its relationship with clinical symptoms remains to be determined. Testing of the remaining samples in the registry of explanted surgical mesh, including both COMPOSIX™ EX and other brands, is ongoing.

References:

(Casey E. Tissue Digestion Methods Suitable for Explanted Hernia Mesh. Poster session presented at: 4th Annual Biomaterials Day; 2014 Oct. 10; Atlanta, GA.)
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