Testing Compliance of Surgical Meshes Fabricated from Different Polymeric Biomaterials

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Statement of Purpose: The purpose of this research is to measure the compliance of surgical meshes, specifically three types of commercially available hernia meshes. More than 20 million hernia repairs are performed each year worldwide. Intraperitoneal prosthetic mesh implants are used to decrease tension at the suture site, creating significantly less tension than if the wound was closed by sutures alone.[3] Various polymer materials and composites are used, such as expanded polytetrafluoroethylene (ePTFE), polypropylene (PP) of various weights, polyester, and combinations of these materials. The material properties of the different meshes play a large role in different failure modes. Mesh degradation, contraction, migration, and oxidation can alter the mesh compliance and other physical properties ultimately decreasing functionality of the implanted mesh.

Specific failure modes occur more often in certain materials. For example, PP meshes suffer from inferior compliance, while ePTFE meshes have suitable compliance but suffer from high shrinkage in vivo. [3] Different shrinkage rates in composite of PP and ePTFE can cause shape deformation. Such loss of mesh flexibility during normal flexion in the abdominal region during activity can lead to pain, suggesting that measurement of mesh compliance and flexural rigidity may be useful for predicting in vivo performance.

Methods: Three different unused surgical meshes were tested, including Composix E/X (CR Bard / Davol Inc), Ultrapro (Ethicon Inc) and Parietex Composite (Covidien/Sofradim), each having different materials and structures (Table 1). All mesh samples were cut into 25 mm x 25 mm strips and placed in 1X phosphate buffered saline (PBS) at 37°C for 18 hours to equilibrate at physiological conditions. A mechanical test of mesh compliance/stiffness ("slot test") was devised to simulate mesh bending that occurs in vivo during trunk flexion movements.[Costello 2006] Each mesh strip was laid over a 5x100 mm rectangular slotted test fixture while a rectangular aluminum indenter probe (3x90 mm) was loaded perpendicular to the slot and used to bend the mesh and push it through the slot. These fixtures were attached to an MTS load frame with a10 N load cell and loaded at 0.2 mm/sec in order to generate load-displacement curves. The peak load [N] was measured and the total work required to push the mesh through the slot [J] was calculated as the area under the curve from initial load to peak load.

Results: Results from the slot test show that Composix E/X endured a significantly (ANOVA, $p<0.05$) higher peak load [N] compared to the other meshes (Figure 1). Composize E/X had the lowest compliance, requiring the greatest magnitude of work to push it through the slot [J]. Ultrapro and Parietex had similar peak loads, but Ultrapro required greater work to push through the slot.

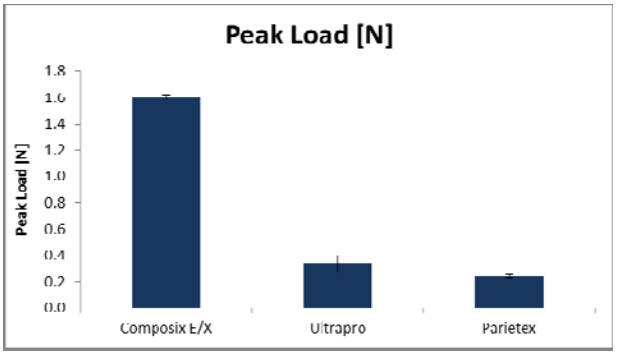

Figure 1. Average peak load results for slot test

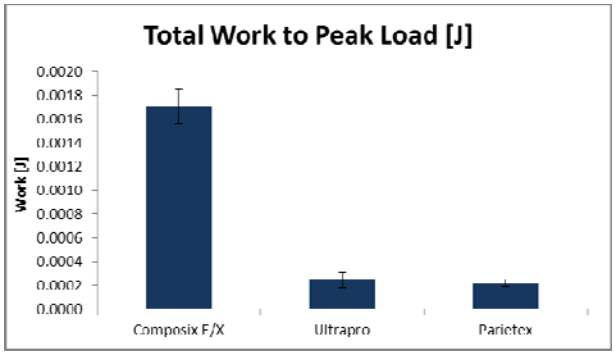

Figure 2. Average total work to peak load in slot test

Mesh	Materials	Structure
Composix E/X	PP sewn to thin ePTFE backing	Knitted monofilament PP
Ultrapro	PP with absorbable poliglecaprone monofilament	Woven PP with interwoven poliglecaprone
Parietex Composite	Polyester mesh with absorbable collagen-polyethylene glycol-glycerol coating	Multi-fiber polyester knitted with 3-D structure and double thickness

Table 1: Mesh Materials and Structure [1,3,4]

Conclusions: After exposure to a physiological environment, mesh material can experience changes in compliance and other altered mechanical properties compared to pristine meshes.[REF Costello 2007; Cobb 2006] In the current study, Composix E/X proved to be the least compliant of the meshes tested and required significantly more work to achieve a flexed orientation compared to the other meshes. These results, combined with surgical handling attributes and clinical outcomes for these meshes, will help improve the predictive capability of this compliance test.

References:

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