Patient Factor Correlation of Explanted Composite Hernia Mesh Material Properties

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Statement of Purpose: Defects in the connective tissue of the abdominal wall are termed hernias. Severe herniations can lead to organ protrusion and complications such as bowel obstruction or strangulation. To prevent this from occurring, surgeons routinely suture synthetic or biologic mesh over the intra-abdominal side of the defect to provide structural support. However, many synthetic meshes are not entirely biocompatible. One solution involves using several different synthetic materials to form composite meshes that capitalize on the individual strengths of the materials while also compensating for their weaknesses. Yet, these composites still exhibit biologic incompatibilities such as adhesions and bowel obstruction, which often mandates their removal.

The purpose of this study was to conduct material characterization on human explanted composites comprised of layered polypropylene (PP) and polytetrafluoroethylene (PTFE) meshes which encase a polyethylene terepthalate (PET) ring. Thermal and spectral analysis of the explants revealed the extent of their *in vivo* degradation. Furthermore, the material characterization results were analyzed for correlation with patient factors such as age, body mass index (BMI), and implantation time. Identification of patient factor influence on the outcome of hernia mesh implants could increase hernia repair success rates by allowing surgeons to choose repair meshes based on patient history.

Methods: Explanted composite meshes were removed from patients at the University Hospitals in Columbia, MO via an approved IRB. Tissue was removed from 11 PP, PET, and PTFE composite explants by sodium hypochlorite immersion. Digital images were recorded to document macroscopic damage to the explants while scanning electron microscopy (SEM) was used to document microscopic damage. Spectra were collected using Attenuated Total Reflectance Fourier Transform Infrared Spectroscopy (ATR-FTIR) to demonstrate differences in chemical bonds between the explant and pristine samples. Thermal analysis was conducted by Modulated Differential Scanning Calorimetry (MDSC) and Thermogravimetric Analysis (TGA) to determine structural integrity of materials as measured by heat of fusion (J/g) and rate of mass loss (%·min/°C), respectively.

Results: SEM images of pristine PTFE, PP, and PET samples showed smooth surfaces absent of defects. PTFE, PET, and PP explants displayed changes in the overall texture with roughening of the surfaces. Also noted was fraying of the PET ring and stress cracks at the weave junction in PP (Figure 1). ATR-FTIR spectra for PTFE demonstrated significant increases in peak area for C-H stretching and carbonyl (C=O) peaks in 10 of the 11 explants ($p<0.05$). PP also exhibited a significant increase in C=O peak area for 6 explants ($p<0.05$). MDSC scans showed an increase in heat of fusion for 1 PP ($p<0.01$), 7 PTFE ($p<0.01$), and 7 PET ($p<0.05$) samples. TGA results displayed a decrease in rate of mass loss from pristine for 8 PP explants while PET showed no difference from pristine except for two explants which had a lower rate of mass loss. PTFE showed a decreased rate of mass loss for all but 3 explants, one of which showed an increased rate of mass loss. No direct correlation was found between ATR-FTIR, DSC, or TGA results with patient factors of age, BMI, or implantation time.

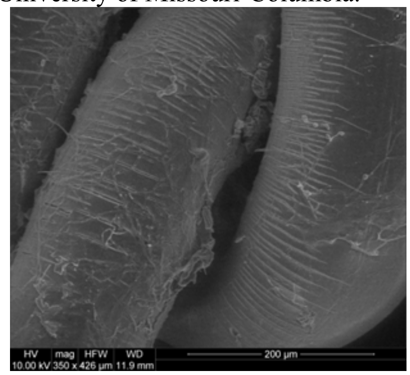

Figure 1. SEM of stress cracks at a PP weave junction

Conclusions: The explanted PET, PTFE, and PP composite hernia meshes experienced degradation *in vivo*. This is qualitatively evident from visual observations using macroscopic and microscopic digital imaging which indicated an increased roughness of the overall texture in addition to fraying of PET and stress cracks in PP. ATR-FTIR spectra displayed increased C-H stretch and C=O peaks suggesting that PTFE is more susceptible to oxidative degradation than PP. MDSC data for PTFE and PET showed an increase in heat of fusion, indicative of high cross-linking, implying that these two materials experienced enhanced cross-linking *in vivo* while PP did not. Furthermore, decreases in rate of mass loss, as measured by TGA, showed higher levels of degradation for PP and PTFE, but not PET. However, none of these effects of degradation could be specifically correlated with age, BMI, or implantation time. Thus, it is likely that these altered chemical and physical material properties are the result of an interaction of patient factors.

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