High Tenacity Polyester Yarns: the New Generation of High Performance Biomaterials

[1]Martin W. King, [2]Christopher M. Pastore and [3]Robert Torgerson.
[1]College of Textiles, North Carolina State University, Raleigh, NC,
[2]Kanbar College of Design, Engineering & Commerce, Philadelphia University, Philadelphia, PA
[3]RxFiber LLC, Windsor, CA

Statement of Purpose:

In the past open surgical procedures were the norm for cardiovascular operations, and normal tenacity polyester (polyethylene terephthalate or Dacron®) yarns provided a flexible and biocompatible, albeit thrombogenic, FDA approved textile material for a wide range of cardiovascular and other applications. However, there are a number of reports of adverse events related to the limited biostability of normal tenacity polyester yarns, particularly when exposed to an infection [1,2].

Today endovascular devices, heart valves and stents are routinely implanted endoscopically using a catheter-based system. Since the diameter of the delivery system is limited by the size of the vessel it needs to pass through, companies developing the next generation of devices are seeking stronger and thinner biomaterials that will reduce the device's profile. This will facilitate the deployment of larger size devices through the same small caliber vessels. A good proportion of eligible patients have small diameter and tortuous anatomies that require smaller diameter and more flexible delivery systems. This in turn requires a minimal volume of biomaterial to be compacted into the catheter-based system for delivery to the site. For instance, trans-catheter stent-grafts currently use fairly large diameter yarns (40 - 70 denier), which require at least a 20F delivery system. To reduce the profile and maintain the integrity of the implantable device, finer and stronger yarns need to be developed. This has led companies such as RxFiber to develop a range of finer denier high tenacity polyester yarns (such as 20 denier or lower) for this type of application.

The objective of the present study was to evaluate the mechanical properties of high tenacity polyester yarn, and compare its performance with regular tenacity polyester (such as Dacron®) as well as ultra high molecular weight polyethylene yarns (UHMWPE) that are sometimes used for orthopedic and medical load bearing biomaterial applications.

Materials and Methods:

Samples of the three yarns were obtained as follows: i) high tenacity (HT) 20 denier, 18 filament PET yarn under the tradename RxFibron HT®, and ii) normal tenacity (NT) 40 denier 27 filament PET yarn under the tradename RxFibron® were supplied by RxFiber LLC (Windsor, CA) and iii) 22.5 denier ultra high molecular weight polyethylene yarn (UHMWPE) under the tradename Dyneema® was supplied by DSM Biomedical (Exton, PA). The yarns were subjected to uniaxial mechanical testing to failure so as to determine their tensile strength and initial modulus. The standard ASTM D2256 test method was followed.

Results:

The average results for yarn tensile strength and initial modulus are summarized in Table 1, and stress-strain curves for the three different yarns are shown in Figure 1.

Material	Tensile Strength (g/den)	Initial Modulus (g/den)
NT PET	4.2	128.9
HT PET	6.6	204.3
UHMWPE	37.0	1166.9

Table 1: Average tensile test results

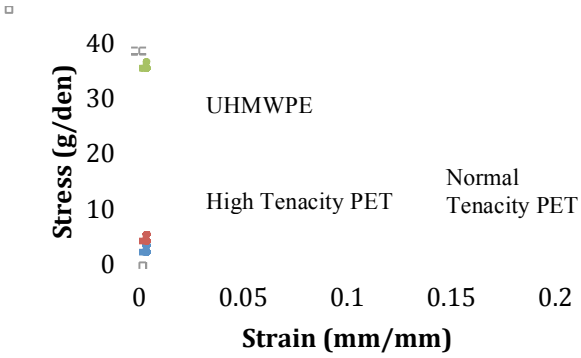

Figure 1. Typical Stress-Strain Curves for high tenacity PET, normal tenacity PET and UHMWPE yarns.

Conclusions:

The results confirm that the tensile properties of the high tenacity polyester yarn lie between those of the normal tenacity PET and the UHMWPE yarn. This indicates that the use of the thinner high tenacity PET yarn would reduce the profile of the biotextile device currently fabricated from normal tenacity PET yarn. This will enable easier folding and loading into the delivery catheter as well as easier delivery. Further comparative testing of the biocompatibility, thermal and abrasion properties is continuing, and will provide an assessment of the ability of the HT polyester yarn to avoid raveling when thermally treated with a hot cautery and to provide a less abrasive surface when deployed against bone and soft tissues. Additional information about the preferred sterilization procedures will be presented.

References:

[1] King MW, Guidoin R, Blais P et al. "Degradation of polyester arterial prostheses; a physical or chemical mechanism?" Corrosion and Degradation of Implant Materials: 2nd Symposium, ASTM STP 859, AC Fraker and CD Griffin (Eds), ASTM, West Conshohocken, PA, 1985, pp.294-307.

[2] Riepe G, Loos J, Imig H et al. "Long-term in vivo alterations of polyester vascular grafts in humans", Eur J Vasc Endovasc Surg 13, 540-548 (1997).

©2014 Society for Biomaterials