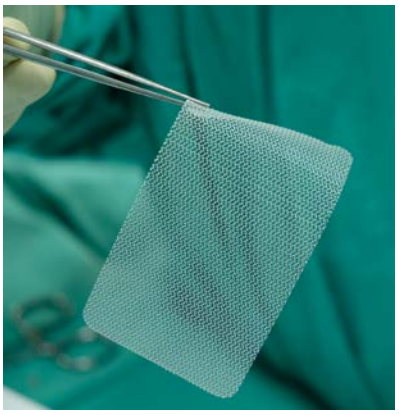
Hernia Mesh Testing



Hernias occur when an organ, intestine or fatty tissue squeezes through a hole or a weak spot in the surrounding muscle or connective tissue. An estimated 2.3 million inpatient abdominal hernia repairs were performed from 2001 to 2010 in the US with an estimated 567,000 performed emergently (JAMA Surg 2015, 150(3):194-200).

Hernias have a high rate of recurrence, and surgeons often use a surgical mesh to strengthen the hernia repair and reduce the rate of recurrence. Most of the surgical mesh devices that are currently available for use are constructed from synthetic materials (absorbable or non-absorbable) or animal tissue.

Hernia mesh properties such as tensile strength, pore size, weight, reactivity/biocompatibility, elasticity, constitution (mono- or multi-filament) and shrinkage largely determine the types of complications that may occur (Ann R Coll Surg Engl 2010, 92:272-278). FDA's Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh outlines product characterization information critical in determining equivalence of a proposed device including:

- tensile strength
- device stiffness
- suture pullout strength
- burst strength
- tear resistance

The FDA issued a press release in January of 2016 strengthening the data requirements for surgical meshes that repair pelvic organ prolapse transvaginally, reclassifying them from class II to class III medical devices and requiring a premarket approval (PMA) application to demonstrate safety and effectiveness. There is an ASTM standard, *F881-94(2014): Standard specification for silicone elastomer facial implants*, that specifically covers the requirements for silicone elastomer implants used in facial surgery (chin, nasal, malar, and ear implants).

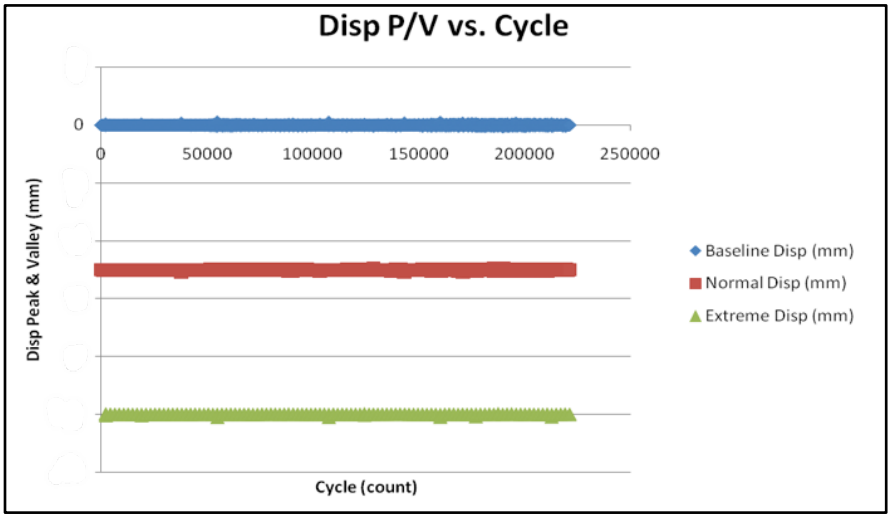
Having tested surgical meshes for over 10 years, our engineering team is experienced in assessing the mechanical properties of these devices using suitable fixtures for sample gripping and loading and well-designed test protocols.

Bending Fatigue

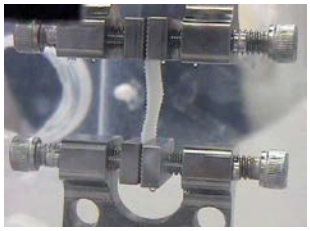
Although fatigue testing is not specified in the FDA guidance document, device manufacturers often include fatigue testing data in their regulatory submissions. This type of test is used to characterize surgical mesh performance through simulated displacements that represent activities of daily living. Tests are performed in heated saline solution by applying a sinusoidal waveform at 1 Hz. A custom indenter with an appropriate radius of curvature is typically designed for the 3-point bend test, and

worst-case loading conditions may be simulated by clamping the device at the extreme ends and loading at the half point.

The data below are peak and valley displacements plotted against number of cycles. A custom waveform was designed that alternated between normal and extreme displacement conditions. Load data was also recorded throughout testing (not shown).



Characterization Testing



In addition to bending fatigue testing, there are several other quasi-static tests that are performed to characterize the mechanical properties of the surgical mesh materials. Tensile (see image on the left), suture pullout, and burst strength testing follow standard protocols; however, sample gripping and loading fixtures and loading rates may vary depending on the type of surgical mesh tested and its intended application.

Planar biaxial testing may also be utilized to characterize mesh properties and assess anisotropy. A recent study performed biaxial mechanical evaluation of six absorbable and non-absorbable synthetic surgical meshes used for hernia repair and found that only one exhibited planar isotropy (Ann Biomed Eng 2016, 44(7):2181-8).

Consultation

If you would like assistance with your device's bench testing, please fill out our test questionnaire or call us at 952-933-1152 to discuss how we can help.

Element Materials Technology offers the broadest scope of medical device testing, so if you are looking for services such as package testing, microbiological testing, accelerated shelf life testing or EMC/EMI testing, contact us to connect with the right lab.