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Issue 34

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Application Article

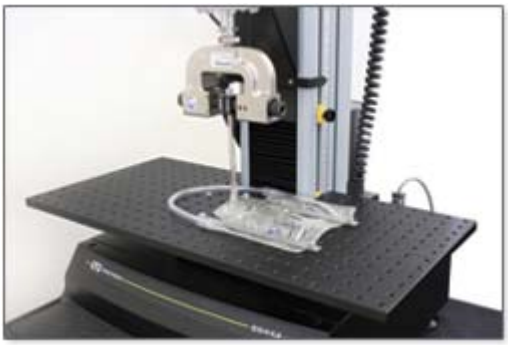
Study Shows Differences in Mesh Materials for Hernia Repair

Twenty years ago a patient undergoing hernia surgery would be marked by a noticeable scar, endure a long recovery time, and according to a medical study, up to 20% of these patients would experience a recurrent hernia. Due to medical advancements, hernia surgery is now less invasive, has a quicker recovery time, and decreased risk of recurrence (less than 1%). What is this magical medical advancement? Laparoscopic surgery.

According to Dr. Corey Deeken, Director of the Biomedical Engineering and Biomaterials Laboratory at Washington University's School of Medicine, it is important for surgeons to choose an appropriate prosthetic mesh material when performing laparoscopic hernia repair.

"In the world of hernia repair, there are so many materials and pre-formed sizes available for surgeons to choose from," Deeken said. "The mesh that is right for a particular patient and type of repair may not be the best choice for the next patient."

Deeken, a biomedical engineer, wants to give surgeons more standardized information to compare when choosing what is best for their patients. This includes a recent project to characterize the properties of a variety of mesh materials available for hernia repair applications. During this project, Deeken and her team used a tensile testing system to measure the biomechanical properties of more than 25 different hernia repair materials using techniques such as suture retention and tear testing, as well as standard uniaxial and mesh strength testing. Deeken hopes to present the data from this study at an upcoming surgical conference to make surgeons aware of differences in the biomechanical properties of hernia repair materials.



Tech Tip

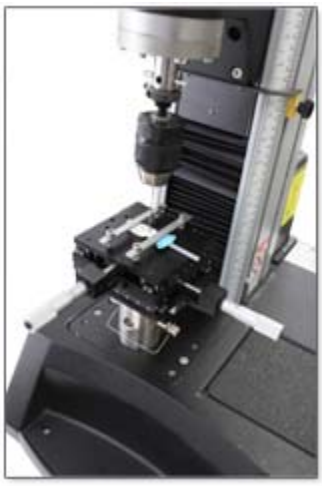
Challenges in Testing Biomedical Components

Medical device manufacturers have been following the ongoing trend of testing the final product instead of coupons or specimens. In so doing, their ability to use standard gripping techniques and fixturing is not practical. Although traditional grips, like pneumatic action or wedge action styles, worked well for standard materials, new test requirements force users to place the product into the testing system for evaluation or validation.

To satisfy this requirement, testing instruments must be designed to accommodate a wide range of device sizes and configurations. We suggest using a component test plate that contains an array of tapped holes. This makes component or specimen attachment simple and repeatable. The plate is sized to satisfy a large range of medical devices and accessories. In the example above, an IV blood bag needs to be held in a specific position so that the connectors for the tubing can be tested for quality and integrity. Because alignment and test angle are critical to mimic the actual usage, a flexible set up is necessary. The component test plate not only allows this flexibility, but is also makes it simple to repeat the set up from test to test, ultimately reducing variability.

For example, a common test for hip replacement prosthesis is a compression test where force is applied to the femoral head while the stem is held fixed. This configuration generates both axial loads and transverse loads due to the geometry of the specimen which sits outside the direct load string. System stiffness and off-center loading must be considered when testing components outside of the direct load string. The resulting side loads can have dramatic affects on the test data. To provide the most accurate and consistent results, the load weighing system (load cell and test frame) should produce minimal off center load effects. The larger the medical device, the more care should be taken for proper placement and alignment.

You Asked – We Answered



Q: How does side loading and specimen/component misalignment of varying geometries of medical devices and implants affect my test results? How should I best address these challenges?

A:ISO and ASTM standards recommend that specimens are aligned so that the axis of force runs through the centerline of the specimen. Since medical device geometries are often odd, there is not a set way to hold specimens. It is very important to make sure the proper grip and a specimen alignment device, such as an XY stage, is used. This can significantly improve specimen placement by ensuring that the specimen is placed in the same location for every test.

With odd shaped specimens, it is essential to take into account the offset loading specifications for the load cell. When failure occurs slightly offset from the primary force axis, there should be minimal deviation in the load reading. When testing cardiac rhythm management devices, like pacemakers, manufacturers must ensure that the leads and lead connections that deliver the electric charges to the heart are robust. Testing these small components requires very precise alignment to guarantee operational effectiveness and quality. Placing these devices in an XY stage allows operators to test at correct angles and index specimens for efficient testing that produces repeatable results.

The combination of proper grip/fixture selection, consistent specimen placement, and minimizing offset loading effects on the load cell will help minimize the effects of side loading, ultimately reducing variation in results. Since the solution varies depending on your application, contact our Application Engineers for assistance.

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