Medical Device Testing's Requirement for Axial-Torsion Loading Regimes

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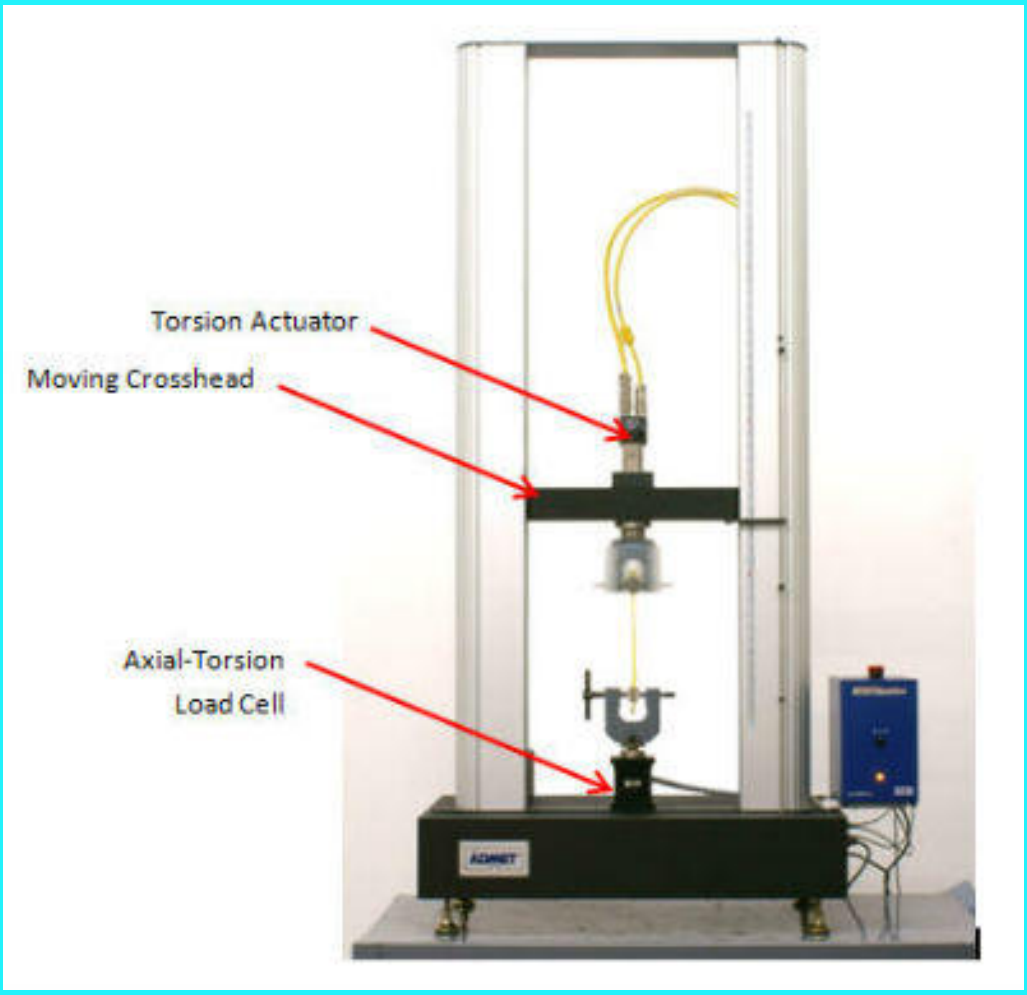
Medical device engineers rely on an array of testing instruments and equipment to verify the safety and efficacy of their products. An axial-torsion testing system is just one of them; however, it has a variety of indications across various device sectors. This article looks at two products for which this testing instrument is invaluable.

What is an Axial-Torsion Testing Machine?



Electro-mechanical and servo hydraulic axial-torsion testing machines are available in a range of capacities for both static and dynamic fatigue testing applications. Uniaxial tension/compression forces are generated by up/down crosshead movement. Torsional loads are applied by the torsion actuator mounted in the moving crosshead. A biaxial transducer that measures uniaxial force and torque is mounted in the base of the machine.

Mechanical testing is critical to the medical device industry. Testing products and materials ensures that implants and devices will not fail when in use, whether in or on the human body. Specifically, axial-torsion test machines (See sidebar) play an important role when testing the quality of a variety of medical products. The American Society for Testing and Materials (ASTM) and International Organization for Standardization (ISO) have developed specifications defining the appropriate way to test particular medical devices. Standards of this nature are necessary so bone screws won't fracture while in the patient's body or a hip replacement doesn't give out in the middle of a recipients stroll, or when a nurse is administrating blood, it is critical that the fittings do not lock together and they operate as they are intended. Clearly mimicking real life stress tests on medical devices is essential. Axial-torsion testing is one solution to this challenge. Two standards that reference axial-torsion testing and are common in the biomedical sector are ASTM F543 "Standard Specification and Test Methods for Metallic Medical Bone Screws" and ISO 594-1,2 "Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment—Lock Fittings."

Bone Screws

Annexes A1 thru A4 of ASTM F543 outline the mechanical performance requirements for metallic medical bone screws. In three of the annexes, an axial-torsion testing machine is needed in order to perform the test.

Annex A1—Test Method for Determining the Torsional Properties of Metallic Bone Screws is used to determine torsional yield strength, maximum torque, and breaking angle. This test requires the thread end of the screw to be clamped while a drive bit engaged with the head of the screw is rotated at a constant speed until failure. During the test, a small compressive force is applied to the drive bit while torque and angle are recorded to failure.

Annex A2—Test Method for Driving Torque of Medical Bone Screws is used to measure the torque required to drive a bone screw into a standard material. The procedure is conducted by driving a bone screw (Figure 1) into a material similar to bone and measuring the maximum torque during the first four revolutions, then reversing direction and recording the maximum torque in the first four revolutions used to remove the screw from the bone material. During the test, a small compressive load is required to maintain engagement between the drive bit and screw head.

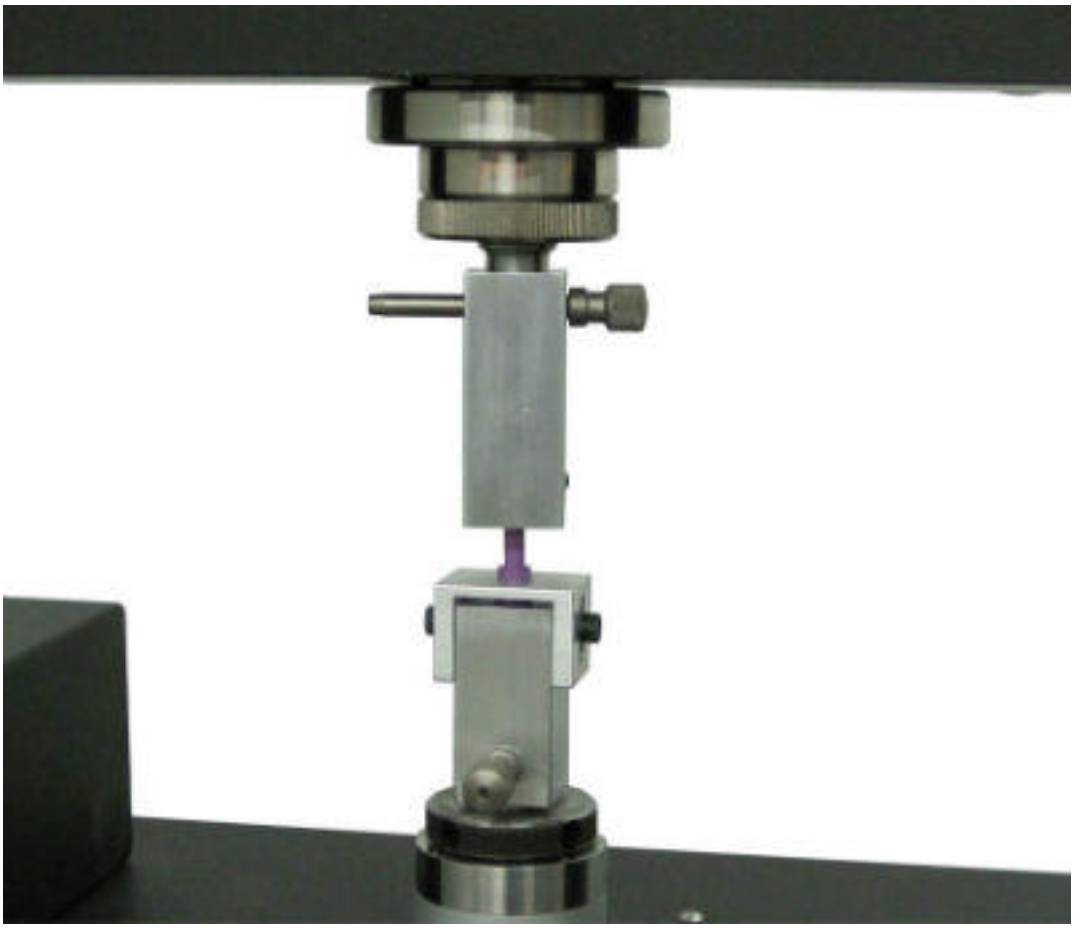
Annex A4—Test Method for Determining the Self-Tapping Performance of Self-Tapping Medical Bone Screws is the most in depth use of an axial torsion testing machine in this standard. This test method is used to determine the compressive force required to engage the self-tapping feature of the bone screw into a standard material. The test procedure is performed by driving a bone screw into a predrilled hole. As the screw is being driven at a constant speed, the compressive force is increased at a specified rate until a marked increase in torque and axial displacement is indicated. This combination signals the engagement of the self-tapping features of the bone screw and the amount of compressive force at that point is recorded.

Luer Locks

The quality and operation of luer locks—a standardized, leak-free medical fitting—are governed by a standard that specifies a series of axial-torsion test procedures. This testing is critical to verify that a luer connection does not fail and leak when a patient is receiving medication or if a patient is giving blood to verify that the fitting can be disconnected. The standard ISO 594-2 "Conical fittings with a 6% (luer) taper for syringes, needles, and certain other medical equipment—General and Lock Fittings" outlines product shapes and materials, and includes seven mechanical tests, the majority of which require an axial torsion testing system.

The seven mechanical pass/fail tests cover a wide spectrum, including introducing environmental conditions and adding substance within the lock. Most of the seven tests require an axial-torsion testing system. The Liquid and Air Leakage Test-1, as well as the Stress Fracture Test-2, require that the fitting is assembled by applying an axial force while simultaneously applying a torque. The Liquid and Air Leakage Test determines if the fitting can hold pressure and maintain substance without leaking. The Stress Fracture Test is used to determine how the fitting reacts to a

higher temperature environment for a prolonged period.



Separation Force-3, Unscrewing Torque-4, and Resistance to Overriding-5 are additional ISO 594 tests that require the same axial-torsion assembly procedure. Figure 2 is a representative test setup for several of the axial-torsion luer lock tests. Once the fitting is assembled, the Separation Force Test is conducted by maintaining an axial force in tension for 10 seconds. The Unscrewing Torque Test is run by applying a defined torque to the assembled fixture for a specified period of time in the unscrewing direction. The Resistance to Overriding Test requires the same axial-torsion assembly procedure. Once assembled, however, the fitting shall be subjected to an additional tightening torque for five seconds.

Conclusion

Luer locks adhering to the ISO 594 Standard and Medical Bone Screws adhering to the ASTM F543 Standard are just two of the many products that require an axial-torsion testing system. Additional medical products that require axial-torsion testing include medical adhesives, medical mesh, and spinal cages.

For more information, visit www.admet.com [1].

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