Mechanical Testing of Medical Implants

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Implants and the materials used for their production undergo extensive tests, which include the evaluation of the static and dynamic mechanical properties of the raw materials, components and systems. Many of these tests are internationally standardized, other testing procedures are specific to a given application. In all cases, advanced testing instruments and clamping fixtures along with flexible, programmable testing software help in the determination and analysis of the relevant data. Stents are small tube-like medical devices, usually constructed of a biocompatible stainless steel or metal alloy, which are used by surgeons to widen or unblock clogged arteries to help restore normal blood flow and reduce risk of heart attack. Today, stenting is a common practice, making up over 70 per cent of total coronary angioplasty procedures.

Manufacturers of medical implants must demonstrate that they have carefully considered the risks of component or system failure and satisfactorily mitigated against them. To this end, such products undergo a variety of mechanical tests prior to their approval, from simple tensile tests on material specimens, through combined compression, torsion or flexure tests, up to the simulation of pressure pulsation on complete implant systems under defined ambient conditions. The examples below illustrate the wide range of testing applications.

Knee Replacements: Fatigue Behavior of Tibial Trays

Fatigue fracture of knee tibial trays has been one of the most commonly reported failure mechanisms in Total Knee Replacements (TKR). It is caused by loss of underlying bone support underneath the implant, which renders the latter mechanically unstable. Cyclic loads imparted by walking cause fatigue cracks, ultimately leading to catastrophic failure. The standard [1] specifies a set of test parameters for determining the fatigue properties of different tibial tray designs.

In practice, servo-hydraulic test systems such as Instron's model 8870 have been found eminently suitable both for determining fundamental material properties such as the resistance to fatigue crack propagation, and testing of the entire tibial tray. One half of the tibial tray is secured in a clamping fixture, simulating a fully supported condyle. The other, unsupported condyle is then subjected to physiologically representative loading.

Figure 1. Compact and space-saving servo-hydraulic test system, prepared for testing the fatigue properties of tibial trays for total knee replacements

A fatigue testing system used frequently for this type of test is Instron's model 8872, a compact table-top test instrument **(Figure 1)**. With a nominal load capacity of 25 kN it is particularly suited to static and dynamic testing of materials and components for biomedical applications. Its adjustable crosshead with integral servo-hydraulic actuator, which accommodates the load cell, and a corrosion-resistant base with T-slot table and drain channel make the instrument eminently suitable for testing in a saline bath, as well as a wide range of other tests. The Console software provides extensive features for PC control of the testing system, including signal generation, calibration, limit setup and status monitoring. In addition, the Wavematrix block programming software can be used for cyclic tests.

Typically, when performing such measurements under dynamic loads, acceleration forces are acting on parts of the system, which are superimposed on the actual forces applied to the specimen. The load cells will therefore also record forces resulting from their own movement and that of the clamping fixtures attached to them. Dyna-cell load cells (with load capacities ranging from 250 N to 2500 kN) reduce these effects even at high test frequencies. In conjunction with the associated 8800 Digital Controller, they enable the automatic compensation of acceleration forces as well as inertial errors such as those caused by hydrodynamic effects that occur when testing in a fluid bath.

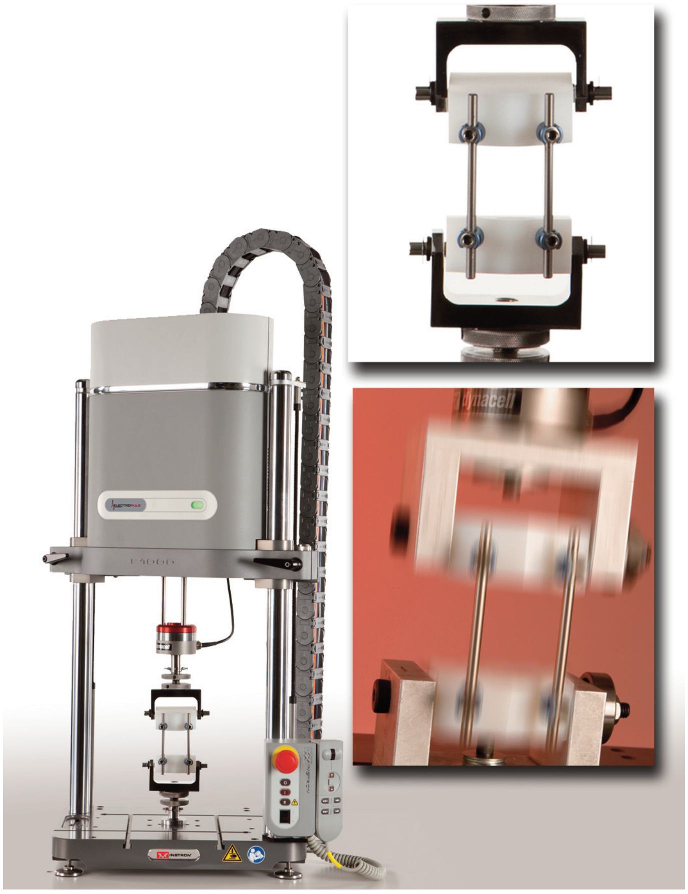

Figure 2. Electro-dynamic testing systems offer exceptional response and high accuracy across a wide frequency range for fatigue testing of spinal constructs.

Spinal Columns: Static, Torsion and Fatigue Testing

In spinal constructs, high loading may lead to catastrophic failure. Hence, static testing must be performed to evaluate the compressive, tensile and torsional loads leading to the fracture of the spinal construct. In addition, service life testing is also critical, as fatigue fracture is more common in actual practice than catastrophic failure. Loading is typically applied with a constant-amplitude, load-controlled sinusoidal waveform, with tests running in excess of five million cycles. The standard [2] specifies test methods for both static and fatigue testing. Testing is usually done with blocks of ultra high molecular weight polyethylene (PE-UHMW) rather than vertebrae, to eliminate vertebra-induced variance.

Universal testing systems are generally well suited for static tensile and compressive testing. Standard test software packages (e.g. Instron's Bluehill 3) can be used to record load-displacement curves and perform the calculations specified in the standard. Table-top torsion testers such as the 55MT MicroTorsion systems offered by Instron (designed for multiple revolutions) are suitable for application of torsional loads.

If an angle of rotation of ±135° is sufficient, the model 8874 fatigue testing system is an efficient solution for handling both axial and tor-sional fatigue testing. The biaxial, table-top servo-hydraulic instrument features a dual-column frame and a combined dynamic actua-tor for axial and torsional loading in the upper crosshead. Once again, the 8800 digital electronic controller and the Dynacell load cell in conjunction with the Console and/or WaveMatrix Software are an ideal complement to the system.

If you need to test the durability of spinal constructs and require exceptional response and accuracy across a wide frequency range, Instron's all-electric test instruments (such as the ElectroPuls E1000, **Figure 2**) combined with the WaveMatrix Software provide the necessary capabilities. These advanced instrument feature a digital control system for easy loop tuning based on specimen stiffness.

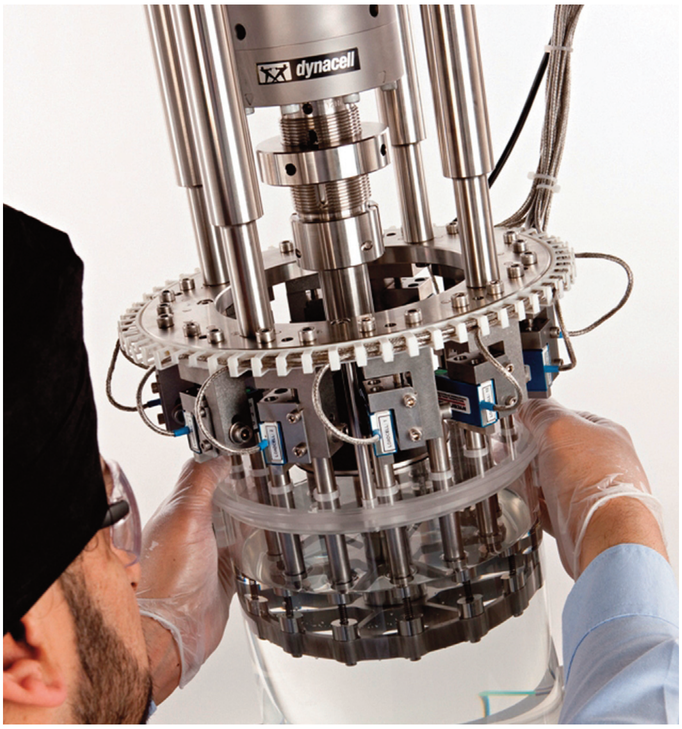

Figure 3. A multi-specimen fixture assists manufacturers of cardio-vascular implants in the evaluation of the fatigue strength of nickel titanium (Nitinol) and stainless steel materials and structures.

The system is fed from a single-phase AC power supply and requires no other utilities for basic operation (such as pneumatic air, hydraulics, or water).

Stents: Efficient Fatigue Testing of Materials and Structures

Traditionally, testing of stents and stent grafts to standards such as e.g. [3] involves subjecting complete devices to pressure pulsation simulating blood flow for a pre-specified number of cycles. To enable a representative sample of specimens to be evaluated and to reduce overall test time, multiple specimens must be tested on a single system. To cater for this requirement, Instron has developed a multi-speci-men fixture for the ElectroPuls E3000 test instrument (**Figure 3**). Each specimen station features a fatigue-rated load cell, precision alignment and grips that are unique to the material or structure undergoing test. The entire assembly is submerged in a temperature controlled bath to test the specimens in vitro. The test is controlled by the WaveMatrix Software, which features integrated temperature control of the fluid bath, a live display of each load cell reading, and trend monitoring of forces to determine specimen fracture.

Wide-ranging experience

The solutions described above only represent a cross-section of a diverse spectrum of standardized and application-specific testing solutions developed by Instron in close partnership with users from the medical device industry. A more comprehensive overview can be found on the website *http://go.instron.com/biomedtesting*. In all cases, the test system manufacturer's application specialists will be prepared to configure, in close cooperation with manufacturers and users, testing systems tailored to specific testing requirements, and to develop unconventional solutions for challenging testing tasks.

Literature

[1] ISO 14879-1: Determination of endurance properties of knee tibial trays
[2] ASTM F1717: Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
[3] ASTM F2477–07: Standard Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents

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