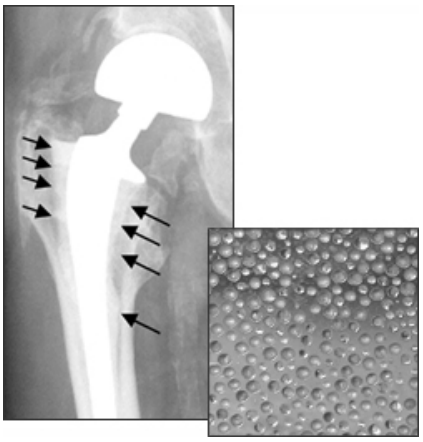
INSTRON
The difference is measurable

TechNotes
Getting the most up-to-date information on materials testing

In This Issue

A New 'Hip' Material



The first surgery to replace a damaged hip joint with an artificial joint was performed just 50 years ago. Today more than 190,000 hip replacement surgeries are performed in the USA alone.

During this time, there have been many improvements to the surgical techniques and to the technologies and materials of the replacement joints but inherent problems remain. One of these is the slow deterioration of bone tissue around the prosthetic material due in part to uneven load distribution between the prosthetic and the bone itself.

Dr. Afsaneh Rabiei, a professor of mechanical, aerospace, and biomedical engineering at North Carolina State University has recently developed a new composite metal foam material that offers, among many other possibilities, the development of new hip joint prostheses that may overcome this problem.

Artificial hip joints are usually manufactured using solid titanium, which is many times stiffer than the bone into which it is secured. The implant therefore assumes the majority of the loads exerted by walking and running. Regular load-bearing exercise is an important factor in good bone health. The bone around the implant, being now deprived of much of the load, loses density and strength, a phenomenon known as stress shielding. In time this deterioration, together with other changes due to biological reactions with the cement used to secure the implants to the bone, can cause the implant to loosen, resulting in the need for further surgery to reseat or replace the joint.

Metal foams have been around since the late 1940s. Most are developed by introducing gases into molten metal, which cools to form a matrix of thin-walled metal. However, the cellular structure is difficult to control, leading to variations in cell wall thickness and random cell shapes and sizes. The resulting mechanical properties of the material are unpredictable and inconsistent.

Dr. Rabiei's composite metal foam material uses preformed hollow metal spheres. These are packed together randomly, and the spaces between the spheres are filled with metal powder. The whole is then sintered to form a sturdy composite structure. The foam displays superior compressive strength and energy absorption capabilities as compared to existing metal foams, while exceeding strength to density ratios.

The ability to control the size, the wall thickness, and the percentage of spheres added to the matrix allows close control of the stiffness and durability of the metal foam. The foam can therefore be manufactured to closely match the stiffness of bone, thus eliminating stress shielding. Other benefits of the new material are energy absorption, so they cushion the shock of each step. The composite's pores also provide places where natural bone can grow and anchor the implant in place.

The combination and predictability of these properties offers promise for use in other applications where light weight, high stiffness and energy absorbsion capabilities are important, such as automobile crumple zones, and structural members in air, naval, and space craft.

Simulating Physiological Conditions of Implants

ISO 7206-4 provides a demanding test method that best simulates the physiological conditions a hip implant can undergo when stress shielding occurs. The implant stem is embedded into a medium and the application of a cyclic load to the head induces two-plane bending and torsion.

It is important to use an ultra-low-friction bearing with the upper portion of the fixture in order to ensure that side loads caused by bending and torsion are not transferred into the machine. Side loads can damage the actuator and cause incorrect load measurements.

Load cell placement for dynamic tests is always a consideration. Mounting the load cell on the base of a machine, rather than the moving actuator, helps to minimize errors associated with inertial loads.

However, in tests with a number of medical devices or components, or when using saline baths, you must mount the load cell on the moving actuator of the test machine. Note that this location induces inertial loads that need to be compensated during the test to ensure the correct fatigue loads are applied to the hip implant.

Q. What testing standards serve as guidelines and requirements for the development and manufacture of hip implants?

A. Research and development of modular hip implants requires a substantial investment in testing the materials and the device itself. New materials and designs are constantly being evaluated. Standardization committees have established a variety of test protocols and procedures that ensure safe and effective development of these medical devices.

The test standards that you should consider in the development of hip replacements includes:

- ISO 7206 – Implants for surgery — Partial and total hip joint prostheses
  - Part 4: Determination of endurance properties and performance of stemmed femoral components
  - Part 6: Determination of endurance properties of head and neck region of stemmed femoral components
  - Part 8: Endurance performance of stemmed femoral components with application of torsion
  - Part 9: Determination of resistance to torque of head fixation of stemmed femoral components
  - Part 10: Determination of resistance to static load of modular femoral heads
- ASTM F 1612 – 95 (2005) — Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion
- ASTM F 1714 – 96 (2008) — Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip-Designs in Simulator Devices
- ASTM F 1875 – 98 (2009) — Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface
- ASTM F 2345 – 03(2008) — Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads
- ISO 14242 – 1 (2002-03) — Implants for Surgery – Wear of Total Hip Prostheses – Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for tests

Instron Worldwide Headquarters
825 University Ave
Norwood, MA 02062
www.instron.com