The behind-the-scenes road to safe implants

How do devices pass the test?

Many AAOS members may be unaware of the rigorous standards testing that occurs behind the scenes prior to the approval of a total hip arthroplasty (THA) implant or other device to be sold on the market. For two decades, the American Society for Testing and Materials International (ASTM) and the International Organization for Standardization (ISO) have developed multiple biomechanical testing methods to ensure that orthopaedic implants will be safe after implantation.

These standards have been developed by experts in engineering and orthopaedic surgery, but without clinical input from surgeons, they may not have been developed in a clinically applicable way. Without input from surgeons and end users of the medical devices, the possibility exists that the standards may not effectively evaluate the clinical integrity of an implant. That is why the Biomedical Engineering Committee of the AAOS participates in the creation of these standards and why it is an important charge of the committee.

Consider, for example, a femoral stem from a THA system. Such a system must meet both the ASTM and ISO standards as well as guidelines from the U.S. Food and Drug Administration (FDA) before it can be submitted for approval.

This article brings to light those standards that have been published to aid in ensuring the safety of new total hip femoral components; it also serves as a reminder that surgeons do not aid in the development of these standards, we risk the establishment of a flawed testing regimen that does not properly ensure the clinical safety of a device and may put our patient outcomes at risk.

The goals of standards

The basic goal of any testing method or standard is to ensure the safety and efficacy of the device being evaluated. Standards should provide design analysis and aid in the optimization of the prototype design. The tests also evaluate various factors such as ultimate strength, fatigue strength, corrosion, and mating properties of modular components.

Any testing is typically performed to simulate the worst possible clinical case scenario, and the data generated help in further research and product development. Once the desired results are achieved, the data are submitted for regulatory approval and marketing support for the product. The FDA has developed a guidance document for use by industry and FDA staff who review the nonclinical tests. Any THA stem (primary and revision) must demonstrate substantial equivalence to predicate devices, at least from a strength standpoint, to gain 510(k) clearance from the FDA. All manufacturers must follow the FDA guidance document on testing methods, whenever they exist for the device in question.

Femoral prostheses standards

The ASTM standard specification for femoral prostheses (ASTM F 2068-03) includes the following classifications for a total hip femoral prosthesis:

Type IA—Single-piece (monoblock), metallic femoral total hip or hemiarthroplasty hip prostheses with an integral stem, neck, and head. The stem is designed such that the center of the head, the axis of the neck, the proximal body, and the distal stem all lie in the same medial/lateral plane. The stem is not tapers (monoblock), metallic femoral total hip or hemiarthroplasty hip prostheses with an integral stem, neck, and head. The stem is designed such that the center of the head, the axis of the neck, the proximal body, and the distal stem do not lie in the same medial/lateral plane. Examples of this type include anteverter necks, proximally curved stems, and distally bowed stems.

Type IIB—Modular metallic femoral hip prostheses that could include a modular (Type II) head, allow for more flexible inventory management and provide a means for adjusting prosthesis neck length and, therefore, leg length at surgery. The stem is designed such that the center of the head, the axis of the neck, the proximal body, and the distal stem all lie in the same mediolateral plane. The stem is embedded in bone cement 80 mm below the center of the highest offset femoral head to simulate the worst case scenario. The test is meant to model a distally well-fixed stem undergoing multiple gait cycles in the clinical setting. The stem is oriented in 10° valgus, 9° flexion to represent the heel-strike phase of the gait cycle.

The test is typically run for 10 million cycles (approximately 10 years of use). Different loads or potting heights can be used as long as it can be shown that the fatigue strength of the stem is equivalent to or better than an FDA-cleared predicate. The test thus determines the minimum stem size and may also determine the proper level of fixation with porous coating.

The neck region test measures the mechanical strength of the neck region when the stem is fully fixed by cement or porous ingrowth. The test is similar to the stem fatigue test, but the stem is potted up to the neck to simulate a clinically well-fixed stem. Although not required by the FDA, this test is performed by some manufacturers to assess the adequacy of the neck strength.

Femoral head tests

The taper disengagement test for the femoral head. The setup on a servohydraulic testing machine allows for the ultimate strength of the modular interlock to be determined.

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