



Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface¹

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1. Scope

1.1 This practice describes the testing, analytical, and characterization methods for evaluating the mechanical stability of the bore and cone interface of the head and stem junction of modular hip implants subjected to cyclic loading by measurements of fretting corrosion **(1-5)**.² Two test methods described are as follows:

1.1.1 *Method I*—The primary purpose of this method is to provide a uniform set of guidelines for long-term testing to determine the amount of damage by measurement of the production of corrosion products and particulate debris from fretting and fretting corrosion. Damage is also assessed by characterization of the damage to the bore and cone surfaces **(4, 5)**.

1.1.2 *Methods II*—This method provides for short-term electrochemical evaluation of the fretting corrosion of the modular interface. It is not the intent of this method to produce damage nor particulate debris but rather to provide a rapid method for qualitative assessment of design changes which do not include material changes **(1-4)**.

1.2 This practice does not provide for judgment or prediction of *in-vivo* implant performance, but rather provides for a uniform set of guidelines for evaluating relative differences in performance between differing implant designs, constructs, or materials with performance defined in the context of the amount of fretting and fretting corrosion. Also, this practice should permit direct comparison of fretting corrosion data between independent research groups, and thus provide for building of a data base on modular implant performance.

1.3 This practice provides for comparative testing of manufactured hip femoral heads and stems and for coupon type specimen testing where the male taper portion of the modular junction does not include the entire hip implant, with the taper

portion of the coupon identical in design, manufacturing, and materials to the taper of the final hip implant **(4,5)**.

1.4 Method I of this practice permits simultaneous evaluation of the fatigue strength of a femoral hip stem (in accordance with Practice **F1440**) and the mechanical stability and debris generated by fretting and fretting corrosion of the modular interface.

1.5 The general concepts and methodologies described in this practice could be applied to the study of other modular interfaces in total joint prostheses.

1.6 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.7 *This standard may involve hazardous materials, operations, and equipment. This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:³

- E4** Practices for Force Verification of Testing Machines
- E466** Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials
- E467** Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System
- F561** Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids
- F746** Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials
- F897** Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws
- F1440** Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without

¹ This practice is under the jurisdiction of ASTM Committee **F04** on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee **F04.15** on Material Test Methods

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² The bold face numbers in parentheses refers to the list of references at the end of this standard.

³ For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

Torsion (Withdrawn 2012)⁴

F1636 Specification for Bores and Cones for Modular Femoral Heads (Withdrawn 2001)⁴

G3 Practice for Conventions Applicable to Electrochemical Measurements in Corrosion Testing

G5 Reference Test Method for Making Potentiodynamic Anodic Polarization Measurements

G15 Terminology Relating to Corrosion and Corrosion Testing (Withdrawn 2010)⁴

G40 Terminology Relating to Wear and Erosion

G61 Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements for Localized Corrosion Susceptibility of Iron-, Nickel-, or Cobalt-Based Alloys

G102 Practice for Calculation of Corrosion Rates and Related Information from Electrochemical Measurements

2.2 ISO Standards:

ISO 7206-7 Endurance Performance of Stemmed Femoral Components Without Application of Torsion⁵

3. Terminology

3.1 Definitions:

3.1.1 *corrosive wear, n*—wear in which chemical or electrochemical reaction with the environment is significant.

3.1.2 *coverage, n*—the length, parallel to the taper surface, that the bore and cone interfaces are in contact.

3.1.3 *crevice corrosion, n*—localized corrosion of a metal surface at, or immediately adjacent to, an area that is shielded from full exposure to the environment because of close proximity between the metal and the surface of another material.

3.1.4 *external circuit, n*—the wires, connectors, measuring devices, current sources, and so forth that are used to bring about or measure the desired electrical conditions within the test cell.

3.1.5 *femoral head neck extension, n*—a distance parallel to the taper axis, from the nominal neck offset length (*k*) as defined in Specification **F1636**, and the center of the head. Such variants from the nominal length are used to adjust for resection level, leg length, and so forth. A positive neck extension equates to the center of the head being located further away from the stem.

3.1.6 *fretting, n*—small amplitude oscillatory motion, usually tangential, between two solid surfaces in contact.

3.1.7 *fretting corrosion, n*—the deterioration at the interface between contacting surfaces as the result of corrosion and slight oscillatory slip between the two surfaces.

3.1.8 *fretting wear, n*—wear arising as a result of fretting.

3.1.9 *total elemental level, n*—the total weight of particulate matter and corrosion ions generated by fretting wear and fretting corrosion. Most analytical techniques are unable to accurately differentiate between ions and particulates, and

therefore, total elemental level refers to all matter and corrosion products released by fretting wear and corrosion.

3.1.10 *wear, n*—damage to a solid surface, generally involving progressive loss of material, due to relative motion between that surface and a contacting substance or substances.

4. Summary of Test Method

4.1 *Method I*—The femoral stem and head components, or coupons to simulate head-taper-neck geometry, are loaded cyclically in a manner similar to that described in Practice **F1440**. The head neck junction is exposed to a saline or proteinaceous solution, either by immersion of the entire device, or with a fluid containing envelope. The cyclic load is applied for a minimum of 10 million cycles. At the conclusion of testing, the isolated fluid is withdrawn for chemical analysis for total elemental level, and characterization of particulate debris. The taper interface is subsequently disengaged and the surfaces inspected for fretting wear and corrosion using optical microscopy and scanning electron microscopy. The output of these methods is a quantitative measure of total elemental level and a qualitative evaluation of damage of the modular interface caused by fretting wear and corrosion.

4.2 *Method II*—A coupon similar to that used in Method I, or an entire femoral stem and head construct, may be mounted in an inverted position in a test chamber. The chamber is filled with an electrolyte solution to a level sufficient to submerge the bore and cone interface and a small portion of the exposed neck. The area of contact and articulation between the ball and the test apparatus is isolated from the electrolyte, either by being above the fill level, or with an elastomeric seal used to isolate the bottom of the test chamber.

4.2.1 *Procedure A*—A saturated calomel electrode with a luggin probe is used as a reference electrode to measure changes in the corrosion potential with an electrometer. A counter electrode also may be employed and the polarization characteristics measured with a potentiostat.

4.2.2 *Procedure B*—A large surface area counter electrode is immersed in the solution to simulate the area of the stem. A zero-resistance ammeter is connected between the test device and the counter electrode. The difference in current, thus measured prior to and during cyclic loading, represents the fretting corrosion current flowing between the modular interface (anode) and the metal sheet (cathode).

5. Significance and Use

5.1 The modular interfaces of total joint prostheses are subjected to micromotion that could result in fretting and corrosion. The release of corrosion products and particulate debris could stimulate adverse biological reactions, as well as lead to accelerated wear at the articulation interface. Methods to assess the stability and corrosion resistance of the modular interfaces, therefore, are an essential component of device testing.

5.2 Long-term *in-vitro* testing is essential to produce damage and debris from fretting of a modular interface (**4,5**). The use of proteinaceous solutions is recommended to best simulate the *in-vivo* environment.

⁴ The last approved version of this historical standard is referenced on www.astm.org.

⁵ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.