Designation: F1875 – 98 (Reapproved 2022)

Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface[1]

This standard is issued under the fixed designation F1875; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

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 *Method 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 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[3]

E4 Practices for Force Calibration and 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

[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 F04.22 on Arthroplasty.

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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.

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 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:*[5]

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

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.

[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.

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.

5.3 Short-term tests often can be useful in evaluations of differences in design during device development (**1-4**). The electrochemical methods provide semiquantitative measures of fretting corrosion rates. The relative contributions of mechanical and electrochemical processes to the total corrosion and particulate release phenomena, however, have not been established; therefore, these tests should not be utilized to compare the effects of changes in material combinations, but rather be utilized to evaluate design changes of bore (head) and cone (stem) components.

5.4 These tests are recommended for evaluating the fretting wear and corrosion of modular interfaces of hip femoral head and stem components. Similar methods may be applied to other modular interfaces where fretting corrosion is of concern.

5.5 These methods are recommended for comparative evaluation of the fretting wear and corrosion of new materials, coatings, or designs, or a combination thereof, under consideration for hip femoral head and neck modular interfaces. Components for testing may be those of a manufactured modular hip device (finished product) or sample coupons, which are designed and manufactured for simulation of the head, taper, and neck region of a modular hip device.

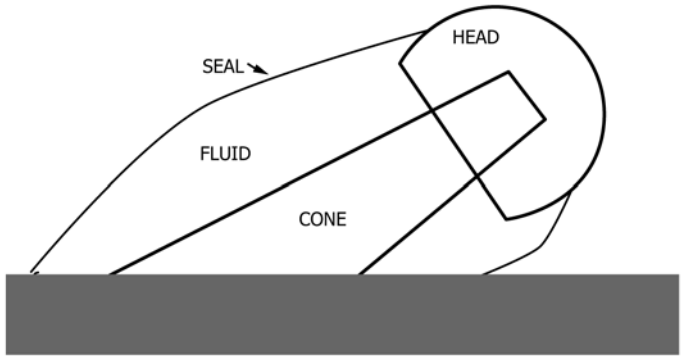
6. Apparatus

6.1 *Testing Machines*—The action of the machine should be analyzed thereafter to ensure that the desired form and periodic force amplitude is maintained for the duration of the test (see Practice E467). The test machine should have a load monitoring system, such as the transducer mounted in line with the specimen. The loads should be monitored continuously in the early stages of the test and periodically thereafter to ensure the desired load cycle is maintained. The varying load as determined by suitable dynamic verification should be maintained at all times to within ±2 % of the maximum force being used in accordance with Practices E4 and E466.

6.2 *Specimen Mounting Devices, Method I*—Modular hip and stem components shall be set up as described in Practice F1440. Coupon samples shall be set up as shown in Fig. 1. The setup must provide for identical loading geometry as that in Practice F1440.

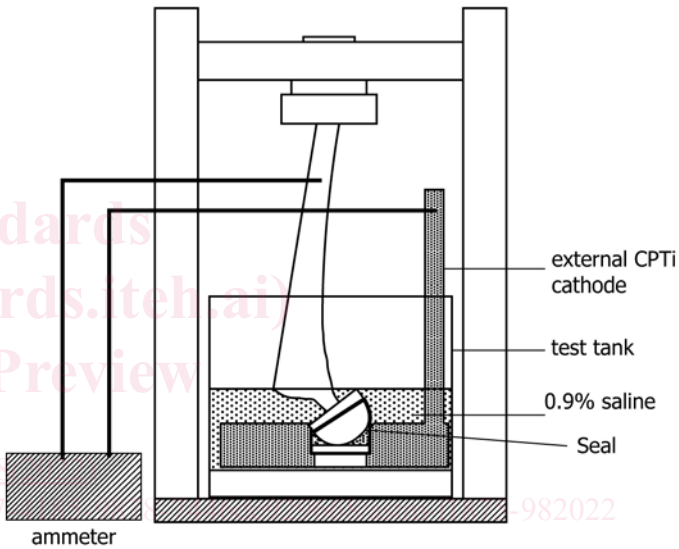
6.3 *Specimen Mounting Devices, Method II*—Modular hip and stem components shall be set up in an inverted position, as shown in Fig. 2. Coupon samples may be set up as shown in Fig. 1, or in an inverted orientation.

6.4 *Environmental Containment, Method I*—The prosthesis may be placed in an environmental chamber, which is filled with the appropriate fluid. Care should be taken to ensure that the contact area between the head and the low-friction thrust bearing is not exposed to the electrolyte solution. The modular interface of the prostheses or coupon samples also may be enclosed in an elastomeric sleeve, which contains the electrolyte. The materials used for such isolation must be nonreactive



NOTE 1—For Method I, the fluid is contained within the sleeve. For Method II, the device should be submerged in an electrolyte while the contact area between the top of the head and the loading apparatus is not exposed to the fluid. A counter electrode is placed in the same bath.

FIG. 1 Sketch of a Coupon Style of Test Specimen



NOTE 1—The cathode sheet surrounds but does not make contact with the device being tested. For Procedure A, the counter electrode is not utilized, and is substituted with a luggin probe and calomel electrode.

FIG. 2 Suggested Setup for Method II Procedure B, Measurements of Fretting Corrosion Currents of a Complete THR

and capable of retaining the fluid environment (that is, prevent leakage) throughout the course of testing. The volume of the chamber shall be between 5 and 100 mL.

NOTE 1—The use of small fluid volumes with the sleeve containment method may not produce as much fretting corrosion as full prosthesis exposure, due to the reduced surface area of the cathodic metal exposed.

6.5 *Environmental Chamber, Method II*—The chamber shall be filled with electrolyte so as to submerge the modular interface. An elastomeric seal is used to isolate the contact area between the head and the load application surface. Similar seals should be employed for coupon sample testing. For coupons oriented as shown in Fig. 1, the chamber fill level shall be kept below the articulation between the head and the loading apparatus.

6.6 *Counter and Reference Electrodes, Method II*—A counter electrode is included in the external circuit of Method II to act as a cathode for measurement of corrosion currents. A reference electrode is employed for measurement of the corrosion potential of the specimen.

6.6.1 *Method II, Procedure A*—The counter electrode and saturated calomel electrode (SCE) shall be employed in accordance with Test Methods G5 and G61.

6.6.2 *Method II, Procedure B*—The counter electrode is used to simulate the surface area of the femoral stem. It should be made of the same alloy as the stem material being tested. A surface area at least equal to the stem and any porous coating should be employed. An area of 400 cm^2 is recommended. The counter electrode should not be in contact with the test specimen, but rather connected to it via the zero resistance ammeter.

6.7 *Potential and Current Measuring Equipment, Method II, Procedure A*—The potential shall be measured by a high-impedance voltmeter. This could either be a free-standing electrometer with an impedance $>10^{10}$ Ω, or the electrometer in a potentiostat in accordance with Test Methods G5 and G61. The potentiostat is used to measure current in potentiostatic or cyclic polarization tests, using the sign conventions of Practice G3. The use of a printer provides a permanent record.

6.8 *Current Measurement Equipment, Method II, Procedure B*—A zero resistance ammeter is used to measure current in Procedure B. The output of the ammeter should be connected to a recording oscilloscope, strip chart recorder, or computer capable of recording the high-frequency components of the current signal.

NOTE 2—Special precautions may be necessary to protect the electronics from vibrations generated by the loading apparatus.

7. Reagents

7.1 *Electrolyte Solutions,* of 0.9 % sodium chloride (NaCl) in distilled water, are used for immersion of modular interface. These solutions provide useful information for comparative studies between designs.

7.2 *Proteinaceous Solutions,* consisting of 10 % solution of calf serum in 0.9 % NaCl in distilled water, are used as an environment for studies where actual damage mechanisms are of interest. These solutions also would be employed in comparative studies of different alloy systems. The use of proteins is associated with the risk of microbial contamination. It is recommended that these tests be conducted under sterile conditions. The use of low-dose antimicrobials for long-term tests is indicated, as well.

8. Test Specimen

8.1 *Modular Hip Devices*—The hip components shall be representative of typical manufactured components; no extraordinary procedures for manufacturing, quality control and assurance, and inspection shall be used. Whenever possible, the size of the hip shall conform to the medium size of a given range of sizes. The length of the femoral head offset shall be the maximum, typical of the hip stem being offered, or the maximum length offered within the product catalog for the tested stem-taper component. In the case of hip products manufactured by different sources where availability of specific components is limited (for example, hip stem size, femoral head off-set, and so forth), comparative testing shall be performed so as to identically match the total head offset, neck angle, and extension. In other words, if two different hip components are to be tested, every effort shall be made to test components that would fulfill the specific needs of a given patient. This is due to the fact that there are many different systems for sizing femoral stem and head components, and they are specific to the manufacturer and design of the hip implant device.

8.2 *Sample Coupons*—Sample coupons shall be designed and manufactured to replicate the taper-head-neck region of a hip prosthesis. An example of such sample coupons is given in Fig. 1. Taper angles and dimensions, with specific references to the critical areas of design, shall be in accordance with Specification F1636. The methods of machining and finishing of the taper surfaces shall be the same as that used for production prostheses.

8.3 *Number of Test Specimens*—Except in the case of product testing, in which component availability may be limited, at least five samples shall be tested for each configuration under evaluation.

9. Procedure

9.1 *Test Method:*

9.1.1 The head-taper components shall be assembled in accordance with Practice F1440, or using standard interoperative surgical protocol for assembly of modular hip devices.

9.1.2 The modular components shall be assembled dry. Apply a single static load of 2000 N, as per head pull-off test.

9.1.3 The modular interface shall be exposed to the test solution in accordance with 6.4.

9.1.4 Cyclic testing of modular interface shall be carried out as prescribed by Practice F1440.

9.1.5 Apply a cyclic load of 3 kN with a minimum load of 300 N and a maximum load of 3.3 kN (67 to 740 lb), in accordance with ISO 7206-7. Tests should be conducted at a frequency of 5 Hz, and be terminated after 10 million cycles.

9.1.6 At the completion of the test, collect the fluid for analysis of total metal content and particle characterization. The procedures for chemical analysis and particle harvesting given in Practice F561 can be used as guide. The fluid shall be reserved in a clean container suitable for subsequent dilution and digestion.

9.1.7 The taper-head components which shall be disassembled in a manner so as to reserve any entrapped fluids and particulate debris, which may include flushing of the interface region with DI water. All collected fluids and debris shall be collected in a common container for subsequent analysis or subsequent digestion prior to chemical analysis. Particles generated in protienaceous solutions may need protein digestion as described in Practice F561 to prevent agglomeration of particulate debris.

9.1.8 Analyze for all major elements in the alloys, using Practice F561 as a guide. Qualitative evaluation of taper surfaces should done by optical microscopy and scanning