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Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices[1]

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1. Scope

1.1 This guide describes a laboratory method using a weight-loss technique for evaluating the wear properties of materials or devices, or both, which are being considered for use as bearing surfaces of human-hip-joint replacement prostheses. The hip prostheses are evaluated in a device intended to simulate the tribological conditions encountered in the human hip joint, for example, use of a fluid such as bovine serum, or equivalent pseudosynovial fluid shown to simulate similar wear mechanisms and debris generation as found *in vivo*, and test frequencies of 1 Hz or less.

1.2 Since the hip simulator method permits the use of actual implant designs, materials, and physiological load/motion combinations, it can represent a more physiological simulation than basic wear-screening tests, such as pin-on-disk (see Practice F732) or ring-on-disk (see ISO 6474).

1.3 It is the intent of this guide to rank the combination of implant designs and materials with regard to material wear-rates, under simulated physiological conditions. It must be recognized, however, that there are many possible variations in the *in vivo* conditions, a single laboratory simulation with a fixed set of parameters may not be universally representative.

1.4 The reference materials for the comparative evaluation of candidate materials, new devices, or components, or a combination thereof, shall be the wear rate of extruded or compression-molded, ultra-high molecular weight (UHMW) polyethylene (see Specification F648) bearing against standard counter faces [stainless steel (see Specification F138); cobalt-chromium-molybdenum alloy (see Specification F75); thermo-mechanically processed cobalt chrome (see Specification F799); alumina ceramic (see Specification F603)], having typical prosthetic quality, surface finish, and geometry similar to those with established clinical history. These reference materials will be tested under the same wear conditions as the candidate materials.

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

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D883 Terminology Relating to Plastics

F75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

F370 Specification for Proximal Femoral Endoprosthesis (Withdrawn 2005)[3]

F565 Practice for Care and Handling of Orthopedic Implants and Instruments

F603 Specification for High-Purity Dense Aluminum Oxide for Medical Application

F648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants

F732 Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses

F799 Specification for Cobalt-28Chromium-6Molybdenum

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[2] 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.

[3] The last approved version of this historical standard is referenced on www.astm.org.

Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)

G40 Terminology Relating to Wear and Erosion

2.2 *ISO Standard:*

ISO 6474 Implants for Surgery–Ceramic Materials Based on Alumina[4]

3. Significance and Use

3.1 This guide uses a weight-loss method of wear determination for the polymeric components used with hip joint prostheses, using serum or demonstrated equivalent fluid for lubrication, and running under a dynamic load profile representative of the human hip-joint forces during walking (**1**,**2**).[5] The basis for this weight-loss method for wear measurement was originally developed (**3**) for pin-on-disk wear studies (see Practice F732) and has been extended to total hip replacements (**4**,**5**) femoral-tibial knee prostheses (**6**), and to femoropatellar knee prostheses (**6**,**7**).

3.2 While wear results in a change in the physical dimensions of the specimen, it is distinct from dimensional changes due to creep or plastic deformation, in that wear generally results in the removal of material in the form of polymeric debris particles, causing a loss in weight of the specimen.

3.3 This guide for measuring wear of the polymeric component is suitable for various simulator devices. These techniques can be used with metal, ceramic, carbon, polymeric, and composite counter faces bearing against a polymeric material (for example, polyethylene, polyacetal, and so forth). This weight-loss method, therefore, has universal application for wear studies of total hip replacements that feature polymeric bearings. This weight-loss method has not been validated for high-density material bearing systems, such as metal-metal, carbon-carbon, or ceramic-ceramic. Progressive wear of such rigid bearing combinations generally has been monitored using a linear, variable-displacement transducers or by other profilometric techniques.

4. Apparatus and Materials

4.1 *Hip Prosthesis Components*—The hip-joint prosthesis comprises a ball-and-socket configuration in which materials such as polymers, composites, metal alloys, ceramics, and carbon have been used in various combinations and designs.

4.2 *Component Configurations*—The diameter of the prosthetic ball may vary from 22 to 54 mm or larger. The design may include ball-socket, trunnion, bipolar, or other configurations.

4.3 *Hip Simulator:*

4.3.1 *Test Chambers*—In the case of a multi-specimen machine, contain the components in individual, isolated chambers to prevent contamination of one set of components with debris from another test. Ensure that the chamber is made entirely of noncorrosive materials, such as acrylic plastic or stainless steel, and is easily removable from the machine for thorough cleaning between tests. Design the wear chambers such that the test bearing surfaces are immersed in the lubricant throughout the test (**3**,**7**).

4.3.2 *Component Clamping Fixtures*—Since wear is to be determined from the weight-loss of the components, the method for mounting the components in the test chamber should not compromise the accuracy of assessment of the weight-loss due to wear.

4.3.3 *Load*—Ensure that the test load profile is representative of that which occurs during the patient's walking cycle, with peak hip-loads ≥2 kN (**2**). The loading apparatus shall be free to follow the specimen as wear occurs, so that the applied load is constant to within ±3 % for the duration of the test. Never allow the applied load to be below that required to keep the chambers seated (for example, 50 N) (**4**).

4.3.4 *Motion*—Ensure that relative motion between the hip components oscillates and simulates the flexion-extension arc of walking. Addition of internal-external or abduction-adduction arcs is at the investigator's discretion. It is recommended that the orientations of the cup and ball relative to each other and to the load-axis be maintained by suitable specimen-holder keying.

4.3.5 *Oscillating Frequency*—Oscillate the hip prostheses at a rate of one cycle per second (1 Hz).

4.3.6 *Cycle Counter*—Include a counter with the hip-simulator to record the total number of wear cycles.

4.3.7 *Friction*—It is recommended that the machine include sensors capable of monitoring the friction forces transmitted across the bearing surfaces during the wear test.

4.4 *Lubricant:*

4.4.1 It is recommended that the specimen be lubricated with bovine blood serum; however, another suitable lubrication medium may be used if validated.

4.4.2 If serum is used, use filtered-sterilized serum rather than pooled serum since the former is less likely to contain hemolyzed blood material, which has been shown to adversely affect the lubricating properties of the serum (**3**). Diluted solutions of serum have also been used for this purpose (**8**). Filtration may remove hard, abrasive, particulate contaminants that might otherwise affect the wear properties of the specimens being tested.

4.4.3 Maintain the volume and concentration of the lubricant nearly constant throughout the test. This may be accomplished by sealing the chambers so that water does not evaporate, or periodically or continuously replacing evaporated water with distilled water.

4.4.4 To retard bacterial degradation, freeze and store the serum until needed for the test. In addition, ensure that the fluid medium in the test contains 0.2 % sodium azide (or other suitable antibiotic) to minimize bacterial degradation. Other lubricants should be evaluated to determine appropriate storage conditions.

4.4.5 It is recommended that ethylene-diaminetetraacetic acid (EDTA) be added to the serum at a concentration of 20 mM to bind calcium in solution and minimize precipitation of calcium phosphate onto the bearing surfaces. The latter event has been shown to strongly affect the friction and wear

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[5] The boldface numbers in parentheses refer to the list of references at the end of this standard.

properties, particularly of polyethylene/ceramic combinations. The addition of EDTA to other lubricant mediums should be evaluated.

4.4.6 A lubricant other than bovine serum may be used if it can be shown that its lubricating properties and, therefore, material wear properties are reasonably physiological (**8**). In such a case, specify the lubricant in the test report.

4.5 Hold the bulk temperature of the lubricant at 37 ± 3°C or as specified, if different.

5. Specimen Preparation

5.1 The governing rule for preparation of component counter faces is that the fabrication process parallels that used or intended for use in the production of actual prostheses, in order to produce a specimen with comparable bulk material properties and surface characteristics (see Practice F86).

5.2 *Polymers and Composites:*

5.2.1 Obtain a fabrication history for each polymeric or composite component, including information such as grade, batch number, and processing variables, including method of forming (extruding, molding, and so forth), temperature, pressure, and forming time used, and any post-forming treatments, including sterilization.

5.2.2 Pretest characterization may include measurement of bulk material properties, such as molecular-weight range and distribution, percent crystallinity, density, or other. The surface finish of specimens may be characterized by profilometry, photomicrography, replication by various plastics, or other techniques.

5.2.3 *Sterilization*—Sterilize the components in a manner typical of that in clinical use for such devices, including total dose and dose rate, as these may affect the wear properties of the materials. Report these processing parameters with the aging time prior to each test when known. Sterilization of all test and control components within a specific test group should be done simultaneously (in a single container), when possible, to minimize variation among the specimens. This wear-simulation procedure makes no attempt to maintain the sterility of specimens during the wear test.

5.2.4 *Cleaning of Polymer Prostheses*—Prior to wear testing, careful cleaning of the polymer specimens is important to remove any contaminants that would not normally be present on the actual prosthesis. During the wear run, the components must be re-cleaned and dried before each weighing to remove any extraneous material that might affect the accuracy of the weighing. A suggested procedure for cleaning and drying of polymeric components is given in Annex A4. With some combinations of materials, wear may result in the transfer of particulate debris which may then become re-imbedded or otherwise attached to polymeric, metal, or composite surfaces. Such an occurrence will render the weight-loss assessment of wear less reliable.

5.2.5 *Weighing of Polymeric Components*—Weigh the polymeric components on an analytical balance having an accuracy on the order of ±10 µg. This degree of sensitivity is necessary to detect the slight loss in weight of polymers, such as UHMW polyethylene, which may wear 30 mg or less per million cycles (**3**,**5**). Always weigh specimens in the clean, dry condition (see Annex A1). Keep the components in a dust-free container and handle with clean tools to prevent contamination that might affect the weight measurement. Weigh each wear and control component three times in rotation to detect random errors in the weighing process.

5.3 *Soaking of Polymeric and Composite Prostheses:*

5.3.1 Polymeric and composite components should be presoaked in the lubricant to minimize fluid sorption during the wear run. Without presoaking, components of very low-wear polymers such as polyethylene may show a net increase in weight during the initial wear intervals, due to fluid sorption (**3**,**4**). The error due to fluid sorption can be reduced through presoaking and the use of control soak specimens. The number of specimens required and the length of presoaking depends on the variability and magnitude of fluid sorption encountered (**4**).

5.3.2 After fabrication and characterization, clean and dry the wear components and three soak-control components of each test material in accordance with Annex A4, and then weigh by precisely controlled and repeatable methods. Place the wear components and soak controls in a container of serum for a specified time interval. Then, remove, clean, dry, and reweigh the components, and calculate the weight-loss (see Annex A4). Repeat the specimens until a steady rate of fluid-sorption has been established. The number of weighings will depend on the amount of fluid sorption exhibited by the specimens.

5.3.3 In general, the weight of the components will stabilize at an asymptotic value in a reasonable time period. With UHMW polyethylene, a presoak period of 30 days has been found adequate (**4**,**7**). In any case, use the weight-gain of the soak controls to correct for ongoing fluid sorption by the wear components during the wear test.

5.4 *Counterfaces of Metal Alloys, Ceramic, or Other Materials:*

5.4.1 *Characterization*—Include with the pretest characterization of metal, ceramic, or other materials, recording of fabrication variables, such as composition, forming method (forging, casting, and so forth) and any postforming processing, such as annealing. Obtain data on material properties relevant to wear (for example, grain structure, hardness, and percentage of contaminants).

5.4.2 *Surface Finish*—In tests that are intended to evaluate an alternate counter face material bearing against the standard UHMWPE, ensure that the counter face finish is appropriate for components intended for clinical use. In tests of alternate materials where a reference metal or ceramic is used, polish the counter face to the prosthesis quality.

5.4.3 Clean, degrease, and passivate components of referenced prosthetic metals or ceramics in accordance with Practice F86. This practice may require modification for components of other materials. Ensure that cleaning of components produces a surface free of any particles, oils, greases, or other contaminants that might influence the wear process.

6. Measurement Procedure

6.1 At the completion of the presoak period, the wear components and soak controls should be removed from the soak bath, cleaned, dried, and weighed by precisely controlled