Designation: F2025 – 06 (Reapproved 2012)

Standard Practice for Gravimetric Measurement of Polymeric Components for Wear Assessment[1]

This standard is issued under the fixed designation F2025; 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 a laboratory method using a weight-loss (that is, mass-loss; see X1.4) technique for evaluating the wear properties of polymeric materials or devices which are being considered for use as bearing surfaces of human joint replacement prostheses. The test specimens are evaluated in a device intended to simulate the tribological conditions encountered in the human joint; for example, use of a fluid such as bovine serum, or equivalent pseudosynovial fluid shown to simulate similar wear mechanisms and debris generation found *in vivo*.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement

D1505 Test Method for Density of Plastics by the Density-Gradient Technique

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

F1714 Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices

2.2 *Other Standards:*[3]

ISO 14242–2 Implants for Surgery—Wear of Total Hip-Joint Prostheses—Part 2: Methods of Measurement

ISO 14243–2 Implants for Surgery—Wear of Total Knee-Joint Prostheses—Part 2: Methods of Measurement

3. Significance and Use

3.1 This practice uses a weight-loss method of wear determination for the polymeric components or materials used in human joint prostheses, using serum or demonstrated equivalent fluid for lubrication, and running under a load profile representative of the appropriate human joint application (**1**,**2**).[4] The basis for this weight-loss method for wear measurement was originally developed (**3**) for pin-on-disk wear studies (Practice F732) and has been extended to total hip replacements (**4**, **5**, ISO 14242–2, and Guide F1714), and to femoro-tibial knee prostheses (**6** and ISO 14243–2), and to femoro-patellar 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 results in the removal of material in the form of polymeric debris particles, causing a loss in weight of the specimen.

3.3 This practice 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). Thus, this weight-loss method has universal application for wear studies of human joint replacements which feature polymeric bearings. This weight-loss method has not been validated for non-polymeric material bearing systems, such as metal-metal, carbon-carbon, or ceramic-ceramic. Progressive wear of such rigid bearing combinations has generally been monitored using linear, variable-displacement transducers, or by other profilometric techniques.

4. Components 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.

4.1.1 *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. If applicable, the normal metal backing for the polymeric component shall be used provided disassembly and reassembly of these components for the measurement does not

[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.

Current edition approved Aug. 15, 2012. Published September 2012. Originally approved in 2000. Last previous edition approved in 2006 as F2025 – 06. DOI: 10.1520/F2025-06R12.

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

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

have an unrepresentative effect on the weight measurements or wear behavior. Otherwise, a modified backing may be used, again provided this has no unrepresentative effect on the weight measurements or wear behavior (see X1.5).

4.2 *Knee Prosthesis Components*—The knee joint comprises femoral, tibial, and patellar configurations in which materials such as metal alloys, ceramics, polymers, and carbon materials have been used in various combinations in different designs.

4.2.1 *Component Configurations*—The polymeric components may be backed by either metal, ceramic, or composite reinforcements. If applicable, the normal metal backing shall be used provided disassembly and reassembly of these components for the measurement does not have an unrepresentative effect on the weight measurements or wear behavior. Otherwise, a modified backing may be used, again provided this has no unrepresentative effect on the weight measurements or wear behavior (see X1.5).

4.3 Other prosthesis components and test coupons may be used to represent other human joint replacement applications.

5. Specimen Preparation

5.1 *Polymers and Composites*—Material Condition:

5.1.1 A fabrication history shall be obtained for each polymeric or composite component, including information such as grade, batch number and processing variables, method of forming (extruding, molding, and so forth), temperature, pressure and forming time used, and any post-forming treatments, including the sterilization method and parameters.

5.1.2 Pretest characterization may include measurement of bulk material properties such as molecular-weight range and distribution, percent crystallinity, or other. Density is a particularly important property because of the conversion of weight measurements to volumetric wear (see 7.4). Density measurements shall be obtained in accordance with Test Methods D792 or Test Method D1505. If it can be justified that previous density measurements are representative of the material used in the current wear test, reference to these previous measurements and suitable justification shall be provided (see also X1.6). The surface finish of specimens may be characterized by profilometry, photomicrography, and replication by various plastics or other techniques.

5.1.3 *Sterilization*—The components shall be sterilized in a manner typical of that in clinical use for such devices, as this may affect the wear properties of the materials. 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. The wear testing procedure makes no attempt to maintain the sterility of specimens during the wear test.

5.2 *Polymer Specimen Cleaning Procedure*—Prior to weighing and 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 test, the components must be re-cleaned and dried before each weighing to remove any extraneous material that might affect the accuracy of the weighing. The procedure for cleaning and drying of polymeric components is given in Annex A1. With some combinations of materials, wear may result in the transfer of particulate debris which may then become reimbedded or otherwise attached to polymeric, metal, or composite surfaces. Such an occurrence will render the weight-loss assessment of wear less reliable.

5.3 *Polymer Specimen Weighing Procedure*—The polymeric components shall be weighed on an analytical balance having a sensitivity on the order of 10 µg. This degree of sensitivity is necessary to detect the slight loss in weight of polymers such as ultra-high-molecular-weight polyethylene (UHMWPE), which may wear 1 mg or less per million cycles. Specimens shall always be weighed in the clean, dry condition (Annex A1). The components shall be kept in a dust-free container and handled with clean tools to prevent contamination which might affect the weight measurement. Each wear and control component shall be weighed three times in rotation to detect random errors in the weighing process.

5.4 *Pre-Soaking of Test Specimens:*

5.4.1 Polymeric and composite components made from materials which absorb fluid initially, but saturate within a few weeks, should be presoaked in the test lubricant to reduce the error due to fluid sorption during the wear run. If the fluid sorption behavior of a particular material is unknown, the investigator shall conduct a preliminary study to determine whether or not the material is exempt from presoaking.

5.4.2 *Preliminary Study*—A minimum of three soak specimens (these can be test coupons or actual devices) per material shall be cleaned and dried in accordance with the procedure in Annex A1, and then weighed by precisely controlled and repeatable methods (Annex A1). The specimens shall then be placed in a container of test lubricant and removed, cleaned, dried, and weighed (in accordance with Annex A1) once or twice a week. The weight change shall be calculated in accordance with Annex A1. The procedure shall be repeated until the specimens have soaked for five weeks. Specimen weight change shall be averaged at each interval and plotted versus time. Data points shall be fit using a second or third order polynomial or hyperbolic function, connecting through zero. The fit of this curve should have an R^2 value of 0.8 or greater. If the slope of this curve at five weeks is ten or more times less than the slope of the curve at zero (see X1.7), then this material shall be subjected to presoaking before wear testing (if gravimetric wear measurement is to be used). Otherwise, it is exempt.

NOTE 1—Even if presoaking is not required, one to three soak control components are still necessary per material condition to account for fluid sorption by the wear components during the wear test.

5.4.3 *Pre-soaking Procedure (if Required)*—After fabrication and characterization, the wear components and one to three soak-control components of each test material shall be cleaned in accordance with the procedure in Annex A1. The wear components and soak control(s) shall then be placed in a container of test lubricant for a minimum of five weeks (35 days).

6. Measurement Procedure

6.1 After fabrication, characterization, and the completion of the presoak period (if required), the wear components and soak control(s) should be cleaned, dried, and weighed by precisely controlled and repeatable methods (Annex A1). These weights shall be recorded as the initial weights of the specimens for purposes of calculating the progressive weight loss during the wear test. The soak control specimen(s) shall be placed in holders in a soak chamber of test lubricant, such that the total surface area exposed to the lubricant is equal to that of the wear components when mounted in the test chamber. The soak chamber temperature shall be maintained at the same temperature as the bulk lubricant in the wear test, or specified if different. It is recommended that the soak chamber be attached to the test machine or otherwise agitated in the same manner as the actual wear chambers. In addition, it may be advantageous to apply a cyclic load to the soak control specimen(s) (without tangential motion) comparable to that applied to the wear specimens, since this can also affect the rate of fluid sorption.

6.2 The wear and soak component(s) shall be removed at specified intervals, washed, rinsed, and dried concurrently, in accordance with the procedure in Annex A1. It is important that both the wear and soak component(s) be treated identically to ensure that they have the same exposure to the wash, rinse, and drying fluids. This will provide the most accurate correction for fluid sorption by the wear specimens.

6.3 After rinsing and drying, the wear components and soak controls shall be weighed on an analytical balance in accordance with 5.3.

6.4 The wear chambers and component surfaces shall be thoroughly rinsed with distilled or deionized water.

6.5 The bearing surfaces of the components shall be inspected, and the characteristics of the wear process noted. Visual, microscopic, profilometric, replication, or other inspection techniques can be used. However, care must be taken that the surfaces do not become contaminated or damaged by any substance or technique which might affect the subsequent wear properties. If contamination occurs, the specimens shall be thoroughly re-cleaned prior to restarting the wear test.

6.6 The wear components and soak control(s) shall be replaced in fresh lubricant and wear cycling continued.

7. Determination of Wear Rates

7.1 *Test Length*—The accuracy of the test method depends on the relative magnitudes of wear and fluid sorption. This is especially true when the fluctuations in the weight due to variation in the amount of surface drying are large in comparison to the incremental weight loss due to wear. For high-wear low-sorption materials, the wear rate may be clearly established in as few as 50 000 wear cycles. With comparatively low-wearing materials, such as UHMWPE, several million cycles or more may be required to clearly establish the long-term wear properties.

7.2 *Number of Measurements per Test*—When specimens can be removed for intermediate weight measurement, at least three measurements per test series shall be made.

7.3 *Correcting for Fluid Sorption*—The average gain (or loss) of the soak control component(s) shall be added to (or subtracted from) the measured weight loss of each wear component (Annex A2.6). This procedure corrects both for systematic sorption as well as random differences in the amount of surface drying (of the entire set of test and control specimens) and balance fluctuations due to environmental or other variables at each interval of weighing.

7.4 *Conversion to Volumetric Wear*—In tests where the wear rates of materials with different densities are evaluated, it may be preferable to compare these on the basis of volumetric wear, rather than weight loss. The volumetric wear rate may be obtained by dividing the weight loss data by the density of the material, in appropriate units. The accuracy of this calculation is dependent on the material being reasonably homogeneous (that is, having a constant density with wear depth). The density value used in this conversion shall be reported.

8. Report

8.1 *Materials:*

8.1.1 Material traceability information shall be provided for each material counter face and shall include pertinent details related to raw material and fabrication or manufacturing history. Examples of such information include material grade, batch number, and processing variables.

8.1.2 Pretest characterization for a plastic counter face may include measurement of bulk material properties such as molecular-weight average, range and distribution, percent crystallinity, density, degree of oxidation, or others. The surface finish of both counter faces may be characterized by profilometry, photomicrography, replication, or other applicable techniques.

8.1.3 The method of sterilization, the sterilization date and test date, and the means of storage post-sterilization and pretest shall be reported. For irradiation-sterilized specimens, total dose and dose rate shall be reported.

8.1.4 If presoaking was not conducted, justification shall be provided.

8.2 *Wear Rates:*

8.2.1 The weight loss of each specimen shall be plotted graphically as a function of wear cycles. Wear may be reported as the weight loss of the bearing component as a function of the number of wear cycles, but is preferentially converted to volumetric wear if the density of the material is known (see X1.6 and X1.8)

8.2.2 In tests where the wear rate is nearly constant, the volumetric (or gravimetric) wear rate shall be calculated by the method of least-squares regression.

8.2.3 If the wear rate changes during the test as with a decrease due to wearing in of the specimens or an increase due to the onset of fatigue wear, linear regression may be applied to separate intervals of the test to indicate the change in wear rate.

8.2.4 At the discretion of the investigator, more complex, nonlinear models may be fitted to the wear test data.

8.2.5 The test duration in cycles shall be reported.

8.2.6 Sliding distance per wear cycle shall be reported, if known.

8.3 *Accuracy and Repeatability:*