



Standard Practice for Gravimetric Measurement of Polymeric Components for Wear Assessment¹

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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, or both. 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 as found in vivo.

2. Referenced Documents

2.1 ASTM Standards:

D 792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement²

D 1505 Test Method for Density of Plastics by the Density-Gradient Technique²

F 732 Practice for Pin-on-Flat Evaluation of Friction and Wear Properties of Polymeric Materials for Use in Total Joint Prostheses

F 1714 Guide for Gravimetric Wear Assessment of Prosthetic Hip-Designs in Simulator Devices³

F 1715 Guide for Gravimetric Wear Assessment of Prosthetic Knee-Designs in Simulator Devices³

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 F 732) and has been extended to total hip replacements (4,5, and Guide F 1714) and to femoro-tibial

knee prostheses (6 and Guide F 1715), 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 a 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 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

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² *Annual Book of ASTM Standards*, Vol 08.01.

³ *Annual Book of ASTM Standards*, Vol 13.01.

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

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 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 or Test Method D 792 or D 1505. 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 re-embedded 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 UHMW polyethylene, 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 must 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 fit 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:*

8.3.1 In multiple tests, where the wear rate is determined from the slope of the graph comparing wear versus test duration (cycles) for each specimen, the individual rates, mean wear rate, and the 95 % confidence intervals for each rate shall be reported.

8.3.2 In cases where the mean wear rate for two materials is different, the level of statistical significance of this difference shall be evaluated and reported.

8.3.3 At the discretion of the investigator, other statistics methods may be used. All statistics methods and related assumptions shall be reported.

8.4 Since the accumulation of wear debris in the lubricant may influence the wear rate, any filtering of the lubricant during operation (continuously or periodically) shall be reported.

8.5 The room temperature and humidity during each weighing session shall be recorded and reported (see X1.9).

8.6 The loading conditions on the soak control specimen(s)

shall be reported. Load soaking which is defined as a pulsing load profile equivalent to the wear profile without the tangen-

tial movement may increase the fluid sorption rate.

ANNEXES

(Mandatory Information)

A1. METHOD FOR CLEANING OF SPECIMENS

A1.1 Gently scrub components with a nonabrasive material to remove all serum particles. Verify under a magnifying glass.

A1.2 Rinse under a stream of deionized water.

A1.3 Clean in an ultrasonic cleaner.

A1.3.1 Five minutes in deionized, particle-free water.

A1.3.2 Rinse in deionized water.

A1.3.3 Ten minutes in 10 mL of liquid ultrasonic cleaning detergent plus 500 mL of water.

A1.3.4 Rinse in deionized water.

A1.3.5 Ten minutes in deionized water.

A1.3.6 Rinse in deionized water.

A1.3.7 Three minutes in deionized water.

A1.3.8 Rinse in deionized water.

A1.4 Dry with a jet of nitrogen or suitable clean, dry gas.

A1.5 Soak in 95 % methyl alcohol for 5 min (see Note A1.1).

A1.6 Dry with a jet of nitrogen or suitable gas.

A1.7 Dry in a vacuum jar at a minimum vacuum 10^{-3} torr for 30 min.

A1.8 Weigh on a micro-balance.

A1.9 To minimize weighing errors, weigh the entire set of specimens three times, in rotation, keeping the same specimen sequence each time. Polymeric cups typically gain or loss weight slightly between each weighing due to additional sorption or evaporation of fluid. The average of the three weights may be used for the wear calculations.

NOTE A1.1—This is a suggested cleaning procedure suitable for metals, ceramics, carbon, and UHMW polyethylene (3). Methyl alcohol shall be used only for polymers that are essentially insoluble in this liquid. For polymers which dissolve or degrade in methyl alcohol, a more appropriate volatile solvent shall be substituted. The purpose of this step is to remove the water from the surface layer of the specimen that otherwise tends to evaporate during the weighing process. Other aspects of this procedure might require modification for the particular polymer being tested.

A2. CALCULATION OF SPECIMEN WEAR

A2.1 *Definitions*—For the sake of clarity, the terms used in the calculation of specimen wear are defined as follows:

A2.1.1 *Measured Values* (“weight” values should be in milligrams):

- n = number of soak control specimens,
- i = one of a series of soak control specimens,
- $W1$ = initial weight of a wear specimen,
- $W2$ = final weight of a wear specimen, not adjusted for fluid sorption, and
- ρ = polymer density (g/mm^3).

A2.1.2 *Calculated Values* (“weight” values should be in milligrams):

- $S1$ = average initial weight of the soak control specimen(s),
- $S2$ = average final weight of the soak control specimen(s),
- S_i = weight gain of a soak control specimen for a wear interval,
- Sn = average weight gain of all soak control specimens for a wear interval ($S2 - S1$),
- $W3$ = final weight of a wear specimen, adjusted for fluid sorption ($W2 + Sn$),

- Wa = apparent gravimetric wear ($W1 - W2$),
- Wn = net gravimetric wear ($W1 - W3$), and
- Vn = net volumetric wear (mm^3).

A2.2 The amount of fluid sorption over a wear interval is determined from the soak control specimen(s), whereby the average weight gain, Sn , is calculated as follows:

$$Sn = (1/n) \sum_i^n S_i \quad (\text{A2.1})$$

A2.3 Since fluid sorption by the wear specimens tends to mask the actual weight loss due to wear, the magnitude of the measured weight loss by the wear specimens shall be increased by the magnitude of the weight-gain of the soak control specimen(s). Where $S1$ equals initial average weight of the soak specimen(s); and $S2$ equals the final average weight of the soak specimen(s).

A2.4 Thus the actual net wear is given as follows:

$$Wn = W1 - W3 \quad (\text{A2.2})$$

However, $W3$ is unknown. On the other hand, the apparent wear is given as follows:

$$Wa = W1 - W2 \quad (\text{A2.3})$$

where:

$W1$ = initial weight of the wear specimen,
 $W2$ = final weight of the wear specimen (including a gain due to fluid sorption), and
 $W3$ = actual final weight of the wear specimen if fluid sorption is subtracted out.

Therefore the net wear (Wn) can be obtained by increasing the apparent wear (Wa) by an amount equal to the net soak gain as follows:

$$Wn = Wa + Sn \quad (\text{A2.4})$$

where $Sn = S2 - S1$,

Thus $Wn = (W1 - W2) + (S2 - S1)$

A2.5 Note that the four weights $W1$, $W2$, $S1$, and $S2$ are actual measured values ($S1$ and $S2$ may be averages of measured values). The sign convention in this equation for Wn takes into account occurrences such as an apparent weight gain by the wear specimen (giving a negative value for Wa) or a net weight loss by the soak specimens (a negative value of Sn). In most cases the net wear, Wn , will be zero or positive.

A2.6 The net volumetric wear is then given as follows:

$$Vn = Wn/\rho \quad (\text{A2.5})$$

where ρ = density of the polymer, expressed in appropriate units.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 For the purpose of this practice, wear is defined as the progressive loss of material from a prosthetic component as a result of tangential motion against its mating component under load. For current designs of total joint prostheses, the polymeric component bearing against a metal, ceramic, composite, or carbon component will be the sacrificial member; that is, polymer will be the predominant source of wear debris. However, the metallic or other non-polymeric components may also contribute either ionic or particulate debris. Thus, depending on the circumstances, wear may be generated by adhesion, two or three body abrasion, surface or subsurface fatigue, or some other process. Depending on the candidate materials and design combinations selected, it may be desirable in some instances to add additional techniques (that is, non-gravimetric) to identify the nature and magnitude of the wear process.

X1.2 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 debris particles, causing a loss in weight of the specimen (3,7).

X1.3 Wear rate is the gravimetric or volumetric wear per million cycles of test.

X1.4 While it is understood that the loss of material caused by wear is technically "mass-loss," the term "weight-loss" is commonly used and appears in existing standards and, for the purpose of this practice, is considered to be synonymous.

X1.5 For many joint replacement devices, a polymeric specimen is normally fit into a metal backing using some type of locking mechanism. In order to make periodic weight measurements during a wear test, the polymeric specimen must be removed. Some locking mechanisms, however, disallow this removal without causing damage to the specimen or the locking mechanism, thus, subjecting the accuracy and relevance of the test to question. Provided it can be justified that

the wear at this secondary interface is negligible or not relevant to the test objectives, a modified backing may be fabricated to facilitate disassembly and reassembly. Adequate justification should be provided that the modified backing maintains clinically relevant wear behavior and accurate weight measurements. Likewise, if the normal backing is to be used, adequate justification should be provided to show that repeated disassembly and reassembly does not change wear behavior or affect weight measurements.

X1.6 It is understood that for some material conditions, such as gamma-irradiated and aged UHMWPE, density can vary with depth into the surface. In general, the error related to such variation is small compared to other factors or to the magnitude of wear (which generally increases when large density gradients are present) and can be ignored. There may, however, be unusual cases where the density gradient in a representative specimen should be measured and accounted for in determining volumetric wear. It should also be noted that the density of a polymer may change under loading.

X1.7 There is no known study that has been conducted specifically to differentiate polymeric materials that quickly saturate in wear test lubricants from those that do not. Relevant studies such as that by Clarke et al (4) suggest that commonly used materials, such as UHMWPE (irradiated and nonirradiated) may exhibit different levels of fluid absorption but do not exhibit a rapid saturation or other unusual absorption behavior. Recent discussions (such as at ASTM F04.22.10, 5/99) have led to agreement that presoaking of such common materials has not improved the accuracy of weight measurements during testing and may even have a nonrepresentative effect on the specimen surface at the start of a wear test. The cutoff specified in 5.4.2 designating a quickly saturating material is indeed arbitrary but selected to allow materials with known absorption and wear behaviors to be exempt from this presoaking procedure.

X1.8 The suggestion of reporting wear in terms of volumetric wear is done for means of standardization. Some wear tests are configured such that only volumetric measurements can be taken. In some cases, volumetric wear measurements may be more accurate than gravimetric measurements. Volumetric wear rates should be reported as cubic millimetres per million cycles, and the sliding distance per cycle should be reported, if possible, to facilitate conversion to wear volume

per unit sliding distance.

X1.9 Minimizing fluctuations in laboratory temperature and humidity may be helpful in avoiding additional variables that can influence results. The use of untested control specimens, however, will theoretically account for the effects of such fluctuations.

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