Designation: F732 – 17

Standard Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses[1]

This standard is issued under the fixed designation F732; 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 test method describes a laboratory method for evaluating the wear properties of combinations of materials that are being considered for use as bearing surfaces of human total joint prostheses. The body of this test method contains general methods which apply to all types of prosthesis wear applications while individual annexes describe specific wear test methods and clinical validation criteria tailored to each distinct wear application (for example, linear reciprocating motion, ball-cup ("hip-type") wear, delamination wear, and so forth). It is the intent of this test method to rank materials, within each wear application, for polymer wear rates under simulated physiological conditions. It must be recognized, however, that contact geometries and wear motions are simplified using such methods. This test method, therefore, represents only an initial stage in the full wear characterization of a candidate material.

1.2 All candidate materials should be tested in an appropriate joint simulator apparatus using prototype prostheses before being used in clinical trials in patients. The tests described in this test method are used to quickly and reliably screen material combinations for wear performance in different orthopaedic wear applications prior to committing them to more expensive and time-consuming joint simulator testing. In addition, these simplified tests can be used to relate material, surface finish, or other parameters to wear behavior on a more practical basis than is possible in joint simulator tests.

1.3 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

1.4 *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:*[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

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

F799 Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)

F1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)

F2025 Practice for Gravimetric Measurement of Polymeric Components for Wear Assessment

G40 Terminology Relating to Wear and Erosion

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *wear*—for the purpose of this test method, the progressive loss of material from the polymer specimen as a result of the oscillating motion against the counterface under load. Wear may be generated by several mechanisms including adhesion, two or three body abrasion, surface fatigue, or other processes.

3.1.2 *wear rate*—the volume of material lost due to wear per unit of sliding distance (or per million wear cycles if complex motion patterns result in a non-uniform sliding distance across the specimen; see 4.3).

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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.

4. Significance and Use

4.1 This test method is intended to be performed in conjunction with pin-on-flat wear machines or similar machines that are designed to evaluate simplified specimen geometries.

NOTE 1—See Haider & Baykal (1)[3] for useful considerations and potential pitfalls in conducting pin on disk testing, interpreting test results and the complex and sometimes conflicting effects of lower stress and higher contact area on wear.

4.2 This test method is designed to evaluate combinations of materials with respect to the amount of polymer wear, where quantifiable wear occurs primarily on the polymeric component. With some combinations of materials, significant wear of the counterface may occur, with subsequent embedding of counterface debris particles in the polymer. Such an occurrence will render the weight loss of the polymer specimen unreliable as an indicator of the polymer wear.

4.3 Wear is reported as volume loss of the polymeric specimen as a function of sliding distance; however, if the sliding distance is not constant across the polymeric specimen surface due to complex motion patterns, wear may be reported as volume loss of the polymeric specimen as a function of wear cycles (in which case a "wear cycle" shall be defined). Volume loss of the polymer specimen is determined by dividing the experimental weight loss by the density of the polymer. For ease of interpretation, wear should be reported as a function of both the number of wear cycles and the sliding distance, when possible.

4.4 The reference for the comparative evaluation of candidate materials shall be the wear rate of ultra-high-molecular-weight polyethylene (UHMWPE) conforming to Specification F648 bearing against counterfaces of cobalt-chromium-molybdenum alloy (in accordance with Specifications F75, F799, or F1537), having prosthetic-quality surface finish and lubricated with bovine blood serum (see 5.2).

5. Apparatus and Materials

5.1 *Orthopaedic Wear Application:*

5.1.1 For linear reciprocating wear motion applications, refer to Annex A1.

5.1.2 For fixed-bearing ball-cup ("hip-type") wear motion applications, refer to Annex A2.

5.1.3 For nominally linear motion delamination wear applications, refer to Annex A3.

NOTE 2—Other types of applications may be addressed in later revisions.

5.2 *Lubricant (see also Annex A4):*

5.2.1 The specimen shall be lubricated with bovine blood serum unless an alternative medium can be justified as described in section 5.2.8. Since different sera differ in composition (protein concentration, and so forth), dilution with deionized water of up to 75 % (volume fraction) may be appropriate. The appropriate dilution shall be based on satisfaction of the clinical validation criteria in the appropriate annex.

5.2.2 A filter-sterilized serum rather than pooled serum should be used since the former is less likely to contain hemolyzed blood material, which has been shown to adversely affect the lubricating properties of the serum (2). Serum must be filtered to remove hard, abrasive, particulate contaminants that might otherwise affect the wear properties of the specimens being tested.

5.2.3 Maintain the volume, concentration, and temperature of the lubricant nearly constant throughout the test. This may be accomplished by sealing the chambers so that water does not evaporate, by periodically or continuously replacing evaporated water with deionized water, or by recirculating the lubricant in a sealed environment.

5.2.4 To retard bacterial degradation, freeze and store the serum between -10 and -40 °C until it is used for testing. Prior to testing, it is recommended, but not mandatory, that a suitable antibacterial agent be added at an appropriate volume fraction. A commonly used antibacterial agent is sodium azide. If sodium azide is used, it is recommended to use a volume fraction of 0.11 to 0.16 % (mass fraction of 0.2 to 0.3 %). The volume and mass fractions of the antibacterial agent references the volume and mass of the final test solution which may be diluted or undiluted serum.

NOTE 3—Sodium azide is a poison and must be handled very carefully.

NOTE 4—It has been shown that the addition of sodium azide may reduce wear, and sodium azide may not inhibit all types of bacterial growth (3).

5.2.5 It is recommended, but not mandatory, that ethylenediaminetetraacetic acid (EDTA) be added to the serum at a concentration of 20 mM [7.45 g/L] 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 properties, particularly of polyethylene/ceramic combinations (4). The molar concentration of the EDTA references the volume of the final test solution which may be diluted or undiluted serum.

NOTE 5—There are multiple forms of EDTA commonly available, such as pure EDTA, EDTA dipostassium salt dihydrate, and so forth. All of these compounds have different molecular weights, and a different amount of each compound is required to achieve the same EDTA concentration. Pure EDTA has a very low solubility in water, and EDTA disodium salt dihydrate is recommended.

5.2.6 Additives such as sodium azide and EDTA shall be dissolved in deionized water and passed through a 0.2-μm filter before adding to bovine serum.

5.2.7 The appropriate interval for replacing used serum depends on how long the serum maintains its composition (for example, lubricating properties) under the specific test conditions/materials being used and the additives present in the serum. There is no minimum replacement interval. The maximum replacement interval is two weeks. The selected interval must meet the validation requirements in the appropriate annex.

5.2.8 A lubricant other than bovine serum shall be used only when it can be shown that the lubricant reproduces clinical wear mechanisms as well or better than bovine serum. In such case the lubricant shall be specified in the test report.

[3] The boldface numbers in parentheses refer to a list of references at the end of this test method.

6. Preparation of Specimens

6.1 The governing rule for specimen preparation 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).

6.2 *Polymers and Composites:*

6.2.1 Obtain a fabrication history for each polymeric or composite specimen, 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, articulation surface preparation methods (see Annex A5) and any post-forming treatments, including sterilization.

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

6.2.3 *Sterilization*—Sterilize the specimens in a manner typical of that in clinical use for such devices unless it can be proven that this has no effect on wear properties of the materials. Report sterilization processing parameters with the aging time prior to each test, if known. Sterilization of all test and control specimens within a specific test group should be done simultaneously (in a single container), when possible, to minimize variation among the specimens.

6.2.4 *Cleaning of Polymer Specimens*—Prior to wear testing, careful cleaning of the polymer specimens is important to remove any contaminants that would not normally be present on an actual prosthesis. During the wear test, the specimens must be re-cleaned and dried before each wear measurement to remove any extraneous material that might affect the accuracy of the measurement. The required procedure for cleaning and drying of polymeric specimens, as defined in Practice F2025, is given in Annex A6.

6.3 *Soaking of Polymeric and Composite Specimens:*

6.3.1 Polymeric and composite specimens should be presoaked in the wear test lubricant to minimize fluid-sorption during the wear test. Without presoaking, specimens made from very low-wear polymers such as UHMWPE could show a net increase in weight or volume during the initial wear intervals due to fluid sorption (**2, 5**). The error due to fluid sorption can be reduced through presoaking and use of control soak specimens. The length of presoaking depends on the variability and magnitude of fluid sorption encountered (**5**). A minimum of one control soak specimen per material condition is required.

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

6.4.1 *Characterization*—Pretest characterization of the counterface material shall include recording of fabrication variables, such as composition, forming method (forging, casting, molding, 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).

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

6.4.3 Ensure that cleaning of specimens produces a surface free of any particles, oils, greases, or other contaminants that might influence the wear process.

7. Procedure

7.1 Make any initial measurements required to determine the subsequent amount of wear of the polymeric specimen (see Practice F2025 for the gravimetric measurement method).

7.2 Place the control soak specimen(s) in a soak chamber of test lubricant, such that the total surface area exposed to the lubricant is equal to that of the wear specimens when mounted in the test chambers. Maintain the soak chamber lubricant temperature at the same nominal temperature as the test chambers. This temperature shall be 37 ± 3°C unless justification can be provided that use of a different temperature will not affect the results.

7.3 Place the wear test specimens in their test chambers, add the lubricant, and activate load(s) and motion(s).

7.4 As testing is commenced, monitor the specimens for signs of erratic behavior that might require early termination of the test.

7.5 Remove the wear and soak specimens at desired intervals, wash, rinse, concurrently in accordance with the procedure in Annex A6 (also defined in Practice F2025). It is important that both the wear and soak components 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, and correction for any other factors which could affect wear measurements.

7.6 After rinsing and drying, conduct wear measurements.

7.7 Thoroughly rinse all test assembly surfaces which have contacted bovine serum using deionized water.

7.8 Inspect the bearing surfaces of the test specimens and note the characteristics of the wear process. Visual, microscopic, profilometric, replication, or other inspection techniques can be used. Care must be taken, however, that the surfaces do not become contaminated or damaged by any substance or technique that might affect the subsequent wear properties. If contamination occurs, thoroughly reclean the specimens prior to restarting the wear test.

7.9 Replace the wear specimens, maintaining original couples and orientation, and soak control(s) in fresh lubricant and continue wear cycling.

7.10 The appropriate wear test duration depends on the objective of the specific test, the duration of run-in effects, the linearity of wear rates, and the potential for wear mechanism

transitions. The minimum duration shall be two million wear cycles. The minimum number of wear measurements, subsequent to the initial measurement shall be four.

8. Report

8.1 *Materials:*

8.1.1 Provide material traceability information from a raw material and fabrication or manufacturing standpoint for each material counterface. Examples of such information include material grade, batch number, and processing variables.

8.1.2 Pretest characterization for a plastic counterface 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 counterfaces may be characterized by profilometry, photomicrography, replication, or other applicable techniques. Surface finish of the harder counterface shall be reported.

8.1.3 Report the method of sterilization, the sterilization and test dates, if known, and the means of storage post-sterilization and pretest.

8.2 *Test Apparatus*—Report the number of stations on the machine and the number of stations used for this test. Report if replicate tests were conducted during more than one test series. Describe the mechanisms used to generate motions and forces, the systems used to measure motions and forces, the arrangement for mounting specimens, a detailed description of the lubricant used, the arrangement for lubricating the articulating surfaces, arrangement for lubricant temperature control, the measured lubricant temperatures, total lubricant volume per station, lubricant replacement interval, and arrangement for the exclusion of contaminant particles. Report the nature and frequency of all calibrations conducted on the test apparatus. Define what constitutes one wear cycle. Confirm and explain how this test method satisfies all eleven test parameter requirements set forth in the corresponding annex.

8.3 *Wear Rates:*

8.3.1 Graphically plot the wear of each specimen as a function of sliding distance and/or wear cycles. Wear shall be reported as the volumetric loss of the bearing component(s) as a function of sliding distance and/or the number of wear cycles. If weight measurements were made, this will require knowing the density of the wear specimen(s).

8.3.2 In tests where the wear rate is nearly constant over the test run, calculate the volumetric wear rate by the method of least squares linear regression.

8.3.3 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.

8.3.4 At the discretion of the investigator, more complex, nonlinear models may be fit to the wear-test data.

8.3.5 Report the test duration in cycles. Explain why the selected test duration was used.

8.3.6 Report the method of calculating polymer sliding distance per wear cycle. Report the test duration in polymer sliding distance in addition to cycles.

8.3.7 An explanation of how the wear rates meet the designated criteria (in the appropriate annex) shall be reported.

8.4 *Wear Mechanisms:*

8.4.1 Provide a description of the articulating surfaces of both components.

8.4.2 An explanation of how the wear mechanisms meet the designated criteria (in the appropriate annex) shall be reported.

8.5 *Accuracy and Repeatability:*

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

8.5.2 In cases where the mean wear rate for two materials is different, evaluate and report the level of statistical significance of this difference.

8.6 Since the accumulation of wear debris in the lubricant may influence the wear rate, report any filtering of the lubricant during operation (continuously or periodically) and the lubricant replacement intervals.

8.7 Report the loading conditions, if any, on the soak control specimen(s). Load soaking, which is defined as a pulsing load profile equivalent to the wear profile without the tangential movement, may increase the fluid sorption rate.

8.8 Include a reference to this test method and to the method used for wear measurement.

9. Precision and Bias

9.1 In order that the screening test wear data be reproducible and comparable among laboratories, it is essential that uniform procedures be established. Sufficient data has not yet been produced using identical materials in different laboratories to permit determining the precision and bias of this procedure. The publication of this test method is intended, in part, to facilitate uniform testing and reporting of data from screening test wear studies. Validation of this methodology, may be achieved through round-robin testing.

10. Keywords

10.1 joint prosthesis materials; pin-on-disk; wear testing

ANNEXES

(Mandatory Information)

A1. TEST METHOD FOR LINEAR RECIPROCATING WEAR MOTION APPLICATIONS

A1.1 Scope

A1.1.1 The "linear reciprocating wear motion" test method describes a laboratory method for evaluating the friction and wear properties of combinations of materials that are being considered for use as the bearing surfaces of human total joint replacement prostheses which experience only linear reciprocating (straight or rotatory) wear motion. Such applications include hinged knees, other hinged joints, trunnion bearings, axle bearings, some mobile bearing knee applications in which the insert/tibial tray attachment mechanisms allow for linear motion only, and any other application in which the wear path at any given contact point reciprocates along a fixed line. Applications which are not relevant to this test method include head/socket articulation in hips and shoulders, fossa/condyle articulation in temporomandibular joints, liner/shell relative motion in hips, all patellofemoral and femorotibial articulation in knees where internal-external rotation may occur, and tibial insert/tibial tray relative motion in knees where rotation may occur. It is the intent of this test method to rank the materials with regard to friction levels and polymer wear rates under simulated physiological conditions. However, it must be recognized that, since any one design of joint replacement, even within this restricted scope, performs under unique conditions of load, motion, and contact geometry, there can be no single universally applicable wear screening test. This test method therefore represents only the first stage in the full characterization of a candidate material.

A1.1.2 All candidate materials should be tested in a joint simulator apparatus using prototype prostheses before being used in clinical trials in patients. The pin-on-disk test described in this test method is used to quickly and reliably identify those low-friction, low-wear materials for which the more expensive and time-consuming joint simulator testing is justified. In addition, the pin-on-disk test can be used to relate wear to material parameters such as polymer molecular weight or counterface surface finish, on a more practical basis than is possible in joint simulator tests.

A1.2 Criteria for Appropriate Test Results

A1.2.1 *Rationale*—Because there are subtle test method variables which will exist, even for a highly detailed test method such as this, it is necessary to identify characteristics of test results which must be met to ensure that they are representative of clinical results. Baseline testing should be conducted utilizing material combinations with significant clinical history such as cast CoCr and gamma-sterilized UHMWPE.

A1.2.2 *Reproduction of* in vivo *Wear Quantities*—The baseline test wear quantities should be compared to clinical results. Clinical data for linear reciprocating wear motion applications are quite sparse. At this time, a suitable guideline for relevant wear quantities is not clear.

A1.2.3 *Reproduction of* in vivo *Wear Mechanisms*—The baseline test wear mechanisms should be representative of those seen clinically. For linear reciprocating wear motion applications, a baseline CoCr/UHMWPE test should exhibit mild microadhesive/micro-abrasive wear mechanisms, resulting in a mild burnished or smeared UHMWPE wear surface and no significant loss of material. The wear motion direction should be apparent on this wear surface. A very thin transfer film may be visible on the CoCr surface.

A1.2.4 *Repeatability and Reproducibility of Results*—A minimum of three replicate tests per condition should be conducted; more if the repeatability relative to mean wear or aggregate wear rate is poor. If the same specimen condition were tested in separate series, there should be no significant difference in results.

A1.3 Apparatus and Materials

A1.3.1 *Description of Specimens and Test Parameters:*

A1.3.1.1 *Polymer Specimen*—The standard polymer specimen is a flat-ended circular cylinder 13 mm [0.50 in.] long and 9.00 mm [0.354 in.] in diameter, providing a cross-sectional area of 63.6 mm^2 [0.0986 $in.^2$]. In the wear machine, the polymer specimen is loaded end-wise against the counterface in a flat-on-flat configuration. This specimen geometry provides a known contact area that remains constant as the test progresses and wear occurs. Care should be taken to ensure alignment of the specimen end face with the counter face.

A1.3.1.2 *Counterface*—The wear counterface may be fabricated in any convenient shape, provided that the contact surface is flat in the plane of motion of the polymer specimen and extends beyond the extremes of travel of the polymer specimen.

A1.3.1.3 *Wear Machine:*

(1) Specimen Chambers—In the case of a multiple specimen machine, the specimens shall be contained in individual isolated chambers to prevent contamination of one set of specimens with debris from another test specimen. The chamber shall be made entirely of corrosion-resistant materials such as acrylic plastic and shall be easily removable from the machine for thorough cleaning between tests. The wear chambers shall be designed such that the specimen surfaces are immersed in the lubricant for the duration of the test.

(2) Load—The test load of 225 N [50.6 lbf] shall be applied along the longitudinal axis of the polymer specimen, such that the average contact stress is 3.54 MPa [513 psi]. The loading apparatus must be free to follow the specimen as wear occurs, such that the applied load is constant to within ±3 % for the duration of the test.

(3) Motion—Relative motion between the specimen and the counterface shall be oscillatory. The orientation between sliding direction and the lay of the surface roughness in each test should be noted. It is recommended that the relative

orientation of the pin and disk be maintained by suitable specimen-holder keying.

(4) Sliding Speed—Specimens shall be run through a 25 mm stroke at a rate of 1 cycle/s, producing an average sliding speed of 50 mm/s.

(5) Cycle Counter—The machine shall include a cycle counter to record the total number of wear cycles.

(6) Friction—It is recommended that the machine include strain gage instrumentation or other transducers capable of providing a continuous readout of the tangential (friction) force transmitted across the specimen interface during the test

A1.3.2 *Summary of Test Parameter Requirements:*

A1.3.2.1 Motion track: linear reciprocating sliding.

A1.3.2.2 Polymer concave/flat/convex: flat-ended cylindrical pin.

A1.3.2.3 Metal concave/flat/convex: flat.

A1.3.2.4 Contact stress: 3.54 MPa.

A1.3.2.5 Lubricant exclusion/exposure: metal re-exposed, polymer not.

A1.3.2.6 Contact "coverage": polymer surface 100 % coverage.

A1.3.2.7 Contact area interaction ratio: metal wear surface area at least 100 % greater than polymer wear surface area.

A1.3.2.8 Cross-shear of polymer (change in angle of motion relative to metal surface) during a wear cycle: none (0°).

A1.3.2.9 Wear cycle frequency: 1 Hz.

A1.3.2.10 Mean polymer sliding distance per wear cycle: 50 mm.

A1.3.2.11 Mean polymer sliding speed: 50 mm/s.

A2. TEST METHOD FOR FIXED-BEARING BALL-CUP ("HIP-TYPE") WEAR APPLICATIONS

A2.1 Scope

A2.1.1 The "hip-type" wear test method describes a laboratory method for evaluating the friction and wear properties of combinations of materials that are being considered for use as the bearing surfaces of fixed-bearing ball/cup devices for total hip replacement. It is the intent of this test method to rank the materials with regard to friction levels and wear rates under simulated physiological conditions. However, it must be recognized that, since any one design of fixed-beating ball-cup joint replacement, even within this restricted scope, performs under slightly different conditions of load, motion, and contact geometry, there may be no single universally applicable wear screening test for this application. This test method therefore represents only the first stage in the full characterization of a candidate material.

A2.1.2 All candidate materials should be tested in a joint simulator apparatus using prototype prostheses before being used in clinical trials in patients. The pin-on-disk test described in this test method is used to quickly and reliably identify those low-friction, low-wear materials for which the more expensive and time-consuming joint simulator testing is justified. In addition, the pin-on-disk test can be used to relate wear to material parameters such as polymer molecular weight or counterface surface finish, on a more practical basis than is possible in joint simulator tests.

A2.2 Criteria for Appropriate Test Results

A2.2.1 *Rationale*—Because there are test method variables which will exist, even for a highly detailed method such as this, it is necessary to identify characteristics of test results which must be met to ensure that they are representative of clinical results. Clinical history of ball-cup wear predominantly involves the CoCr ball/gamma-sterilized UHMWPE cup material combination. This combination should be used in a baseline test series to meet the requirements below.

A2.2.2 *Reproduction of* in vivo *Wear Quantities*—The baseline test wear quantities should be compared to clinical results: 69 ± 33 mm^3/yr for 22 mm balls, 85 ± 33 mm^3/yr for 28 mm balls, and 90 ± 44 mm^3/yr for 32 mm balls (**6**). The wear area of the UHMWPE pin for this test method is roughly ten times smaller than that of a 22 mm cup, so the UHMWPE wear rate for this baseline test should be on the order of 7 mm^3/million cycles (under the assumption that the average patient generates one million activity cycles per leg per year). This is considered a rough guideline; the baseline test should not generate more than three times more or less wear. Another approach is to consider that typical linear penetration rates of cups have historically been in the 0.07 to 0.2 mm/yr range. A baseline pin-on-disk test generating this rate of linear wear (per million cycles) would satisfy this requirement. An additional approach to wear rate validation would be to test different polymers with known clinical history and demonstrate the proper wear rate ranking; for example, PTFE >> polyester > polyacetal ≥ UHMWPE (**6**).

A2.2.3 *Reproduction of* in vivo *Wear Mechanisms*—Wear surfaces and particulate debris from retrieved UHMWPE cups have been characterized (**7**, **8**, **9**, **10**). Typical "clean conditions" macroscopic wear appears as a glossy "wear-polishing" of the UHMWPE surface (**8**, **9**). This pin-on-disk test method should reproduce this appearance. There should not be noticeable pitting or smearing of the UHMWPE or the development of a chemically bonded transfer film on the CoCr counterface. If UHMWPE debris particles are evaluated, they should have characteristics similar to those reported in (**7**) and (**10**); size distributions should be similar to that reported in (**11**).

A2.2.4 *Repeatability and Reproducibility of Results*—A minimum of three replicate tests per condition should be conducted; more if the repeatability relative to mean wear or aggregate wear rate is poor. If the same specimen condition were tested in separate series, there should be no significant difference in results.