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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, etc.). 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.

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.

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 1—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, etc.), 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 **(1)**[3]. 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 until needed for testing. In addition, it is recommended that the serum contains a mass fraction of 0.2 to 0.3 % sodium azide (or other suitable antibacterial agent) to minimize bacterial degradation.

NOTE 2—Sodium azide is a poison and must be handled very carefully.

5.2.5 It is recommended that ethylene-diaminetetraacetic 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 **(2)**.

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.

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, etc.), 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.

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

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 (**1, 3**). 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 (**3**). 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, etc.) 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 (**4**). 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 (**4**).

A2.2.3 *Reproduction of* in vivo *Wear Mechanisms*—Wear surfaces and particulate debris from retrieved UHMWPE cups have been characterized (**5, 6, 7, 8**). Typical "clean conditions" macroscopic wear appears as a glossy "wear-polishing" of the UHMWPE surface (**6, 7**). 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 (**5**) and (**8**); size distributions should be similar to that reported in (**9**).

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.

A2.3 Apparatus and Materials

A2.3.1 *Description of Specimens and Test Parameters:*

A2.3.1.1 *Polymer Specimen*—The standard polymer specimen is a flat-ended circular cylinder. As in the linear reciprocating wear motion method (Annex A1), this specimen may be 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 $in.^2$], but minor modifications to this geometry are acceptable if the other requirements are met. 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 counterface.

A2.3.1.2 *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.

A2.3.1.3 *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—Because different loads (contact stresses) may be required to achieve the same wear characteristics for different

motion patterns, one specific load or contact stress is not required. Load may even be varied using, for example, a physiological load profile if desired. The peak load within each wear cycle should correlate to a peak UHMWPE contact stress in the range of 2 to 10 MPa. The loading apparatus must be free to follow the specimen as wear occurs, such that the applied load (or load profile) stays constant to within ±3 % for the duration of the test.

(3) Motion—Relative motion between the specimen and the counterface must be multidirectional to achieve wear rates and wear mechanisms representative of those in a fixed-bearing ball-cup application **[6, 7**). More specifically, a certain degree of UHMWPE cross-shear must be achieved. The general requirement for relative motion for this test method is that the UHMWPE wear surface must change direction relative to the counterface at an angle of 60° to 90° at some point during the wear cycle. If there is a primary sliding direction, the orientation between sliding direction and the lay of the counterface surface roughness in each test shall be noted. It is recommended that the relative orientation of the pin and flat specimens be maintained by suitable specimen-holder keying.

(4) Sliding Speed—Complex motions may complicate the determination of sliding speeds. The polymer sliding speed should be between 12.5 and 75 mm/s. Wear cycle frequency may be varied from 0.5 to 2.0 Hz as necessary to achieve this sliding speed.

(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.

A2.3.2 *Summary of Test Parameter Requirements:*

A2.3.2.1 Motion track: sliding with non-linear polymer specimen motion.

A2.3.2.2 Polymer concave/flat/convex: flat-ended cylindrical pin.

A2.3.2.3 Metal concave/flat/convex: flat.

A2.3.2.4 Contact stress: peak during wear cycle anywhere from 2 to 10 MPa.

A2.3.2.5 Lubricant exclusion/exposure: metal re-exposed, polymer not.

A2.3.2.6 Contact "coverage": polymer surface 100 % coverage.

A2.3.2.7 Contact area interaction ratio: metal wear surface area at least 100 % greater than polymer wear surface area.

A2.3.2.8 Cross-shear of polymer (change in angle of motion relative to metal surface) during a wear cycle: 60° to 90°.

A2.3.2.9 Wear cycle frequency: 0.5 to 2.0 Hz.

A2.3.2.10 Mean polymer sliding distance per wear cycle: 25 to 150 mm.

A2.3.2.11 Mean polymer sliding speed: 12.5 to 75 mm/s.

A3. TEST METHOD FOR NOMINALLY LINEAR MOTION DELAMINATION WEAR APPLICATIONS

A3.1 Scope

A3.1.1 The delamination wear test method describes a laboratory method for evaluating the potential of a polymer material condition to exhibit delamination wear, a wear mechanism in which surface and sub-surface crack propagation eventually leads to the removal of relatively large pieces of surface material in the form of sheets or chunks. This wear mechanism has been observed clinically in polymer tibial components and patellar components, especially where the following conditions apply:

A3.1.1.1 oxidized (aged) polymer

A3.1.1.2 incongruent metal/polymer contact

A3.1.1.3 predominantly linear reciprocating sliding motion

A3.1.2 It is the intent of this test method to determine a threshold for acceptable resistance to delamination wear and evaluate various polymer material conditions for their performance relative to this threshold under simulated physiological conditions. It must be recognized, however, that there may be multiple clinical applications where delamination is possible; thus, there may be no universally applicable wear screening test for this application. This test method therefore represents only an initial stage in the full characterization of a candidate material.

A3.1.3 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 identify potential limitations in alternative materials or material conditions which are not targeted in other types of wear tests such as biaxial sliding or abrasive wear.

A3.1.4 Because the delamination test method focuses more on the onset and progression of delamination-related wear features, quantitative wear measurements are not required. Thus, all references to mid-test cleaning and wear measurement procedures in the body of this standard may be ignored. Details on measurement procedures for this test are given in A3.4.

A3.2 Criteria for Appropriate Test Results

A3.2.1 *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. Baseline testing for this method should be based on clinical history of materials known to delaminate. The most common material condition in this category is gamma-air-sterilized/shelf-aged UHMWPE. Based on published reports (**10, 11, 12, 13**), this material condition should exhibit rapid and severe delamination wear with ten years of shelf aging; it should exhibit slower and more moderate delamination wear

with five years of shelf-aging. This performance, however, will vary with the precise radiation dose, the resin grade, the device geometry, and other factors.

A3.2.2 *Reproduction of* in vivo *Wear Quantities*—Assessment of the delamination test does not require quantitative wear measurements. The onset and progression of delamination-related wear features are the relevant indicators, but these are more qualitative than quantitative (A3.2.3). The investigator may follow the procedures for wear measurement specified in the body of this standard, but it is not a requirement for conducting or assessing this test method.

A3.2.3 *Reproduction of* in vivo *Wear Mechanisms*—The investigator shall demonstrate that, using this test method, a severely aged gamma-air-sterilized UHMWPE specimen exhibits similar delamination-related features to those reported on retrieved devices of similar material condition. To evaluate candidate material conditions, the investigator should select and justify a baseline material condition which is believed to be representative of the minimum acceptable (or better) clinical performance (resistance to delamination) and show that the candidate material exhibits similar or better resistance to delamination. To satisfy this requirement, the candidate material must demonstrate a similar or longer period until the onset of visible signs of cracking or delamination, and a similar or milder progression of delamination-related wear features such as surface or subsurface cracking and removal of large sheets or chunks of material from the wear surface than the baseline material, under the same test conditions. The test shall be conducted for a minimum of 2 million cycles.

A3.2.4 *Repeatability and Reproducibility of Results*—A minimum of three replicate tests per condition should be conducted, more if the repeatability is poor. If the same specimen condition were tested in separate series, there should be no significant differences in results.

A3.3 Apparatus and Materials

A3.3.1 *Description of Specimens and Test Parameters:*

A3.3.1.1 *Polymer Specimen*—The standard polymer specimen is a flat rectangular or disk-shaped coupon with nominal dimensions of 51 × 25 × 6 mm [2 × 1 × 0.25 in.] thickness; minor modifications in this geometry are acceptable if the requirements in A3.3.2 are met. Specimen thickness, however, may be a critical dimension for a delamination wear test. It is recommended that, for purposes of conducting a "worst-case" test, the minimum thickness for a comparable device for this application, be used. In addition, test coupons of the same nominal dimensions cut from actual devices may be used provided there is not excessive curvature of the surface within the wear region and that all comparative tests are prepared similarly. This may be necessary for evaluating shelf-aged materials as the baseline conditions. In this case, the original articular surface of the device must be maintained and not machined down.

A3.3.1.2 *Counterface*— The wear counterface shall be fabricated from CoCr alloy (Specifications F75, F799, or F1537) and shall have a hemispherical contact surface which creates a ball-on-flat contact geometry with the polymer specimen. The radius of this hemispherical tip shall be within a range necessary to meet the requirements specified in A3.3.2. The wear surface of this counterface shall be polished to a surface roughness (Ra) of 0.05 μm [2 μin.] or smoother to avoid any influence of an abrasive wear mechanism.

A3.3.1.3 *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—In a metal ball on polymer flat configuration, contact stresses will vary within the contact region (Hertzian stress distribution) and they will also vary during the course of the test (due to wear and plastic deformation). The investigator shall determine the appropriate load (and corresponding contact stress) through development of the baseline test. If possible, calculations of the initial peak Hertzian contact stress (see X1.7) and initial average contact stress (load divided by initial contact area) shall be determined. They should fall within the ranges specified in A3.3.2.

(3) Motion—Incidences of delamination observed in clinical applications are typically associated with nominally linear sliding motions such that cross-shear from multiaxial motions would not have a chance to dominate the wear mechanism. Thus, relative motion in this test method shall be linear (unidirectional or reciprocating). If the polymer specimen is removed during this test, there must be provisions to ensure that it is replaced in exactly the same orientation.

(4) Sliding Speed—The polymer sliding speed should be between 12.5 and 75 mm/s. Wear cycle frequency may be varied from 0.5 to 2.0 Hz as necessary to achieve this sliding speed.

(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.

A3.3.2 *Summary of Test Parameter Requirements:*

A3.3.2.1 Motion track: linear (unidirectional or reciprocating) sliding.

A3.3.2.2 Polymer concave/flat/convex: flat (or slightly dished) plate or disk.

A3.3.2.3 Metal concave/flat/convex: convex (hemispherical wear surface).

A3.3.2.4 Contact stress (or peak contact stress if a cyclic load waveform is used) specific to the baseline [CoCr-on-UHMWPE] condition:

(1) Initial average contact stress: 19 to 24 MPa [2800 to 3450 psi].

(2) Initial peak Hertzian contact stress (optional; see X1.7): 29 to 36 MPa [4200 to 5200 psi].

A3.3.2.5 Lubricant exclusion/exposure: polymer re-exposed, metal not.

A3.3.2.6 Contact "coverage": polymer surface less than 50% coverage.

A3.3.2.7 Contact area interaction ratio: polymer wear surface area at least 100% greater than metal wear surface area.

A3.3.2.8 Cross-shear of polymer (change in angle of motion relative to metal surface) during a wear cycle: none (0°).

A3.3.2.9 Wear cycle frequency: 0.5 to 2.0 Hz.

A3.3.2.10 Mean polymer sliding distance per wear cycle: 25 to 150 mm.

A3.3.2.11 Mean polymer sliding speed: 12.5 to 75 mm/s.

A3.4 Measurement Methods

A3.4.1 As for other pin-on-disk test methods, the delamination test shall be conducted for at least 2 million cycles and at least four wear "measurements" shall be made. Quantitative wear measurements, however, are not required for this test. All references to mid-test cleaning and wear measurement procedures in the body of this standard may be ignored. Measurements will consist of periodic observations of the polymer wear surface including notation of the onset of delamination-related features such as cracking and qualitative assessments of the progressing severity of these features relative to the baseline condition. Photographs of the wear surfaces should be taken at the end of the test, and, if feasible, during observation periods. Observation intervals should be weighted towards the beginning of the test with recommended intervals of 50 000, 200 000, 500 000, 1 000 000, and 2 000 000 cycles. Prior to observations and/or photographs, minimum preparation of the wear surfaces shall include scrubbing with a nonabrasive material or device and thorough rinsing with deionized water.

A4. CHOICE OF WEAR TEST LUBRICANT

A4.1 Comparative experiments have shown that distilled or deionized water or saline solutions do not duplicate the lubricating properties of fluids such as serum or synovial fluid that contain physiological concentrations of proteins (**1**). In particular, the heavy transfer of polyethylene to the surface of metal or ceramic implant that is typically observed with water or saline lubrication is not typical of serum-lubricated specimens and is not typical of retrieved components after extended use *in vivo*. Care must be taken in the choice and dilution of bovine serum to ensure that when used in simulated wear tests, it approximates the wear found clinically (see clinical validation criteria in the appropriate annex). Report the choice of lubricant along with the proof of validation for its use.

A5. PRECAUTIONS IN PREPARING SPECIMEN SURFACES

A5.1 Do not polish or otherwise attempt to improve the polymer surfaces with abrasives, for example, aluminum oxide. Particles of the polishing compound may remain embedded in the polymeric material and could strongly affect the wear performance of the bearing materials. The exception to this is if the intent of the wear test is to investigate the effects of different surface finishing methods in which case a detailed description of all surface finishing methods shall be reported.

A6. METHOD FOR CLEANING OF POLYMER SPECIMENS (SEE ALSO PRACTICE F2025)

A6.1 Rinse with tap water to remove bulk contaminants.

A6.2 Wash in an ultrasonic cleaner in a solution of 1 % detergent for 15 min.

A6.3 Rinse in a stream of distilled water.

A6.4 Rinse in an ultrasonic cleaner in distilled water for 5 min.

A6.5 Rinse in a stream of distilled water.

A6.6 Dry with lint-free tissue.

A6.7 Immerse in methyl alcohol (Note A6.1) for 3 min.

NOTE A6.1—This is a suggested cleaning procedure suitable for UHMW polyethylene. Methyl alcohol should be used only for polymers that are essentially insoluble in this solvent. For polymers that are dissolved or degraded in methyl alcohol a more appropriate volatile solvent should 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.

A6.8 Dry with lint-free tissue.

A6.9 Air-dry in a dust-free environment at room temperature for 30 min.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 There is not one single screening wear test which can generate the relevant wear mechanisms for the many different types of orthopaedic wear applications. At the Fall 1997 ASTM F.04.15.09 meeting, Dr. Harry McKellop, originator of F732 (later revised to F2025), explained that there are at least four factors in addition to those addressed in the existing standard which should be considered, even for a screening test. These include: (*1*) motion track, (*2*) contact geometry (convex/concave/flat), (*3*) surface area ratio (size of specimens relative to each other, and (*4*) lubricant exclusion at wear surfaces. The present standard attempts to correlate such factors with the specific clinical wear application to generate the appropriate wear mechanism and prevent misleading results.

X1.2 The screening test wear studies of materials may involve three types of evaluation:

X1.2.1 Comparing the wear rate of a candidate polymeric material to that of polyethylene, both bearing against one of the reference metal or ceramic counterfaces.

X1.2.2 Comparing the polyethylene wear on the candidate counterface material to that of polyethylene wear on the reference metal or ceramic component.

X1.2.3 Comparing the wear rate of a new combination of candidate materials to the reference combinations.

X1.3 For the purpose of this test method, wear is defined as the progressive loss of material from a test specimen as a result of tangential motion against its mating component under load. For this test method, the polymeric specimen bearing against metal, ceramic, composite, or carbon specimens will be the sacrificial member, that is, the polymer will be the predominant source of wear debris. The metallic or other non-polymeric specimens, however, also may contribute either ionic or particulate debris. Depending on circumstances, therefore, wear may be generated by adhesion, two or three body abrasion, surface or subsurface fatigue, or some other process. Depending on the candidate materials selected, it may be desirable in some instances to add additional techniques to identify the nature and magnitude of the wear process.

X1.4 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 debris particles, causing loss in weight of the specimen (**1**, **14**).

X1.5 Wear rate is the gravimetric or volumetric wear per million wear cycles of test.

X1.6 During wear testing in serum, calcium phosphate may precipitate on the surface of the test specimens, particularly those of ceramic, and strongly affect the friction and wear properties. The addition of 20 mM EDTA in the lubricant may reduce such precipitation.

X1.7 Hertzian contact stress distributions occur when a rigid ball is pressed into a deformable flat surface. The peak Hertzian contact stress occurs at the center of the contact region, assuming normal loading. Hertzian stress calculations assume elastic deformation of the deforming material. The test conditions described in A3.3.2.4 involve stresses which begin to exceed the yield stress of the deforming material (UHMWPE, approximately 21 MPa). Thus, there is an increasing degree of error involved in this calculation as loads are increased. The initial average contact stress (load divided by contact area) is the primary requirement for this method; calculations of Hertzian stresses are optional and are to be used as relative values only.

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