Designation: F 732 – ~~98~~00

Standard Test Method for ~~Pin-on-Flat Wear Test for~~ Wear Testing of Polymeric Materials Used in Total Joint Prostheses ~~which Experience Linear Reciprocating Wear Motion~~[1]

This standard is issued under the fixed designation F 732; 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 ~~covers~~ 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 that experience only linear reciprocating~~ prostheses. The body of this standard contains general methods which apply to all types of prosthesis wear ~~motion. Such~~ applications ~~include hinged knees, other hinged joints, trunnion bearings, and any other application in which the~~ while individual annexes describe specific wear ~~path at any given contact point reciprocates along a fixed line. Applications that are *not* relevant to this~~ test ~~method include head/socket articulation in hips~~ methods and ~~shoulders, liner/shell relative motion in hips, all patello-femoral and femoro-tibial articulation in knees where internal-external rotation may occur, and tibial insert/tibial tray relative motion in knees.~~ 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 ~~the materials with regard to friction levels and~~ materials, within each wear application, for polymer wear rates under simulated physiological conditions. ~~However, it~~ It must be ~~recognized that, since any one design of joint replacement, even with this restricted scope, performs under unique conditions of load, motion, and~~ recognized, however, that contact ~~geometry, there can be no single, universally applicable~~ geometries and wear ~~screening test.~~ motions are simplified using such methods. This test method, therefore, represents only ~~the first state~~ 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 ~~pin-on-disk test~~ tests described in this test method ~~is~~ are used to quickly and reliably ~~identify those low-friction, low-wear materials~~ screen material combinations for wear performance in different orthopaedic~~h~~ wear applications prior to committing them to more expensive and time-consuming joint simulator ~~testing is justified.~~ testing. In addition, ~~the pin-on-disk test~~ these simplified tests can be used to relate ~~wear to material parameters such as polymer molecular weight or counterface~~ material, surface finish, or other parameters to wear behavior on a more practical basis than is possible in joint simulator tests.

2. Referenced Documents

2.1 *ASTM Standards:*

~~F 75 Specification for Cobalt 28–Chromium — 6 Molybdenum Casting Alloy and Cast Products for Surgical Implantss (UNS R30075)~~

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[1] This test method is under the jurisdiction of ASTM Committee ~~F-4~~ F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Materials Test Methods.

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D 883 Definitions of Terms Relating to Plastics[2]
F 86 Practice 75 Specification for Surface Preparation and Marking of Metallic Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications[3]
F 138 Specification 86 Practice for Wrought 18 Chromium — 14 Nickel — 2.5 Molybdenum Stainless Steel Bar Surface Preparation and Wire for Marking of Metallic Surgical Implants (UNS S31673)[23]
F 648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants[3]
F 1537 99 Specification for Thermomechanically Processed Cobalt-Chrome-Molybdenum Alloy for Surgical Implants[3]
F 1537 Specification for Wrought Cobalt-28-Chromium-6 Molybdenum Alloy for Surgical Implants[3]
F 2025 Practice for Gravimetric Measurement of Polymeric Components for Wear Assessment[3]
G 40 Terminology Relating to Erosion and Wear[4]

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 fracture, fatigue, or other processes.

3.1.1.1 *Discussion*—While wear results in a change in the volume of the specimen, it is distinct from volume changes due to creep deformation 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 **(1, 2, 3).**[3]

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[2] *Annual Book of ASTM Standards*, Vol 13.01. 08.01.
[3] The boldface numbers in parentheses refer to the list
[3] *Annual Book of references at the end of this test method. ASTM Standards*, Vol 13.01.
[4] *Annual Book of ASTM Standards*, Vol 03.02.

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).

4. Significance and Use

4.1 This test method is intended to be performed in conjunction with reciprocating pin-on-flat type wear machines, with a polymer pin rubbing against a counterface of metal, ceramic, machines or other material, as shown in Fig. 1. 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 measured experimental weight loss by the density of the polymer. For ease of interpretation, wear should be reported as volume loss of the polymer specimen 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 ram-extruded or compression-molded GUR 4150 HP (or GUR 1150) ultra-high molecular weight (UHMW) ultra-high-molecular-weight polyethylene (UHMWPE) conforming to Specification F 648) bearing against a counterfaces of either stainless steel (in accordance with Specification F 138) or cobalt-chromium-molybdenum alloy (in accordance with Specifications F 75, F 799, or F 1537), having prosthetic-quality surface finish and lubricated with bovine blood serum.

4.5 The evaluation of materials may involve three types of tests:

4.5.1 Comparison of the wear rate of a candidate polymer to that of the reference UHMW polyethylene bearing against the reference counterface materials,

4.5.2 Comparison of the wear of UHMW polyethylene specimens when bearing against the reference counterface metals and candidate counterface materials, or

4.5.3 Comparison of the wear rate of a new combination of candidate polymer and counterface material to the reference combinations.

4.6 This test method is intended in part to facilitate round-robin testing of the method. serum (see 5.2).

5. Apparatus and Materials

5.1 *Polymer Specimen*—The standard polymer specimen (see Fig. 1) is a flat-ended circular cylinder 13 mm (0.50 in.) long and 9.00 mm (0.354 in.) in diameter, providing a crosssectional area of 63.6 mm^2(0.0986 in^2). In theOrthopaedic Wear Application :

5.1.1 For linear reciprocating wear machine, the polymer specimen is loaded end-wise against the counterface in a flat-on-flat configuration (see Fig. 2). This specimen geometry provides a known contact area that remains constant as the test progresses and motion applications, refer to Annex A1.

5.1.2 For fixed-bearing ball-cup ("hip-type") wear occurs. Care should be taken motion applications, refer to ensure alignment Annex A2.

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

NOTE 1—Other types of the specimen end face with the counterface. applications may be addressed in later revisions.

5.2 *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.

5.3 *Wear MachineLubricant (see also* Annex A4*)* :

5.3.1 *Specimen Chambers*—In the case of a multiple

5.2.1 The 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.

5.3.2 *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.

5.3.3 *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.

5.3.4 *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.

5.3.5 *Cycle Counter*—The machine shall include a cycle counter to record the total number of wear cycles.

5.3.6 *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.

5.4 *Lubricant*:

5.4.1 The specimen shall be lubricated with bovine blood serum unless an alternative medium can be justified as described in 5.4.7. Comparative experiments have shown that distilled section 5.2.8. Since different sera differ in composition (protein concentration, etc.), dilution with deionized water or saline solution do not duplicate the lubricating properties of fluids such as serum or synovial fluid that contain physiological concentrations of proteins **(2, 4, 5, 6).**

5.4.2 Filter-sterilized calf serum up to 75 % (volume fraction) may be appropriate. The appropriate dilution shall be u 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 hemaolyzed blood material, which has been shown to adversely affect the lubricating properties of the serum **(2)**. Filtration removes**(1)**[5]. Serum must be filtered to remove hard, abrasive, particulate contaminants such as hard abrasive particles that might otherwise affect the friction and wear properties of the specimens being tested.

5.42.3 TMaintain the s volume, concentruation, and tem sperature of the lubricant nearlly constant throughout the test. This may be accomplished by sealing the chambers so that water does not evaporate, by period fically 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 test to retard bacterial degradation. The addition testing. In addition, it is recommended that the serum contains a mass fraction of 0.2 to 0.3 % (mass fraction) of 0.3 % sodium azide (or other suitable biocide) antibacterial agent) to minimize bacterial degradation during the wear test degradation.

NOTE 2—Sodium azide is recommended, but not required, if the serum a poison and must be handled very carefully.

5.2.5 It is changed frequently enough recommended that ethylene-diaminetetraacetic acid (EDTA) be added to avoid a change in lubricating behavior (see 5.4.6). Another optional the serum additive is 20 mM at a concentration of EDTA (disodium dihydrogen ethylenediaminetetraacetate) 20 mM (7.45 g/L) to inhibit the bind calcium in solution and minimize precipitation of calcium from the serum phosphate onto the test specimens.

5.4.4 It is recommended, but not required, that the serum be filtered after thawing using a 0.2 µm filter bearing surfaces. The latter event has been shown to remove fibrin strongly affect the friction and calcium precipitates which may have formed during freezing and thawing. If wear properties, particularly of polyethylene/ceramic combinations **(2)**.

5.2.6 Additives such as sodium azide or and EDTA solutions are added to the serum, these shall be dissolved in deionized water and passed through a 0.2-µm filter either before or after combining them with the thawed serum.

5.4.5 The volume and concentration of the serum lubricant shall be maintained constant throughout the test. This may be accomplished by (*a*) sealing the chambers so that no water evaporation occurs, (*b*) continually replacing evaporated water with fresh distilled water from a reservoir, or (*c*) continually supplying fresh serum adding to the chamber and draining off the overflow.

5.4.6 The bovine serum.

5.2.7 The appropriate interval for replacing used serum depends on many factors such as how long the serum volume, heat generation during test, serum composition, maintains its composition (for example, lubricating properties) under the specific test conditions/materials being used and antibacterial additives. Serum should be replaced frequently enough to avoid a change the additives present in lubricating behavior. This the serum. There is no minimum replacement interval. The maximum replacement interval is typically one week or less and shall not be greater than two weeks. The selected interval must meet the validation requirements in the appropriate annex.

5.42.78 A lubricant other than bovine blood serum shall be used only when it can be shown that the lubricating properties and therefore the material lubricant reproduces clinical wear properties are not significantly different. mechanisms as well or better than bovine serum. In such case the lubricant shall be specified in the test report.

5.4.8 *Temperature*—The bulk temperature of the lubricant shall be held at 37 ± 1°C (body temperature) or specified, if different.

6. Preparation of Specimens

6.1 *General*—The

6.1 The governing rule for preparation of both the polymer specimen and the counterface shall be preparation is that the fabrication process parallels that used or intended for use in the production of actual prosthetic component, prostheses, in order to produce a specimen with comparable bulk material properties and surface characteristics (see Practice F 86).

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, such as including method of forming (extruding, molding, etc.), temperature, pressure, and forming time used, articulation surface preparation methods (see Annex A5) and any post-forming annealing or other treatments.

6.2.2 Pretest treatments, including sterilization.

6.2.2 Pre-test characterization may include measurement of bulk material properties, such as density, molecular weight molecular-weight range and distribution, percent crystallinity, density, or others. The surface finish of polymer specimens may be

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

characterized by profilometry, photomicrography, replication by various plastics, or other techniques. However, no attempt should be made to improve the polymer surface finish by polishing with hard abrasives such as aluminum oxide, since particles of the polishing compound may become embedded in the softer polymer and affect the wear properties of the material combination being tested. techniques.

6.2.3 *Sterilization*—Sterilize polymer specimens using the method and dosage appropriate for actual prostheses specimens in a manner typical of that in clinical use for such devices unless it can be proven that this material. This may involve gamma irradiation, ethylene oxide gas, steam-autoclaving, or other processes. 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, carefully cleaning of the polymer specimens is important to remove any contaminants that might affect the wear process. would not normally be present on an actual prosthesis. During the wear run, reclean test, the specimens must be re-cleaned and dry dried before each weighing wear measurement to remove any extraneous material that might affect the accuracy of the weighings. A suggested measurement. The required procedure for cleaning and drying of polymer specimens is given in Appendix X1.

6.2.5 *Weighing of Polymer Specimens*— Weigh the polymer specimens on an analytical balance with a precision of + 10 µg. This degree of sensitivity is necessary to detect the slight weight loss of specimens of polymers such as UHMW polyethylene, which may wear less than 100 µg per million cycles **(2)**. Always weigh specimens in the clean, dry condition (Appendix X1). Keep the specimens in a dust-free container and handle with clean clamp or tongs to prevent contamination which might affect the weight measurement. Weigh each specimen at least twice to detect random errors in the weighing process.

6.2.5.1 After fabrication and characterization, clean and dry the wear specimens and three soak-control specimens in accordance with Appendix X1, and then weigh on the analytical balance.

6.2.6 *Soaking of Polymer Specimens*:

6.2.6.1 Presoak polymer specimens in the lubricant to minimize fluid sorption during the wear run. Without presoaking, specimens of low-wear polymers such as polyethylene may actually show a net increase in weight after the wear test due to fluid sorption **(3).** The error due to fluid sorption can be reduced through presoaking and the use of control soak specimens. The number of specimens required and the length of presoaking depends on the variability and magnitude of fluid sorption **(2, 3).**

6.2.6.2 Place the wear specimens and soak controls in a container of serum for 48 h. Then remove the three control polymeric specimens, clean, dry, reweigh, and calculate the weight gains. Replace the soak specimens in the serum for an additional 48 h and repeat the weighing process until equilibrium or a steady rate of fluid sorption has been established. For some materials, there may be little or no fluid sorption. The number of weighings will depend on the amount of fluid sorption exhibited by the specimens. Low sorption materials such as PTFE may stabilize after one or two weighings. With materials for which sorption continues for a relatively long period, the 48-h intervals may be extended appropriately to reduce the number of intermediate weighings. Ideally, the weight of the specimens will stabilize at an asymptotic value defined in a reasonable time period; for example, 2 or 3 weeks for polyethylene. With some materials fluid sorption may continue indefinitely, and it will be necessary to begin testing before the weights have stabilized. In either case, use the weight gain of the soak controls to correct for fluid absorption by the wear specimens during the wear test, as described Practice F 2025, is given in 8.3. Annex A6.

6.3 *Counterfaces**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 metal or ceramic the counterface material shall include recording of fabrication variables, such as composition, forming method (forging, casting, sintering, molding, etc.) and any post-forming processing, such as annealing. D Obtain data on material properties relevant to wear (for example, grain structure, hardness, inclusions, precipitates, porosity) should be obtained.

6.3.2 and percentage of contaminants).

6.4.2 *Surface Finish*—In tests that are intended to evaluate an alternate counterface material bearing against the standard UHMW polyethylene, UHMWPE, ensure that the counterface finish shall be typical of that which is achieved or is expected to be achieved on actual prosthetic components. appropriate for components intended for clinical use. In tests of alternate polymers, materials where a reference stainless steel metal or cobalt-chromium alloy counterface ceramic is used, polish the counterface to the typical prosthetic quality prosthesis quality.

6.4.3 Ensure that cleaning of 0.025 to 0.1 µm rms(1 to 4 µin. rms).

6.3.3 Clean, degrease, and passivate counterfaces of reference prosthetic metals in accordance with Recommended Practice F 86. This may require modification for counterfaces of other experimental materials. Cleaning of counterfaces shall produce

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

7. ~~Measurement Procedure~~

~~7.1 Remove~~Procedure

7.1 Make any initial measurements required to determine the subsequent amount of wear ~~specimens and soak controls from the soak bath, then clean, dry, and weigh. Record these weights as the initial weights~~ of the polymeric specimen (see Practice F 2025 for ~~purposes of calculating~~ the ~~progressive weight loss during~~ gravimetric measurement method).

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

7.3 Place the wear ~~machine or otherwise agitated in the same manner as the actual wear chambers.~~

~~7.2 Place the polymer~~ test specimens ~~and the counterfaces~~ in ~~the wear machine,~~ their test chambers, add the lubricant, ~~apply the load,~~ and ~~commence cycling of~~ activate load(s) and motion(s).

7.4 As testing is commenced, monitor the ~~specimens. Simultaneously record the frictional force with the test oscillations.~~

~~7.3 Monitor the~~ specimens for signs of ~~extreme friction or wear~~ erratic behavior that might require ~~an~~ early termination of the test.

7.~~4~~5 Remove the wear and soak specimens at ~~intervals of approximately 250 000 or 500 000 cycles (frequently enough to achieve at least five data points), place in the same container and~~ desired intervals, wash, rinse, ~~and dry~~ concurrently in accordance with the procedure in ~~Appendix X1.~~ Annex A6 (also defined in Practice F 2025). It is important that both the wear and soak ~~specimens~~ components be treated identically to ensure that ~~these~~ they have the same exposure to the wash, rinse, and drying fluids. This will provide the ~~optimum~~ most accurate correction for fluid ~~ab~~ sorption by the wear ~~specimens.~~

~~7.5 After drying, weigh the wear specimens~~ specimens, and ~~soak controls on the analytical balance.~~

~~7.6 Thoroughly rinse the~~ correction for any other factors which could affect wear ~~chambers~~ 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.

~~7.7 At this point, inspect~~

7.8 Inspect the ~~contact~~ bearing surfaces of the ~~polymer specimen~~ test specimens and ~~counterface and~~ note the characteristics of the ~~progress of wear. Inspection may be by visual,~~ wear process. Visual, microscopic, profilometric, replication, or other ~~suitable nondestructive technique. However, take care~~ inspection techniques can be used. Care must be taken, however, that the ~~specimens are~~ surfaces do not become contaminated or damaged by any substance ~~which~~ or technique that might affect the subsequent wear ~~properties of the materials.~~ properties. If contamination occurs, thoroughly reclean the specimens prior to restarting the wear test.

7.~~8~~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. ~~Determining Wear Rates~~ Report

8.1 ~~*Test Length*—The accuracy of the test method depends on the relative magnitudes of wear~~Materials:

8.1.1 Provide material traceability information from a raw material and ~~fluid sorption. For high-wear, low-sorption materials~~ fabrication or manufacturing standpoint for each material counterface. Examples of such ~~as PTFE, the wear rate~~ information include material grade, batch number, and processing variables.

8.1.2 Pretest characterization for a plastic counterface may ~~be clearly established in as few as 50 000 wear cycles. With comparatively low wearing materials,~~ include measurement of bulk material properties, such as ~~UHMW polyethylene, several million wear cycles~~ molecular-weight average, range, and distribution, percent crystallinity, density, degree of oxidation, or others. The surface finish of both counterfaces may be ~~required to generate sufficient wear for accurate measurement. This is especially true when~~ characterized by profilometry, photomicrography, replication, or other applicable techniques. Surface finish of the ~~fluctuations in~~ harder counterface shall be reported.

8.1.3 Report the ~~weight due to variation in the amount~~ method of ~~surface drying are large in comparison to~~ sterilization, the ~~incremental weight loss due to wear.~~ sterilization and test dates, if known, and the means of storage post-sterilization and pretest.

8.2 ~~*N**Test Apparatus*—Report the number of ~~Replicate Tests—A minimum~~ stations on the machine and the number of ~~three replicate specimens should be tested~~ stations used for ~~each material couple. If statistically significant comparisons between mean values are~~ this test. Report if replicate tests were conducted during more than one test series. Describe the mechanisms used to ~~be determined,~~ generate motions and forces, the systems used to measure motions and forces, the arrangement for mounting specimbens, a detailed description of ~~replicates should be chosen consistent with~~ 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 ~~mean results.~~ the corresponding annex.

8.3 ~~*Correcting for Fluid Sorption*— Take the average weight gain (or loss) of the three soak control specimens and add to (or subtract from) the measured weight loss of each wear specimen (see Appendix X2). This procedure corrects both for systematic absorption as well as random differences in the amount of surface drying at each interval weighing.~~

8.4 ~~*Conversion to Volumetric Wear*— Since the density of different polymers may vary considerably, compare the wear rates on a volumetric basis. Divide the weight loss of the wear specimens (corrected for fluid sorption) by the density of the material (in appropriate units) to obtain the incremental volume loss. Then plot wear or tabulate as a function of total cycles and sliding distance. Report the density value used in this conversion.~~

~~9. Reporting Results~~

~~9.1 *Friction*—Report the average magnitude and the range of the friction, either as frictional force or coefficient of friction, for each combination of materials. Any significant increase or decrease in friction during the test shall be reported.~~

~~9.2~~ *Wear Rates*:

~~9.2.1 In~~

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.

~~9.2.2 If~~

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 ~~late~~ the onset of fatigue wear, linear regression may be applied to separate ~~portions~~ intervals of the test to indicate the change in wear ~~rate. More complex wear-distance relationships~~ rate.

8.3.4 At the discretion of the investigator, more complex, nonlinear models may be ~~reported graphically or with a more sophisticated~~ 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 ~~curve-fitting.~~

~~9.3 *Accuracy and Repeatability*~~ *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 ~~Results~~ how the wear rates meet the designated criteria (in the appropriate annex) shall be reported.

8.4 *Wear Mechanisms*:

~~9~~

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

~~9~~8.3~~5~~.2 In cases where the ~~average~~ 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.

~~10~~9. Precision and Bias

~~10.1 *Precision*-The~~

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 ~~being established. Test results that might allow statistical evaluation for this statement are solicited herewith.~~

~~10.2 *Bias*-The bias of these test methods includes quantitative estimates of the uncertainties of gravimetric measuring devices, the design~~ intended, in part, to facilitate uniform testing and ~~calibrations~~ reporting of data from screening test ~~equipment, and the skill~~ wear studies. Validation of ~~the operators. At~~ this ~~time, statements on bias should~~ methodology, may be ~~limited to the documented performance of particular laboratories.~~

~~11.~~ **achieved through round-robin testing.**

10. Keywords

~~11.1 linear motion;~~
10.1 joint prosthesis materials; ~~pin-on-flat; polymer; total joint prosthesis;~~ pin-on-disk; wear testing

~~APPENDIXES~~

~~(Nonmandatory~~

ANNEXES

(Mandatory Information)

~~X~~A1. TEST METHOD FOR ~~CLEANING OF POLYMER SPECIMENS~~

~~X1.1 Rinse with tap water to remove bulk contaminants.~~

~~X1.2 Wash in an ultrasonic cleaner in~~ LINEAR RECIPROCATING WEAR MOTION APPLICATIONS

A1.1 Scope

A1.1.1 The "linear reciprocating wear motion" test method describes a ~~s~~ laboratory method for evaluating the friction and wear properties of ~~1 % detergent~~ combinations of materials that are being considered for ~~15 min.~~

~~X1.3 Rinse in a stream~~ use as the bearing surfaces of ~~distilled water.~~

~~X1.4 Rinse~~ 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 ~~an ultrasonic cleaner in distilled water~~ which the insert/tibial tray attachment mechanisms allow for ~~5 min.~~

~~X1.5 Rinse~~ 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 ~~distilled water.~~

~~X1.6 Dry~~ this test method to rank the materials with ~~lint-free tissue.~~

~~X1.7 Immerse~~ 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 ~~methyl alcohol (Note X1.1) for 3 min.~~

~~NOTE X1.1—This is~~ the full characterization of a ~~suggested cleaning procedure suitable for UHMW polyethylene. Methyl alcohol~~ candidate material.

A1.1.2 All candidate materials should be tested in a joint simulator apparatus using prototype prostheses before being used ~~only for polymers that are essentially insoluble~~ in ~~this solvent. For polymers that are dissolved or degraded~~ clinical trials in ~~methyl alcohol a more appropriate volatile solvent should be substituted.~~ patients. The ~~purpose of~~ pin-on-disk test described in this test mepthod is used to ~~remove~~ quickly and reliably identify those low-friction, low-wear materials for which the ~~water from~~ 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 ~~the specimen that otherwise tends~~ test results which must be met to ~~evaporate during the weighing process. Other aspects~~ ensure that they are representative of ~~this procedure might require modification for the particular polymer being tested.~~

~~X1.8 Dry~~ clinical results. Baseline testing should be conducted utilizing material combinations with ~~lint-free tissue.~~

X1.9 Air-dry significant clinical history such as cast CoCr and gamma-sterilized UHMWPE.

A1.2.2 *Reproduction of* in a dust-free environment at room temperature vivo *wear quantities*—The baseline test wear quantities should be compared to clinical results. Clinical data for 30 min.

X2. CALCULATION OF SPECIMEN WEAR

X2.1 The amount of fluid sorption over linear reciprocating wear motion applications are quite sparse. At this time, a suitable guideline for relevant wear interval quantities is determined from the three soak controls, whereby the average weight gain, not clear.

A1.2.3 *Reproduction of S* in vivo *n*, is calculated as follows:

$$S_n = 1/3\,(S_a + S_b + S_c) \quad \text{(X2.1)}$$

X2.2 Since fluid sorption by the *wear specimens tends to mask the actual weight loss due to wear, the magnitude 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 sighnificant loss by the of material. The wear specimens motion direction should be increased by apparent on this wear surface. A very thin transfer film may be visible on the magnitude CoCr surface.

A1.2.4 *Repeatability and reproducibility of the weight-gain results*—A minimum of three replicate tests per condition should be conducted; more if the soak specimens. Fig. X2.1 illustrates repeatability relative to mean wear or aggregate wear rate is poor. If the weight changes for a single same specimen covndition 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 wear interval, along with the average gain 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 the three soak control, where: W_1 = initial weight of the wear specimen; $W_{63.6\ mm^2}$ = final weight of the wear specimen (including a gain due to fluid sorption); W_3 = actual final weight of the wear specimen if fluid sorption is substracted out; S_1 = initial average weight of the three soak specimens; and $S_{(0.0986\ in^2}$ = final). 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 w 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 three soak specimens.

X2.3 Thus 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 given by:

$$W_n = W_1 - W_3 \quad \text{(X2.2)}$$

However, 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 ~~W~~

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 ~~unknown. On~~ roughly ten times smaller than that of a 22 mm cup, so the ~~other hand, the apparent~~ 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 ~~given by:~~

~~$$W_a = W_1 - W_2 \quad \text{(X2.3)}$$~~

~~Therefore~~ 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 ~~(W_n) can~~ (per million cycles) would satisfy this requirement. An additional approach to wear rate validation would be ~~obtained by increasing~~ to test different polymers with known clinical history and demonstrate the ~~apparent~~ proper wear ~~(W~~ *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 ~~) by an amount equal to~~ glossy "wear-polishing" of the ~~net soak gain,~~ UHMWPE surface ~~$W_n = W_a + S_n$; where:~~**(6, 7)** ~~*S*~~**. 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)** ~~*n* = *S*~~ 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 ~~— S_1. Thus~~(0.0986 in^2 ~~W_n~~ = $(W_1 - W_2) + (S_2 - S_1)$.

~~X2.4 Note~~), 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 ~~four weights W_1, W_2, S_1,~~ test progresses and ~~S_2 are actual measured (positive) values.~~ wear occurs. Care should be taken to ensure alignment of the specimen end face with the counterface.

A2.3.1.2 *Counterface*— The ~~sign convention~~ wear counterface may be fabricated in any convenient shape, provided that the contact surface~~q~~ 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 ~~W_n takes into account occurrences~~ 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 ~~negative value for~~ 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 ~~W_a)~~

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:

- oxidized (aged) polymer
- incongruent metal/polymer contact
- predominantly linear reciprocating sliding motion

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, t-hat 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 ~~soak specimens (a negative value~~ full characterization of ~~S_n). In~~ a candidate material.

A3.1.2 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 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.

A3.1.3 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, t~~-w~~he resin grade, the device geometry, and other factors.

A3.2.2 *Reproduction of ~~W~~ in vivo ~~n, will~~ 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 ~~z~~ representative of the minimum acceptable (or better) clinical performance (resistance to delamination) and show that the candidate material exhibits similar or ~~positive.~~

~~X2.5~~ 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 *Repeat ~~v~~ability 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 mm (2 in.) x 25 mm (1 in.) x 6 mm (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 ~~then given by:~~

~~$$V_n = W_n/\rho \qquad \text{(X2.4)}$$~~

~~where: ρ~~ 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 mat~~y~~erials 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 (F 75, F 799, or F 1537) and shall have a hemispherical contact surface which creates a ball-on-flat contact geometry with the polymer~~,~~ spe~~x~~cimen. The radius of this hemispherical tip shall be within a range necessary to meet the requirements specified in ~~appropriate units.~~

~~X3. RATIONALE~~

~~X3.1 This pin-on-flat~~ A3.3.2. The wear surface of this counterface shall be polished to a surface roughness (Ra) of 0.05 um (2 uinch) 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 specime~~t~~n. The chamber shall be made entirely of corrosion-resistant materials such as acrylic plastic and ~~w~~ shall be easily removable from the machine for thorough cleaning between tests. The wear chambers shall~~y~~ be designed such that the sp~~p~~ecimen sur~~ov~~faces are immersed in ~~1982~~ 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 ~~1991. Since then, developments~~ A3.3.2.

*(3) Motion*Incidences of delamination observed in clinical applications are typically associated with no~~p~~minally linear sliding motions such that cr~~e~~oss-shear~~ch~~ 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:

- Initial average contact stress: 19 to 24 MPa (2800 to 3450 psi)
- 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 ~~regard~~ 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

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

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 F 2025)

A6.1 Rinse with tap water to remove bulk contaminants. ~~7-10).~~

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 ~~F04.15.09 task group~~ F.04.15.09 meeting, Dr. Harry McKellop, originator of ~~Practice F 732, elaborated on these developments. He~~ F 732 (later revised to F 2025), explained that there are at least four factors in addition to those addressed in the existing standard which should be considered, even for a ~~simple~~ 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. ~~Correlation of these~~ The present standard attempts to correlate such factors with the specific clinical wear application ~~of interest may be required in some or all cases~~ to generate the appropriate wear mechanism and prevent misleading results.

X31.2 The screening test wear studies of materials may involve three types of evaluation:

X1.2.1 Comparing the wear rate of a ceandidate 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 candidates counterface materibal 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 has remained largely method, wear is defined as the progressive loss of material from a te, bst 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 then 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 reflect add additional techniques to identify the limited clinical nature and magnitude of the wear applications for which process.

X1.4 While wear results in a change in the physical dimensions of the specimen, it is appropriate. Other screening 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 methods designed for other categories specimens, particularly those of cleramic, and strongly affect the friction alnd wear applications properties. The addition of 20 mM EDTA in the lubricant may be developed for future standards. In short, there reduce such precipitation.

X1.7 Hertzian contact stress distributions occur when a rigid ball is not pressed into a deformable flat surface. The peak Hertziangl contact stress occurs at the center of the contact region, assuming w normal loading. Hertzian stress calculations assume elastic deformation of the deforming material. The test conditions described in A3.3.2.4 involve stresses which can generate begin to exceed the relevant wear mechanisms for yield stress of the many different types deforming material (UHMWPE, approximately 21 MPa). Thus, there is an increasing degree of error involved in this calculatiopn as loads are increased. The initial average c wontact stress (load divided by contact area) is the pplrimary requirement for this method; calculations of Hertzian stresses are optional and are to be used as relative values only.

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