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Standard Guide for Wear Assessment of Prosthetic Knee Designs in Simulator Devices[1]

This standard is issued under the fixed designation F 1715; 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 guide covers a laboratory method for evaluating the wear properties of materials or devices, or both, that are being considered for use as the bearing surfaces of human knee joint replacement prostheses. The knee prostheses are evaluated in a device intended to simulate the tribological conditions encountered in the human knee joint.

1.2 The methods described in this guide are intended to apply to a number of fundamentally different types of knee wear simulators. These include apparatuses which are designed to apply some combination of axial load, flexion/extension angular motion, AP displacement or shear force, and tibial rotational displacement or torque to femoral and tibial wear test specimens.

1.3 Since the knee simulator method permits the use of actual implant designs, materials, and physiological load/motion combinations, it can represent a more physiological simulation than basic wear-screening tests, such as "pin-on-disc" (Test Method F 732) or "ring-on-disc" (ISO-6474).

1.4 It is the intent of this guide to rank the combination of implant designs and materials with regard to material wear-rates, under simulated physiological conditions. It must be recognized, however, since there are many possible variations in the in vivo conditions, a single laboratory simulation with a fixed set of parameters may not be universally representative **(1,2)**[2]

1.5 The reference materials for the comparative evaluation of candidate materials, designs, and processes shall be the wear rate of extruded or compression-molded ultra-high molecular weight (UHMW) polyethylene (Specification F 648) bearing against standard counter faces [cobalt-chromium-molybdenum alloy (Specification F 75); thermomechanically processed cobalt chrome (Specification F 799 or F 1537)], having typical prosthetic-quality surface finish and geometry similar to those with established clinical history. These reference materials will have been tested under the same wear conditions as the candidate materials.

2. Referenced Documents

2.1 *ASTM Standards:*

D 883 Terminology Relating to Plastics[3]

F 75 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications[4]

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants[5]

F 648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants[5]

F 732 Test Method for Pin-on-Flat Wear Test for Polymeric Materials for Used in Total Joint Prostheses Which Experience Linear Reciprocating Wear Motion[5]

F 799 Specification for Thermomechanically Processed Cobalt-Chrome-Molybdenum Alloy for Surgical Implants[5]

F 1537 Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloy for Surgical Implants[5]

F XXXX Practice for Gravimetric Measurement of Polymeric Components for Wear Assessment[5]

G 40 Terminology Relating to Erosion and Wear[5]

2.2 *ISO Standard:*

ISO 6474 Implants for Surgery–Ceramic Materials Based on Alumina[6]

3. Terminology

3.1 *Definitions*—For definitions of terms in this guide relating to plastics, refer to Definitions D 883. For definitions relating to erosion and wear, refer to Terminology G 40.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *wear, n*—the progressive loss of material from a prosthetic component as a result of tangential motion against its mating component under load.

4. Significance and Use

4.1 This guide provides general guidelines for establishing test conditions, obtaining wear measurements, and determining the appropriateness of results for wear simulation of the femoro-tibial components of knee joint prostheses. Fundamental aspects of these methods include the use of bovine serum or

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[2] The boldface numbers given in parentheses refer to the list of references at the end of the text.

[3] *Annual Book of ASTM Standards*, Vol 08.01.

[4] *Annual Book of ASTM Standards*, Vol 13.01.

[5] *Annual Book of ASTM Standards*, Vol 03.02.

[6] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

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demonstrated equivalent lubricant, and use of dynamic load and motion profiles representative of the human knee joint during activities of daily living. **(3)** The addition or substitution of other patient activities is at the discretion of the investigator.

4.2 While wear results in a change in the physical dimensions of the specimen, it is distinct from dimensional changes due to creep or plastic deformation, in that wear results in the removal of material in the form of debris particles, causing a loss in weight of the specimen.

4.3 This guide for generating wear of the polymeric component is suitable for various simulator devices. These techniques can be used with metal, ceramic, carbon, polymeric and composite counter faces bearing against a polymeric material, (for example, polyethylene, polyacetal, etc.). Thus, this method has universal application for wear studies of total-knee replacements which feature polymeric bearings. This method has not been validated for high-density material bearing systems, such as metal-metal, carbon-carbon, or ceramic-ceramic.

5. Apparatus and Materials

5.1 *Knee Prosthesis Components*:

5.1.1 The knee joint comprises femoral and tibial specimens in which materials such as metal alloys, ceramics, polymers, and carbon have been used in various combinations in different designs.

5.1.2 There shall be at least one control specimen, identical to the wear test specimens.

5.2 *Component Configurations*:

5.2.1 Polymeric tibial inserts used in some modular knee implants may contain geometrical features that either damage the polymer on removal or reduce the ability to satisfactorily clean the component. It may be necessary to modify the polymeric insert or the insert's immediate backing to a simple configuration to permit use of the weight-loss technique of wear assessment (Practice F XXXX). Care must be taken to avoid altering knee design features that could affect the wear performance.

5.2.2 The knee joint components shall be assembled in a manner similar to that in which they would function *in vivo*. The exception to this would be if the intent of the wear test was to investigate the effect of improper assembly or implantation.

5.3 *Knee Simulator*:

5.3.1 *Test Chambers*—In the case of a multi-specimen machine, contain the components in individual, isolated chambers to prevent contamination of one set of components with debris from another test. Design the chamber of entirely of noncorrosive materials, such as acrylic plastic or stainless steel, and ensure that it is easily removable from the machine for thorough cleaning between tests. Design the wear chambers such that the test bearing surfaces are immersed in the lubricant throughout the test **(3, 6)**.

5.3.2 *Component Clamping Fixtures*—If wear is to be determined from the weight loss of the components, the method for mounting the components in the test chamber should not compromise the accuracy of assessment of weight-loss due to wear.

5.3.3 *Load*—Ensure that the axial load profile is representative of that which occurs during the patient's walking cycle, with peak loads equal to or greater than 2 kN **(4)**. The loading apparatus must be free to follow the specimen as wear occurs, such that the applied peak load is constant to within ± 3 % for the duration of the test. Never allow the applied load to be below that required to keep the chambers seated (for example, 50 N) **(6)**. If AP shear force or IE rotation torque profiles are used, these should also be representative of that which occurs during a patient's activity cycle **(7)** and the loading apparatus must be free to follow the specimen as wear occurs, maintaining a tolerance of ± 3 % on the peak load for the duration of the test. Selection of these loading profiles should also be based on satisfaction of the criteria set forth the Annex A1.

5.3.4 *Motion*—Ensure that the flexion-extension motion between the knee components is oscillatory and simulates that of the targeted activity. Addition of internal-external rotation or AP displacement profiles is at the investigator's discretion. Selection of these motion profiles should also be based on satisfaction of the criteria set forth in Annex A1. It is recommended that the orientations of the knee components relative to each other and to the load-axis be maintained by suitable specimen-holder keying.

5.3.5 *Oscillating Frequency*—Oscillate the knee prostheses at a nominal rate of 0.5 to 2.0 cycles per second (0.5 to 2.0 Hz). The selected frequency should maintain the criteria set forth in Annex A1.

5.3.6 *Cycle Counter*—Include with the knee-simulator a counter to record the total number of wear cycles.

5.4 *Lubricant*:

5.4.1 It is recommended the specimen be lubricated with bovine blood serum; however, another suitable lubrication medium may be used if validated (see Annex A1 and Annex A2).

5.4.2 Since different bovine sera differ in composition (protein concentration, etc.), dilution with deionized water of up to 75 % may be appropriate. The appropriate dilution shall be based on satisfaction of the criteria set forth in Annex A1.

5.4.3 If serum is used, then use filtered-sterilized serum since it is less likely to contain hemolyzed blood material, which has been shown to adversely affect the lubricating properties of the serum **(3)**. Diluted solutions of serum also have been used for this purpose **(9)**. Filtration may remove hard, abrasive, particulate contaminants or other impurities that might otherwise affect the wear properties of the specimens being tested.

5.4.4 Maintain the volume and concentration 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.

5.4.5 To retard bacterial degradation, freeze and store the serum until needed for the test. In addition, it is recommended that the fluid medium in the test contains 0.2 to 0.3 % (weight fraction) sodium azide, or other suitable biocide, to minimize bacterial degradation. Other lubricants should be evaluated to determine appropriate storage conditions.

5.4.6 It is recommended that disodium dihydrogen ethylenediaminetetraacetate (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 **(8)**. The addition of EDTA to other lubricant mediums should be evaluated.

5.4.7 Additives such as sodium azide and EDTA should be dissolved in deionized water and passed through a 0.2-μm filter before adding to the test lubricant.

5.4.8 The appropriate interval for replacing used serum depends on how the serum maintains its functional composition (that is, lubricating properties). This depends on factors such as the specific test conditions and materials being used and the additives present in the serum. There is no minimum replacement interval. The maximum recommended replacement interval is two weeks. The selected interval should again maintain the criteria set forth in Annex A1.

5.4.9 A lubricant other than bovine serum may be used when it can be shown that its lubricating properties and, therefore, the material wear properties are reasonably physiological **(7)** and the criteria set forth in Annex A1 can be met. In such a case, specify the lubricant in the test report.

5.5 The bulk temperature of the lubricant should be maintained at a given temperature, ± 3°C, within the range of 21 to 39°C, or reported if different.

6. Specimen Preparation

6.1 The governing rule for preparation of component counterfaces 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 (Practice F 86).

6.1.1 Because variations in geometrical tolerances between the total knee components may influence the friction and wear performance, check the overall dimensions of the knee components for consistency and record any differences.

6.1.2 In knee joint combinations where polyethylene components are gripped directly, the clamping should not induce distortion of polyethylene components that could affect the friction and wear performance.

6.1.3 Obtain a fabrication history for each polymeric or composite component, including information such as grade, batch number and processing variables, method of forming (extruding, molding, etc.), temperature, pressure and forming time used, articular surface preparation methods (see Annex A3), and any post-forming treatments, including sterilization methods and parameters.

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

6.1.5 *Sterilization*—Sterilize the polymeric components in a manner typical of that in clinical use for such devices, as this may affect the wear properties of the materials. Report sterilization processing parameters with the aging time prior to each test. Sterilization of all test and control components within a specific test group should be done simultaneously (in a single container) when possible to minimize variation among the specimens. This wear-simulation procedure makes no attempt to maintain the sterility of specimens during the wear test.

6.1.6 *Cleaning of Polymer Prostheses*—Prior to wear testing, careful cleaning of the polymer specimens is important to remove any contaminants that normally would not be present on the actual prosthesis. During the wear test, the components must be re-cleaned and dried before each wear measurement to remove any extraneous material that might affect the accuracy of the measurement. The recommended procedure for cleaning and drying of polymeric components is given in Annex A4 (also, see Practice F XXXX).

NOTE 1—With some combinations of materials, wear may result in the transfer of particulate debris that may then become reimbedded or otherwise attached to polymeric, metal or composite surfaces. Such an occurrence will render the weight-loss assessment of wear less reliable.

6.2 *Soaking of Polymeric and Composite Prostheses*:

6.2.1 Polymeric and composite components should be presoaked in the test lubricant to minimize fluid sorption during the wear test. Without pre-soaking, components of very low-wear polymers, such as UHMWPE, may show a net increase in weight or volume during the initial wear intervals, due to fluid sorption **(3, 10)**. The error due to fluid sorption can be reduced through pre-soaking 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 encountered **(10)**.

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

6.3.1 *Characterization*—Include with pre-test characterization of metal, ceramic, or other materials recording of fabrication variables such as composition, forming method (forging, casting, etc.), and any post-forming processing, such as annealing. Obtain data on material properties relevant to wear, for example, grain structure, hardness, percentage of contaminants.

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

6.3.3 Clean, degrease, and passivate components of referenced prosthetic metals or ceramics according to Practice F 86. This practice may require modification for components of other materials. Clean components to produce 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 (refer to Practice F XXXX for gravimetric techniques).

7.2 Place the soak control specimen(s) in a soak chamber of test lubricant such that the total surface area exposed to the lubricant is similar to that of the wear components during testing. Maintain the soak chamber temperature at the wear test lubricant temperature. It is recommended that the soak chamber be attached to the simulator or otherwise agitated in the same manner as the actual wear chambers. In addition, it may

be advantageous to apply a cyclic load to the soak control specimen(s) (without tangential motion) comparable to that applied to the wear specimens since this can also affect the rate of fluid sorption.

NOTE 2—Cyclic loading of the soak control specimen(s) is necessary if a dimensional wear measurement method is to be used.

7.3 Place the wear test components in the simulator, add the lubricant, apply the load, and commence cyclic loads and motions.

7.4 As testing is commenced, monitor the components for signs of erratic friction or wear behavior that might require an early termination of the test.

7.5 Remove the wear and soak components at specified intervals, wash, rinse, and dry concurrently, according to the procedure in the Annex A4. 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 treatment will provide the most accurate correction for fluid sorption by the wear specimens.

7.6 After rinsing and drying, conduct wear measurements.

7.7 Thoroughly rinse all test assembly surfaces which have contacted the test lubricant using deionized water.

7.8 Inspect the bearing surfaces of the knee components 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 clean the specimens prior to re-starting the wear test.

7.9 Replace the wear components and soak controls in fresh lubricant and continue wear cycling.

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

7.10.1 Completion of 5×10^6 cycles;

7.10.2 Breaking up of articulating surfaces, detachment of particles greater than 1 mm^2, or delamination;

7.10.3 Failure of the test machine to maintain the force and displacement parameters within the given tolerances.

7.10.4 If the wear test involves a bearing surface with variable sub-surface properties or one in which fatigue wear may potentially develop, it may be necessary to continue the wear test until 1×10^7 cycles or more.

7.11 *Number of Replicate Tests*—Perform tests intended to determine the relative wear rates of two conditions with at least three sets of specimens for each condition to provide an indication of the repeatability of the results. As for any such experimental comparison, the total number of specimens eventually needed will depend on the magnitude of the difference to be established, the repeatability of the results (standard deviation) and the level of statistical significance desired.

8. Reporting Results

8.1 *Materials*:

8.1.1 Provide material traceability information (raw material and fabrication or manufacturing methods and lots) 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 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; these data should be reported.

8.1.3 The method of sterilization, the sterilization and test dates, and the means of storage post-sterilization/pretest should be reported, if known. For irradiation-sterilized specimens, total dose and dose rate should be reported.

8.2 *Test Apparatus and Methodology*:

8.2.1 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 the motions and forces, the systems used to measure motions and forces, the arrangement for mounting specimens, a description of the lubricant used, the arrangement for lubricating the articular surfaces, the arrangement for lubricant temperature control, total lubricant volume per station, lubricant replacement interval, and arrangement for the exclusion of contaminant particles.

8.2.2 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.

8.2.3 Record and report the room temperature and humidity during each weighing session.

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

8.3 *Wear Rates*:

8.3.1 Plot the wear of each specimen graphically as a function of wear cycles. Wear may be reported as the volumetric loss of the bearing component as a function of the number of wear cycles. If weight measurements are used, this will require knowing the density of the wear specimen material.

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 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, non-linear models may be fit to the wear test data.

8.3.5 Report the test duration in cycles. If this was less than

5×10^6 cycles, explain why.

8.3.6 Report the load and motion curves used.

8.3.7 Report how the wear mechanisms and wear rates resemble clinical wear behavior (in accordance with Annex A1). Provide a description of the articulating surfaces of all wear specimens.

8.4 *Accuracy and Repeatability*:

8.4.1 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 wear rates, mean wear rate, and the 95 % confidence intervals for each rate.

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

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

8.5 Include a reference to this guide and to the standard used for the wear measurement method.

9. Precision and Bias

9.1 For knee simulator wear data to be reproducible and comparable among laboratories, uniform procedures should 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 guide is intended, in part, to facilitate uniform testing and reporting of data from knee joint simulator wear studies. Validation of this methodology may be achieved through round-robin testing.

10. Keywords

10.1 joint simulator; knee prosthesis; wear testing

ANNEXES

(Mandatory Information)

A1. GUIDELINES FOR DEMONSTRATING THAT KNEE SIMULATOR WEAR BEHAVIOR IS SIMILAR TO CLINICAL WEAR BEHAVIOR

A1.1 It is necessary to identify characteristics of test results which suggest that clinical wear behavior is being reproduced. It is suggested that a baseline result be established using the configuration with the most clinical history; a CoCr alloy femoral component articulating against a gamma-sterilized UHMWPE tibial component (unaged, or aged less than five years). This combination should be evaluated in a baseline test series and demonstrate to meet the requirements below.

A1.2 Reproduction of *in vivo* wear quantities

A1.2.1 Clinical wear rates for tibial component materials in knee prostheses are very scarcely documented, mostly because of geometrical complexities. One study by Collier et al. **(11)** found the average penetration rate of EtO-sterilized UHMWPE tibial components to be less than 0.1 mm/yr, and for gamma-air-sterilized UHMWPE tibial components, greater than 0.5 mm/yr. The latter group may have been influenced by post-irradiation aging (and a subsequent fatigue wear mechanism). The many different wear mechanisms that have been reported in TKA **(12-15)** further complicates the target wear rate.

A1.2.2 A summary of reported knee simulator wear rates is listed in Table A1.1. As shown, there is a wide range of results, probably a reflection of the variability in machines and methods, and to some extent, different designs and materials. Wear rates ranging from imperceptible to catastrophic have been observed clinically; thus, it is different to provide guidelines unless the targeted clinical result is defined. Investigators who show convincing evidence that their simulator and clinical wear specimen surfaces look similar (A1.3) strengthen their argument that the wear rate they measure is appropriate. As such evidence is gathered, it will become more clear how narrow the range of wear rates, as shown in Table A1.1 should be.

A1.2.3 The appropriate duration of a laboratory wear test depends on the magnitude of wear, the linearity of wear rate as it is affected by the duration of a break-in period, predominating wear mechanism and wear transitions, the potential for long-term fatigue or other late failure mechanisms, and repeatability of results. It may be justifiable to run a test for as little as one million cycles based on these considerations, or it may be appropriate to extend the test to ten million cycles or more in some cases.

A1.3 Reproduction of *in vivo* wear mechanisms.

A1.3.1 Because of the dearth of clinical data on wear rates, the appropriateness of knee simulator wear tests must rely on reproducing *in vivo* wear surfaces and debris characteristics. Many different wear mechanisms have been reported to predominate depending on UHMWPE sterilization method and shelf-age, patient and surgical factors, device design, heat-pressed surfaces, presence of cement particles or other debris, etc. The clinical target becomes an issue in light of these numerous conditions. Based on the methods described in this guide, one of two target wear mechanisms should be selected:

A1.3.1.1 Wear-polishing (to include burnishing or micro-abrasive/micro-adhesive wear)

A1.3.1.2 Delamination (fatigue wear mechanism)

Wear-polishing has been reported in the absence of aging and abrasion **(28)**. This mechanism may be accompanied by striations or ripples **(29,30)** as well as microcracks **(30)**. The delamination mechanism should be selected when the clinical

TABLE A1.1 Reported UHMWPE Wear Rates from Knee Simulator Wear Tests

Study	Duration (10^6 cycles)	Knee Design	Wear Rate ($mm^3/10^6$ cycles)
Treharne et al.[16]	1.0	RMC	1.59
		Total Condylar	3.71
		Townley	13.8
		Anametric	13.9
		UCI-type	32.6
Dowson et al.[17]	2.0	Geomedic	78.0
	1.5	Freeman-Swanson	79.5
	1.0	Polycentric	77.4
Dowson et al.[18]	1.0	Leeds	55.5
		Freeman-Swanson	47.3
Walker[19]	2.1	Genesis (small)	3.8
Hastings[20]	4	AMK: gamma-N_2/aged	6
	2	AMK: gamma/aged	43-97
Polenini[20]	?	Howmedica	16
Burgess et al.[21]	8.0	Kinemax	2.82
Sauer et al.[22]	3.37	Genesis II, size 1-2	
		EtO/aged	14.5
		gamma-N_2/aged	8.4
Sauer et al.[23,27]	2.6	Genesis II, size 5, group A	1.6
	5.6	Genesis II, size 5, group B	1.4
Kawanabe et al.[24]	1.7	AGC (with AP translation)	34.1
	8.8	AGC (without AP translation)	9.9
Hastings[25]	10	AMK gas-plasma/aged	2.8
	10	AMK crosslinked/aged	0.7
Hastings[26]	10	AMK gamma/unaged	3.6
Gilbertson[27]	variable	MG-simulator A	1.9
		MG-simulator B	18.8
		MG-simulator B, no IE rotation	0.8
		MG-simulator B, no AP translation	1.9
Rieker[27]	. . .	Sulzer	2.2
Essner[27]	. . .	Howmedica, 13.5° rotation	14.2
		Howmedica, no IE rotation	3.5

target exhibits sub-surface cracking **(12,31)**. This wear mechanism is considered a form of fatigue wear, typically requiring a certain latency period, but eventually overriding early wear mechanisms and resulting in the removal of relatively large amounts of material. Delamination wear has been successfully generated in knee simulator testing **(32)**.

A1.3.2 Wear debris particles may also be evaluated for assessing the appropriateness of the wear test method. If the size and morphology characteristics can be shown to be comparable to clinically retrieved debris for a comparable device, this may even substitute for the above validation criteria for wear mechanisms.

A1.4 Repeatability and reproducibility of results. A minimum of three and up to six replicate tests per condition should be conducted depending on repeatability. If the same specimen condition were tested in a separate series, there should be no significant difference in results.

A2. CHOICE OF WEAR-TEST LUBRICANT

A2.1 Comparative experiments have shown that distilled water or saline solutions do not duplicate the lubricating properties of fluids such as serum or synovial fluid that contain physiological concentrations of proteins **(3)**. In particular, the heavy transfer of polyethylene to the surface of a metal or ceramic implant that is typically observed with water or saline lubrication, but 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 (or equivalent) to ensure that when used in simulated knee wear tests it approximates the wear found clinically (see Annex A1). Report the choice of lubricant along with the proof of validation for its use.

A3. PRECAUTIONS IN PREPARING SPECIMEN SURFACES

A3.1 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.

A4. METHOD FOR CLEANING OF SPECIMENS (FROM PRACTICE F XXXX)

A4.1 Gently scrub specimens with a nonabrasive material to remove all serum particles. Verify under a magnifying glass.

A4.2 Rinse under a stream of deionized water.

A4.3 Clean in an ultrasonic cleaner:

A4.3.1 5 min in deionized, particle-free water,
A4.3.2 Rinse in deionized water,
A4.3.3 10 min in 10 mL of liquid ultrasonic cleaning detergent plus 500 mL of water,
A4.3.4 Rinse in deionized water,
A4.3.5 10 min in deionized water,
A4.3.6 Rinse in deionized water,
A4.3.7 3 min in deionized water, and
A4.3.8 Rinse in deionized water.

A4.4 Dry with a jet of nitrogen or suitable clean, dry gas.

A4.5 Soak in 95 % methyl alcohol, for 5 minutes (see Note A4.1).

A4.6 Dry with a jet of nitrogen or suitable gas.

A4.7 Dry in a vacuum jar at a minimum vacuum of 10^{-3} torr for 30 min.

A4.8 Powder-free gloves should be used during all specimen handling procedures.

NOTE A4.1—This is a suggested cleaning procedure suitable for metals, ceramics, carbon, and UHMW polyethylene **(3)**. Use methyl alcohol only for polymers that are essentially insoluble in such liquids. For polymers that dissolve or degrade in methyl alcohol, substitute a more appropriate volatile solvent. 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.

A5. COMPONENT CLAMPING FIXTURES

A5.1 One technique that has proven practical is to clamp each component in a mold (for example, polyurethane) that replicates the outer shape of the test component. The mounting mold is then press-fit into the base of each chamber **(6)**. The mounting method should permit the test components to be removed periodically for cleaning and wear measurement without this procedure damaging the test components or causing a separate loss of volume of the test components. If there is doubt, it is recommended that several specimens be mounted and removed from the machine several times each, and measured each time to detect any volumetric change caused by the mounting procedure.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 For the purpose of the guide, wear is defined as the progressive loss of material from a prosthetic component as a result of tangential motion against its mating component under load. For current designs of total knee prostheses used since 1971 in the USA, the polymeric component bearing against metal, ceramic, composite or carbon inserts will be the sacrificial member; that is, the polymer will be the predominant source of wear debris. The metallic or other non-polymeric components, 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 and design combinations selected, it may be desirable in some instances to add additional techniques to identify the nature and magnitude of the wear process.

X1.2 While wear results in a change in the physical dimensions of the specimen, it is distinct from dimensional changes due to creep or plastic deformation in that wear generally results in the removal of material in the form of debris particles, causing a loss in weight of the specimen **(3,6)**.

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

X1.4 During wear testing in serum, calcium phosphate may precipitate on the surface of the test balls, particularly those of

ceramic, and strongly affect the friction and wear properties. The addition of 20 mM EDTA in the lubricant may eliminate such precipitation.

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