Designation: F 1715 – 00ε1

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.

ε[1] NOTE—Section 2 was editorially corrected in June 2001.

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 2025 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

[1] This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devicesand is the direct responsibility of Subcommittee F04.22on Arthroplasty.

Current edition approved May 10, 2000. Published August 2000. Originally published as F 1715 – 96. Last previous edition F 1715 – 96.

[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, 25 W. 43rd St., 4th Floor, New York, NY 10036.

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 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 caused by 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, and so forth). 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 clean the component satisfactorily. 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 2025). 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 multispecimen 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 as a result of 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, and so forth), 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 affect the lubricating properties of the serum adversely **(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 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 in which 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, and so forth), temperature, pressure and forming time used, articular surface preparation methods (see Annex A3), and any postforming treatments, including sterilization methods and parameters.

6.1.4 Pretest 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 before 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*—Before 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 recleaned 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 2025).

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 presoaking, components of very low-wear polymers, such as UHMWPE, may show a net increase in weight or volume during the initial wear intervals as a result of fluid sorption **(3,10)**. The error caused by 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 encountered **(10)**.

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

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

6.3.2 *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 in which 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