APPENDIX J – Ankle Testing Guidance Documents

Guide for Wear Assessment of Prosthetic, Unconstrained, Meniscal Bearing, Ankle Designs in Simulator Devices[1]

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 ankle joint replacement prostheses. The ankle prostheses are evaluated in a device intended to simulate the tribological conditions encountered in the human ankle joint.

1.2 The methods described in this guide are intended to apply to a number of fundamentally different types of ankle wear simulators. These include apparatuses which are designed to apply some combination of axial load, plantar/dorsiflexion angular motion, AP displacement and talar rotational displacement to talar and tibial wear test specimens.

1.3 Since the ankle 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 estimate the wear characteristics and to allow comparison of 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 guide counter faces [cobalt-chromium-molybdenum alloy (Specification F 75); thermomechanically processed cobalt chrome (Specification F 799 or F 1537)], or Ceramic coated titanium (Endotec specification S-017) 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 Guides:*

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[4]

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

F 799 Specification for Thermomechanically Processed Cobalt-Chrome-Molybdenum Alloy for Surgical Implantss

F 1537 Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloy for Surgical Implantss

F 2025 Practice for Gravimetric Measurement of Polymeric Components for Wear Assessments

G 40 Terminology Relating to Erosion and Wear[5]

2.2 *ISO Guide:*

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 Guide:*

3.2.1 *wear, n*—the progressive loss of material from a prosthetic component as a result of motion against it's mating components 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 intermediate bearing component of ankle 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. **(3,4)** 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 ankle 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.

[1] Adapted from ASTM F 1715

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

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

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

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

[6] Available from American National Guides Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

5. Apparatus and Materials

5.1 *Ankle Prosthesis Components*:

5.1.1 The ankle joint comprises talar and tibial specimens and intermediate bearing 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 The ankle 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 *Ankle 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 or splashed with 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)**. The AP or IE rotation motion profiles used, these should be representative of that which occurs during a patient's activity cycle 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 ankle components relative to each other and to the load axis be maintained by suitable specimen-holder keying.

5.3.5 *Oscillating Frequency*—Oscillate the ankle 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 ankle 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 it's 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 ankle 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 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.

6.1.3 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.

6.1.5 *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 guide, 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 the subsequent amount of wear (refer to ASTM F 2025 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 ankle 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 before restarting 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 as a result of variation in the amount of surface drying are large in comparison to the incremental weight loss caused by 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 subsurface 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 (guide 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 ystems 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 in which 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 caused by wearing-in of the specimens, or an increase as a result of the onset of fatigue wear, linear regression may be applied to separate intervals of the test to indicate the change in wear rate.

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

8.3.5 Report the test duration in cycles. 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 in which 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 in which 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 guide used for the wear measurement method.

9. Precision and Bias

9.1 For ankle 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 ankle joint simulator wear studies. Validation of this methodology may be achieved through round-robin testing.

10. Keywords

10.1 joint simulator; ankle prosthesis; wear testing

ANNEXES

(Mandatory Information)

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

A1.1 It is necessary to identify characteristics of test results that 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 components 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 Wear rates ranging from imperceptible to catastrophic have been observed clinically; thus, it is difficult to provide guidelines unless the targeted clinical result is defined.

A1.2.2 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 ankle 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 contact stress, UHMWPE sterilization method and shelf age, patient and surgical factors, device design, heat pressed surfaces, presence of cement particles or other debris, and so forth. 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 microabrasive/microadhesive wear).

A1.3.1.2 *Delamination (fatigue wear mechanism)* Wear polishing has been reported in the absence of aging and abrasion **(11)**. This mechanism may be accompanied by striations or ripples **(12,13)** as well as micro cracks **(13)**. The delamination mechanism should be selected when the clinical target exhibits subsurface cracking **(14,15)**. 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 **(16)**.

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.

A2.2 TiN surfaces, however, do not develop a transfer film and thus the use of distilled water and saline may be useful.

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 ASTM F 2025)

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 min (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

(No mandatory 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 motion against its mating component under load. For current designs of total ankle prostheses used since 1971 in the United States, 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 no 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 caused by 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.

REFERENCES

(1) Rae, T., "Comparative Laboratory Studies on the Production of Soluble and Particulate Metal by Total Joint Prostheses," *Arch. Orthop. Traumat. Surg.*, 95:71, 1979.

(2) Treharne, R. W., Young, R. W., and Young, S. R., "Wear of Artificial Joint Materials III: Simulation of the Knee Joint Using a Computer Controlled System," *Engineering in Medicine*, Vol 10, No. 3, 1981, pp. 137–142.

(3) McKellop, H. A., Clarke, I. C., Markolf, K., and Amstutz, H. C., "Wear Characteristics of UHMW Polyethylene: A Method for Accurately Measuring Extremely Low Wear Rates," *J. Biomed. Mat. Res.*, 12:895, 1978.

(4) Stauffer RN et al: Force and motion analysis of the normal, diseased and prosthetic ankle joints. Proceedings of the 23rd Annual Meeting of the ORS, Las Vegas, Nevada, 1977, p. 44.

(5) McKellop, H. A., Lu, B., and Benya, P., "Friction, Lubrication and Wear of Cobalt-Chromium, Alumina and Zirconia Hip Prostheses Compared on a Joint Simulator," *Trans. Orthop. Res. Soc.*, 1992.

(6) McKellop, H. A., and Clarke, I. C.," Degradation and Wear of Ultra-High-Molecular-Weight Polyethylene," *Special Technical Publication 859*, ASTM 1985.

(7) ISO/DIS 14243-1 Implants for Surgery - Wear of Total Knee Joint Prostheses, Part 1: Loading and Displacement Parameters for Wear Testing Machines with Load Control and Corresponding Environmental Conditions for Test, July 1999.

(8) McKellop, H., Lu, B., and Benya, P., "Friction, Lubrication, and Wear of Cobalt-Chromium, Alumina, and Zirconia Hip Prostheses Compared on a Joint Simulator," *Ceramors*, 92.

(9) Streicher, R. M., "Ceramic Surfaces as Wear Partners for Polyethylene," Bioceramics, Vol 4, Eds W. Bonfield, G. W. Hastings, K. F. Tanner, Butterworth-Heinemann Ltd, London, 1991.

(10) Clarke, I. C., Starkebaum,W., Hosseinian, A., McGuire P., Okuda, R., Salovey, R., and Young, R., "Fluid-Sorption Phenomena in Sterilized Polyethylene Acetabular Prostheses," *J. Biomat.*, 6:184, 1985.

(11) Cornwall, G.B., Bryant, J.T., Hansson, C.M., Rudan, J., Kennedy, L.A., and Cooke, T.D.V.," A Quantitative Technique for Reporting Surface Degradation Patterns of UHMWPE Components of Retrieved Total Knee Replacements," *J. Applied Biomaterials*, 6, 1995, pp. 9-18.

(12) Wimmer, M.A., Loos, J., Andriacchi, T.P., and Schneider, E., "The Morphology of the Straited Wear Pattern in Total Knee Replacement." *Trans. 44th ORS*, New Orleans, March 1998: 354.

(13) Walker, P.S., Blunn, G.W., and Lilley, P.A., "Wear Testing of Materials and Surfaces for Total Knee Replacement," *J. Bio Mater. Res.*, 33, 1996, pp. 159-175.

(14) Engh, G.A., Dywer, K.D., and Hanes, C.K., "Polyethylene Wear of Metal-Backed Tibial Components in Total and Unicompartmental Knee Prostheses," *JBJS*, 74-B (1), 1992, pp. 9-17.

(15) Blunn, G.W., Walker, P.S., Joshi, A., and Hardinge, K., "The Dominance of Cyclic Sliding in Producing Wear in Total Knee Replacements," *Clin. Orthop.*, 273, 1991, pp. 253-260.

(16) Walker, P.S., Blunn, G.W., Bell, C.J., Sathasivam, S., Andriacchi, T.P., Paul, J.P., and Campbell, P., "Methodology for Long-Term Wear Testing of Total Knee Replacement," *Trans 44th ORS*, New Orleans, March 1998.

Guide for Cyclic Fatigue Testing of Components of Total Ankle Joint Replacements[1]

1. Scope

1.1 This test method covers a procedure for the fatigue testing of metallic and plastic component used in ankle joint replacements. This test method covers the procedures for the performance of fatigue tests on ankle components using a cyclic, constant-amplitude force. This test method may require modifications to accommodate some ankle designs.

1.2 This test method is intended to provide useful, consistent, and reproducible information about the fatigue performance of ankle designs.

1.3 The values stated in SI units are regarded as the guide. The inch-pound units given in parentheses are for information only.

1.4 *This guide does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this guide to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Guides:*

E 4 Practices for Force Verification of Testing Machines

E 467 Practice for Verification of Constant Amplitude Dynamic Loads in an Axial Load Fatigue Testing System

E 468 Practice for the Presentation of Constant Amplitude Fatigue Results for Metallic Materials

E 1150 Definitions of Terms Relating to Fatigue

3. Terminology

3.1 *Definitions:*

3.1.1 *R value*—The R value is the ratio of the minimum load to the maximum load.

$$R = \text{minimum load/maximum load}$$

3.2 *Definitions of Terms Specific to This Guide:*

3.2.1 *anteroposterior centerline*—a line that passes through the center of the prosthetic joint, parallel to the sagittal plane and perpendicular to the line of load application. For asymmetric tibial tray designs, the appropriate center of the tibial tray shall be determined by the investigator and the rationale reported.

3.2.2 *fixture centerline*—a line that passes through the center of the fixture, parallel to the anteroposterior centerline. This line represents the separation between the supported and unsupported portions of the test fixture.

3.2.3 *mediolateral centerline*—a line that passes through the center of the prosthetic joint, parallel to the coronal, or frontal, plane and perpendicular to the line of load application. For asymmetric tibial tray designs, the appropriate center of the tibial tray shall be determined by the investigator and the rationale reported.

3.2.4 *moment arm, d_{ap}*—the perpendicular distance between the mediolateral centerline of the tibia component and the line of load application.

4. Significance and Use

4.1 This test method can be used to describe the effects of materials, manufacturing, and design variables on the fatigue performance of and plastic components subject to cyclic loading for relatively large numbers of cycles.

4.2 The loading of ankle designs *in vivo* will, in general, differ from the loading defined in this test method. The results obtained here cannot be used to directly predict *in vivo* performance. However, this test method is designed to allow for comparisons between the fatigue performances of different metallic device designs, when tested under similar conditions.

4.3 In order for fatigue data to be comparable, reproducible, and capable of being correlated among laboratories, it is essential that uniform procedures be established.

5. Specimen Selection

5.1 The test component selected shall have the same geometry and materials as the final product, and shall be in finished condition.

6. Apparatus

6.1 The device shall be mounted to simulate off center loading as illustrated in Fig. 1. This off center loading should simulate that observed clinically. **(1)**[2] Care shall be taken to ensure that the fixation of the tibial tray does not produce abnormal stress concentrations that could change the failure mode of the part. The tibial and talar components should be mounted on porous polyurethane[3] or other material that simulates the flexural properties of bone.

6.2 The tibial tray shall be positioned such that the anteroposterior centerline and the fixture centerline are aligned with an accuracy of ±1 mm and ±2°.

6.3 The fixturing shall be constructed so that the load shall be applied perpendicular to the undeflected superior surface of the tibial tray.

6.4. The load shall be applied parallel to the tibial component axis as shown in Fig.1 and d_{ap} shall be determined developed fro Ref. 1 and will be used for all testing of that design in that size.

6.5 Where there is a risk of fracture of the talar component it should be mounted in a position of worst case loading as illustrated in Fig.1.

6.6 The load shall be applied by means of a spherical indenter.

6.7 The peak loading should simulate a maximum physiological load such as given in Ref. 2 but not less than 2,500N.

[1] Adapted from ASTM F 1800

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

[3] May be obtained for Koch-Otto York

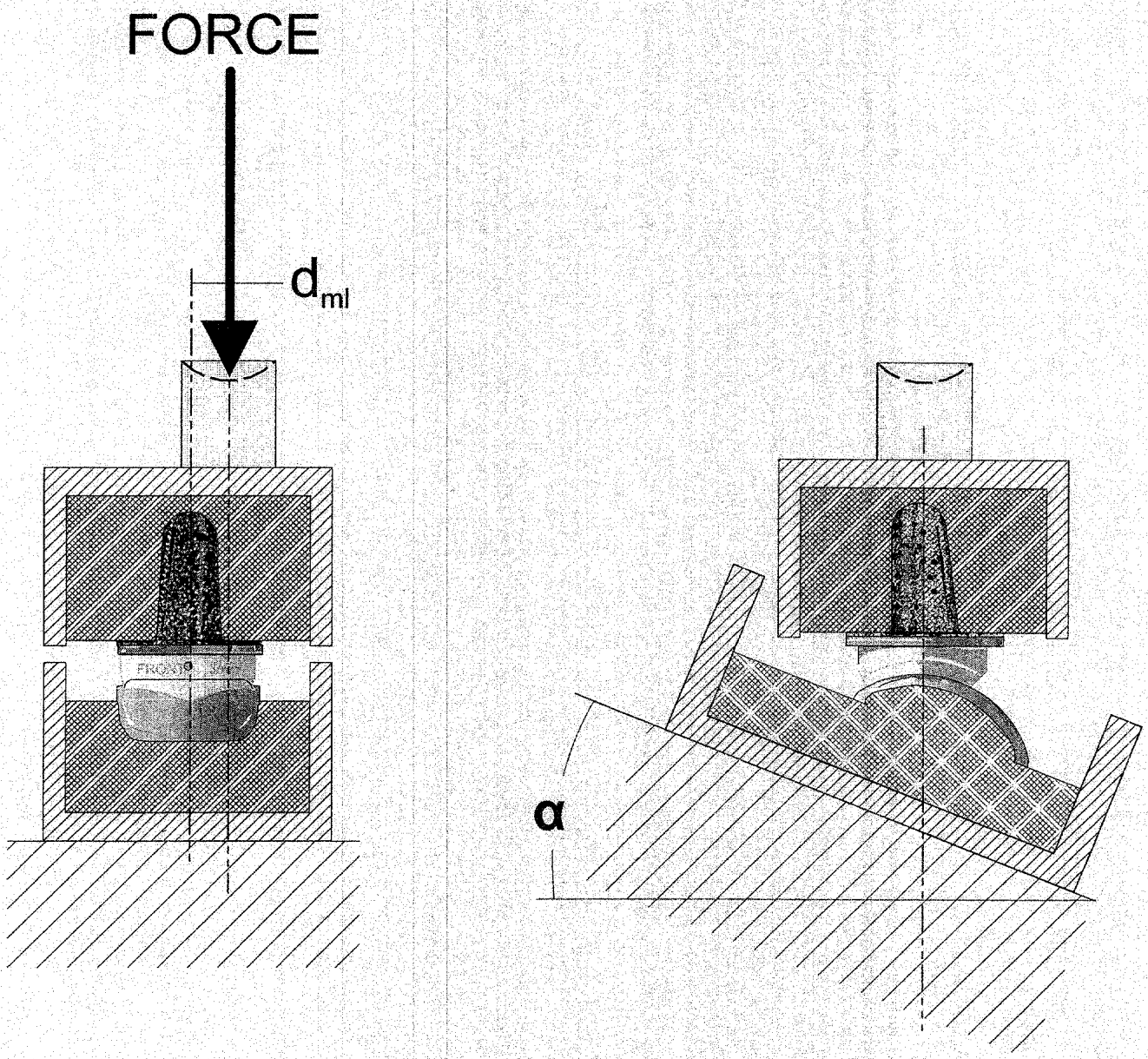

FIG. 1 Schematic of Test Setup

7. Equipment Characteristics

7.1 Perform the tests on a fatigue test machine with adequate load capacity.

7.2 Analyze the action of the machine to ensure that the desired form and periodic force amplitude is maintained for the duration of the test (see Practice E 467 or use a validated strain gaged part).

7.3 The test machine shall have a load monitoring system such as the transducer mounted in line with the specimen. Monitor the test loads continuously in the early stages of the test and periodically thereafter to ensure the desired load cycle is maintained. Maintain the varying load as determined by suitable dynamic verification at all times to within ±2 % of the largest compressive force being used.

8. Procedure

8.1 Determine the size of the ankle components used by the investigator. Dimensions shall be reported.

8.2 Position the test specimen such that the load axis is perpendicular to the undeflected superior surface of the tray since the tray surface will not remain perpendicular to the load axis during loading.

8.3 Mount one side of a symmetric tibial component on the fixture (see Fig. 1 and Fig. 2). If asymmetrical, fix the tibial component such that a worst case condition is tested. Report the criteria used to distinguish the worst case condition.

8.4 *Test frequency*—Run all tests at a frequency of 30 Hz or less. Take care to ensure that the test machine can maintain the applied load at the chosen frequency and that resonant conditions are not reached.

8.5 *R value*—Run all tests with an *R* value of 10.0

.

NOTE 2—In strict terms, since the force applied is compressive, the maximum force is the smallest negative amplitude. Consequently, the *R* value is ten when the negative signs cancel each other. See Terminology E 1150 for the definition of the *R* value.

8.6 Measure the vertical deflection of the tibial tray using a dial gage, displacement transducer, and so forth. Record the point at which the deflection is measured (that is, under the applied load, at the point of maximum deflection).

8.7 Report the test environment used.

9. Test Termination

9.1 Continue the test until the a component fails or until a predetermined number of cycles has been applied to the implant. The suggested number of cycles is ten million. Failure may be defined as: a fracture of the fracture of any component; or in the case of the metallic components formation of a crack detectable by eye, fluorescent dye penetrant, or other non-destructive means; or exceeding a predetermined deflection limit.

10. Report

10.1 Report the fatigue test specimens, procedures, and results in accordance with Practice E 468.

10.2 In addition, report the following parameters: tibial tray material, spacer diameter and thickness, indenter diameter, overall anteroposterior and mediolateral dimensions of the tray, location of anteroposterior and mediolateral centerlines (for asymmetric tibial trays), d_{ap}, fixation method, largest compressive load, *R* value, cycles to failure, mode and location of failures, test environment, and test frequency. The method for determining the loading location on the tibial tray (that is, and d_{ap}) shall be documented.

11. Precision and Bias

11.1 The precision and bias of this test method needs to be established. Test results that can be used to establish precision and bias are solicited.

12. Keywords

12.1 arthroplasty; orthopaedic medical devices; ankle components; total ankle arthroplasty

APPENDIX

(No mandatory Information)

X1. RATIONALE

X1.1 It is recognized that for some materials the environment may have an effect on the response to cyclic loading. The test environment used and the rationale for that choice shall be described in the test report.

X1.2 It is also recognized that actual *in vivo* loading conditions are not constant amplitude. However, there is insufficient information available to create guide load spectrums for metallic and plastic ankle components. Accordingly, a simple periodic constant amplitude force is recommended.

X1.3 Worst case loading may vary depending on material, design, and clinical indications. The researcher shall evaluate the possible clinical and design related failure modes and attempt to determine a worst case situation. Also, as the method of heat treatment can affect the strength of the metal component material, it shall be considered. For example, the high temperature sintering treatment used to apply a porous coating may affect the fatigue strength of the metal components.

X1.4 The size of device to be tested shall be determined by the investigator. In general, the worst case size shall be chosen based on evaluation or experience, or both. In a design with a constant tray thickness, maximizing the d_{ap} will result in the largest moment arm and therefore the highest stresses in the tray; however, a tray of non-uniform thickness may not adhere to this rule. There may also be a reason why an investigator wishes to test a size that is not worst case. This test method may also be used for this purpose.

X1.5 The required tolerance limits (±1 mm and ±2°) were chosen to minimize the change in stress while ensuring a reasonable test setup.

X1.6 It is recommended that testing be terminated at ten million cycles if failure of some component has not occurred. The device design addressed in this testing are designed to replace the ankle joint and intended to carry load over the life of the implant. Ten million cycles represents the number of loading cycles a tibial tray might experience over ten years of clinical use (estimated at one million loading cycles per year). It is recognized that in this support condition, the implant may not be required to withstand this number of loading cycles prior to revision.

REFERENCES

(1) Komistek RD et al: A determination of ankle kinematics using fluoroscopy. *Foot and Ankle International* 21, 4:343-350, April 2000

(2) Stauffer RN et al: Force and motion analysis of the normal, diseased and prosthetic ankle joints. Proceedings of the 23rd Annual Meeting of the ORS, Las Vegas, Nevada, 1977, p. 44.