Designation: F2777 – 23

Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion[1]

This standard is issued under the fixed designation F2777; 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 standard specifies a test method for determining the endurance properties and deformation, under specified laboratory conditions, of ultra high molecular weight polyethylene (UHMWPE) tibial bearing components used in bicompartmental or tricompartmental knee prosthesis designs.

1.2 This test method is intended to simulate near posterior edge loading similar to the type of loading that would occur during high flexion motions such as squatting or kneeling.

1.3 Although the methodology described attempts to identify physiological orientations and loading conditions, the interpretation of results is limited to an *in vitro* comparison between knee prosthesis designs and their ability to resist deformation and fracture under stated test conditions.

1.4 This test method applies to bearing components manufactured from UHMWPE.

1.5 This test method could be adapted to address unicompartmental total knee replacement (TKR) systems, provided that the designs of the unicompartmental systems have sufficient constraint to allow use of this test method. This test method does not include instructions for testing two unicompartmental knees as a bicompartmental system.

1.6 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.7 *This standard 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 standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F1223 Test Method for Determination of Total Knee Replacement Constraint

F2003 Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene After Gamma Irradiation in Air

F2083 Specification for Knee Replacement Prosthesis

2.2 *Other Standards:*[3]

ISO 4965-1 Metallic Materials—Dynamic Force Calibration for Uniaxial Fatigue Testing—Part 1: Testing System

ISO 5833 Implants for Surgery—Acrylic Resin Cements

ISO 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

ISO 14243-3 Implants for Surgery—Wear of Total Knee-joint Prostheses—Part 3: Loading and Displacement Parameters for Wear-testing Machines with Displacement Control and Corresponding Environmental Conditions for Test

3. Terminology

3.1 *Definitions:*

3.1.1 *anatomic (mechanical) axis of the femur*—the line between the center of the femoral head and the center of the femoral knee.

3.1.2 *bearing centerline*—the line running anteroposterior that is the mirror line of the tibial bearing (tibial insert). For asymmetric tibial bearing designs, the appropriate tibial bearing centerline shall be determined and reported along with the rationale for the location.

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

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.1.3 *bearing retention mechanism*—mechanical means for preventing tibial tray/bearing disassociation.

3.1.4 *femoral component centerline*—a line running anteroposterior between the femoral condyles and parallel to the femoral condyles. The line should be equidistant between the condyles. For asymmetric or non-parallel condyles designs, the appropriate centerline shall be determined, and the rationale for that location reported.

3.1.5 *fixed bearing system*—a knee prosthesis system comprised of a femoral component and a tibial component, where the tibial articulating surface is not intended to move relative to the tibial tray.

3.1.6 *mobile bearing component*—the component between fixed femoral and tibial knee components with an articulating surface on both the inferior and superior sides.

3.1.7 *mobile bearing knee system*—a knee prosthesis system comprised of a femoral component, a tibial component, and a mobile bearing component that can rotate and/or translate relative to the tibial component.

3.1.8 *posterior slope*—the angle that the perpendicular axis of the tibial tray makes when it is tilted posteriorly away from the tibial axis (see Fig. 1).

3.1.9 *R value*—the ratio of the minimum force to the maximum force (that is, R = minimum force/maximum force).

3.1.10 *tibial axis*—nominal longitudinal axis of the tibia, which corresponds with the central axis of the medullary cavity of the proximal tibia.

3.1.11 *tibial tray/bearing disassociation*—unrecoverable physical separation of the tibial bearing and tibial tray components as a result of bearing distraction or tilting.

3.1.12 *tibial tray centerline*—a line running anteroposterior that is the mirror line of the tibial articulating surface. For asymmetric bearing tibial tray designs, the appropriate tibial tray centerline shall be determined and reported along with the rationale for the location.

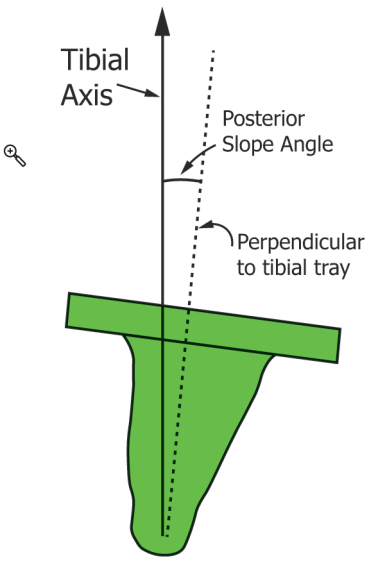

FIG. 1 Incline of the Tibial Tray Relative to the Tibial Axis at the Recommended Angle (Posterior Slope)

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/cyclic creep performance of UHMWPE bearing components subject to substantial rotation in the transverse plane (relative to the tibial tray) for a relatively large number of cycles.

4.2 The loading and kinematics of bearing component designs *in vivo* will, in general, differ from the loading and kinematics 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 enable comparisons between the fatigue performance of different bearing component designs when tested under similar conditions.

4.3 The test described is applicable to any bicompartmental knee design, including mobile bearing knees that have mechanisms in the tibial articulating component to constrain the posterior movement of the femoral component and a built-in retention mechanism to keep the articulating component on the tibial plate.

5. Apparatus and Materials

5.1 *Testing Machine,* with the following characteristics:

5.1.1 A sinusoidal, dynamic-forcing waveform.

5.1.2 An error in applied force not greater than ±2 % at the maximum force magnitude (in accordance with ISO 4965-1).

5.1.3 Axial force peak representative of what could occur during daily activities of high flexion (about 2275 N). During the tests, the values of the maximum and minimum forces shall be maintained to an accuracy of ±2 % of the maximum force. The test shall be stopped if this accuracy is not maintained.

5.1.4 The forcing accuracy must be maintained as bearing component deformation occurs.

5.1.5 Instrumentation to record the number of cycles.

5.2 *Fixturing,* with the following characteristics:

5.2.1 Means of mounting and enclosing the test specimens using a corrosion-resistant material that is capable of holding the femoral component and tibial tray.

5.2.2 The fixtures shall maintain the tibial and femoral components in their required orientations for the duration of the test.

5.2.3 If necessary, bone cement (see ISO 5833) or a high-strength epoxy may be used to lock the femoral and tibial components in their fixtures.

5.2.4 The test apparatus or fixture should allow the force to be applied through the center of the femoral component and ensure equal force transmission through the medial and lateral condyles or offset medially as given by ISO 14243-1 and ISO 14243-3.

5.2.5 The test apparatus or fixture shall allow for varus-valgus self-alignment of the femoral or tibial component.

5.3 *Fluid Medium:*

5.3.1 The test assembly shall be immersed in deionized water at 37 ± 2 °C.

5.3.2 Deionized water should be added as necessary to keep the test components at the test temperature for the duration of the test.

6. Specimen Selection

6.1 The metallic components shall follow the complete manufacturing process (machining, surface treatment, laser marking, passivation, cleaning, and so forth) until the sterilization stage. Because sterilization has no known effect on the mechanical properties for metallic components, it is not necessary for these to be sterilized. The UHMWPE components shall be sterilized in a manner consistent with the clinical use for such devices, except when the mechanical properties of the UHMWPE have been proven not to be detrimentally affected by the sterilization process.

6.2 The UHMWPE component(s) shall be artificially aged according to Practice F2003, except when the mechanical properties of the UHMWPE have been proven not to be detrimentally affected by aging.

6.3 Most of the knee systems allow the tibial tray to be upsized, size for size, or downsized relative to the bearing component size. Consistent with the principle of this test method, the smallest tibial tray compatible with a given bearing component size (according to the manufacturer) shall be used.

6.4 There may be some small variation in the amount of cold flow of the bearing component depending on the tibial bearing thickness. However, the possible effect of the cold flow is worst on the thinnest bearing components. Consequently, the thinnest bearing component in the knee system scope shall be used in this test.

7. Procedure

7.1 On all samples, make the initial measurements on the bearing surface to characterize the subsequent amount of bearing deformation after completion of the test. Use of a coordinate measuring machine (CMM) or non-contact 3D measuring machine (for example, laser scanner, structured light scanner, etc.) are the recommended methods of making the measurements. The measurements should be in the form of a grid of points, referenced to a fixed plane on the UHMWPE bearing, at a maximum of 1.5 mm apart over the entire superior surface of the UHMWPE bearing. The measurements should be made with the bearing at 20 ± 2 °C.

7.2 On one representative sample, perform the "A-P Draw Test" (Section 9.2) and the "Rotary Laxity Test" (Section 9.4) from Test Method F1223 at the same flexion angle used in 7.6 of this test method.

7.3 Condition the UHMWPE bearing in a deionized water environment at 37 ± 2 °C prior to initiation of the test for a long enough time to bring the bearing into equilibrium with the fluid temperature.

7.4 Mount the tibial tray in the test machine. The main proximal planar surface shall be inclined at the posterior slope recommended by the manufacturer (see Fig. 1). If more than one slope is recommended, the largest slope should be used. Mount the bearing component on the tibial tray using the method recommended by the manufacturer.

NOTE 1—The tibial slope will generate a shear force and a resulting bending moment on the test frame actuator. This may cause a significant error of the load cell, depending on the sensitivity of the load cell to off-axis loading. This should be addressed in the test setup.

7.5 Measure vertical distraction (when appropriate for the design) and bearing tilt (Fig. 2).

7.5.1 To measure the vertical distraction, use appropriately sized feeler gauges, one set under each condyle to lift the bearing away from the tibial plate, keeping the posterior surface of the bearing parallel to the superior surface of the tibial plate, until the gauges will not fit easily in the gap. The thickness of the feeler gauges is the vertical distraction value.

7.5.2 To measure the posterior bearing tilt displacement, push the bearing posteriorly and raise the posterior edge of the bearing by hand. Select a location on the posterior edge of the bearing and measure the perpendicular distance from that location to the tibial plate. Change in these displacements after testing may be useful as an indicator of damage.

7.6 Mount the femoral component in the test machine with an alignment such that the component is flexed in the sagittal plane at the maximum flexion angle (including the posterior slope angle) the manufacturer recommends (see Fig. 3) according to the method in Section 6.2.3 of Specification F2083.

7.7 The femoral component should be placed so that it contacts the bearing component close to the posterior edge of the bearing. The specific contact points between components should be recorded and justified. At minimum, it should be demonstrated that the anterior-posterior placement of the components would permit flexion and rotation of the femur to the prescribed angles without impingement between the femur and tibia.

NOTE 2—If the mobile bearing knee design allows anterior-posterior translation of the mobile bearing, translate the bearing component posteriorly relative to the tibial tray (according to the maximum translation allowed by the knee system) to simulate a worst-case condition.

7.8 Initially align all components in neutral rotation to set the maximum flexion angle. In this position, the femoral component, the bearing component, and the tibial tray should be aligned in the coronal plane according to the manufacturer's intended neutral alignment (see Fig. 4).

7.9 *Rotational Alignment:*

7.9.1 For mobile bearing knee system designs, simulate 20° of internal rotation for the tibial tray with respect to the femoral and bearing components (see Fig. 5).

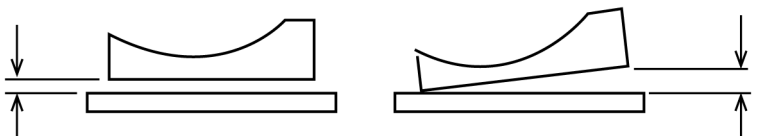

FIG. 2 Vertical Distraction and Posterior Bearing Tilt Displacement

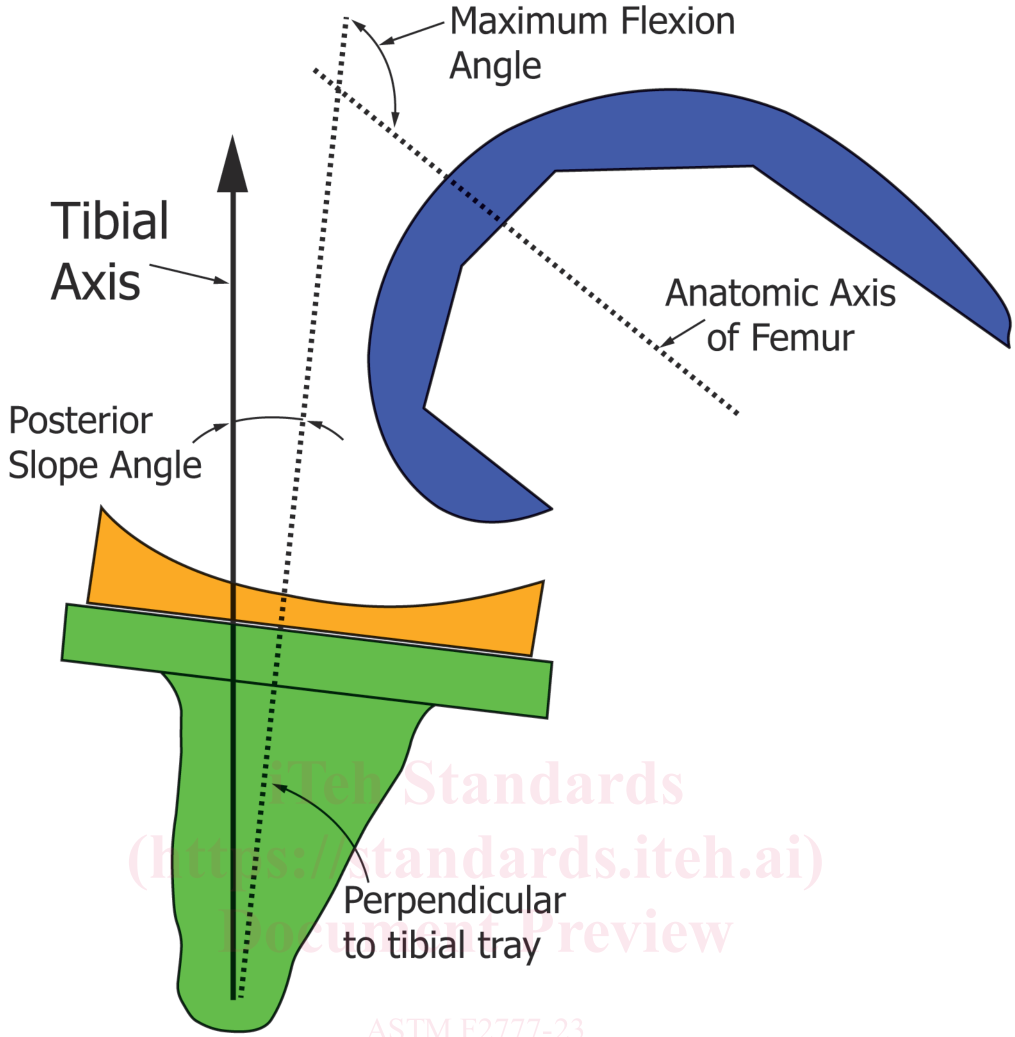

FIG. 3 Rotate the Femoral Component Until the Maximum Flexion Angle is Reached

NOTE 3—The femoral component and the anteroposterior centerlines of the bearing component are still collinear.

7.9.2 For fixed designs, the components should simulate 20° of internal rotation for the tibial tray with respect to the femoral component (see Fig. 6). If a smaller angle is used, the rotation angle at maximum internal rotation as determined according to Test Method F1223 shall be used. On a fixed bearing system, only one femoral condyle shall be at the maximum posterior contact point after the internal rotation is simulated. The other condyle shall be closer to the center of the bearing. It may be necessary to achieve the 20° rotation by rotating the femoral component, as long as the appropriate flexion and load line are correct.

7.9.3 The line of force application shall be set to pass through the femoral component centerline, intersecting at or posterior to the contact points.

7.10 Introduce the deionized water to completely immerse the test specimen contact surfaces.

7.11 Start the test machine and apply a cyclical force with a peak of 2275 N to the bearing component with the femoral component at the specified force. For these tests, the ratio of the minimum force magnitude to the maximum force magnitude should be 0.1.

7.12 Operate the testing machine at a fixed frequency between 0.5 to 2.0 Hz.

7.13 Continue the test until one of the following events occur:

7.13.1 The bearing component fractures or is no longer attached to the tibial component (disassociates). This can be determined by either the test machine measured force or displacement ranges exceeding preset limits. These preset limits should be the same for all tests.

7.13.2 A test duration of 220 000 cycles is achieved. (See X1.4 for details of how this number was derived.)

7.14 After testing, the same measurements described in 7.5 should be performed on the test sample before removing the bearing from the tibial component.

7.15 If the samples have not fractured or dissociated, measure tibial deformation by repeating the measurements

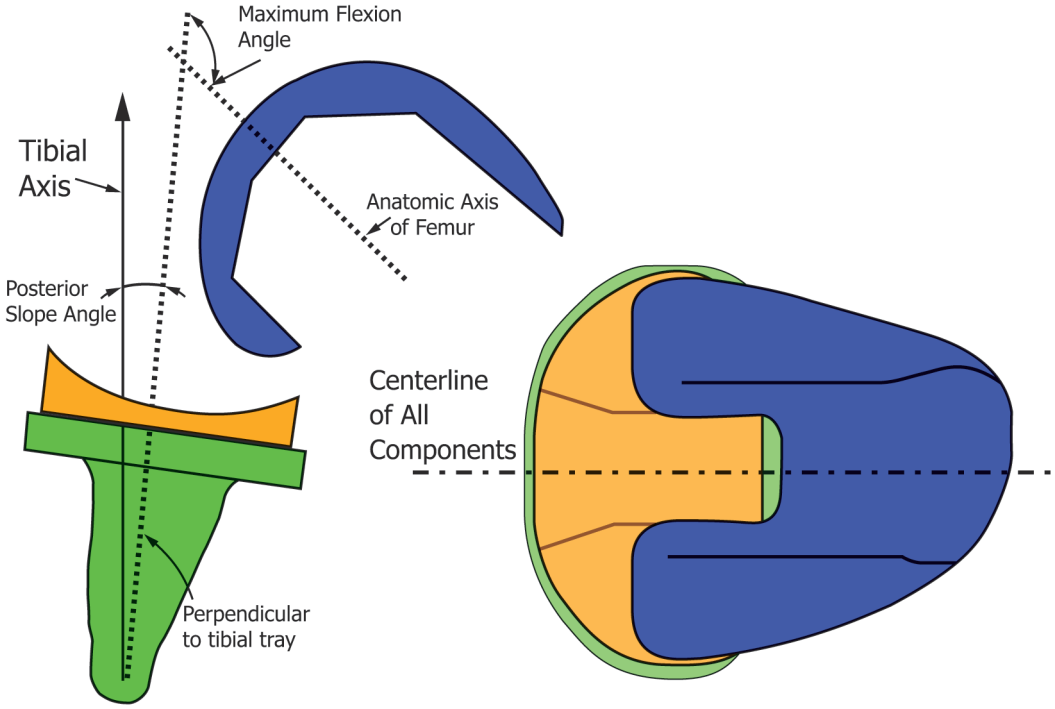

FIG. 4 Illustration of Initial Neutral Rotation Alignment

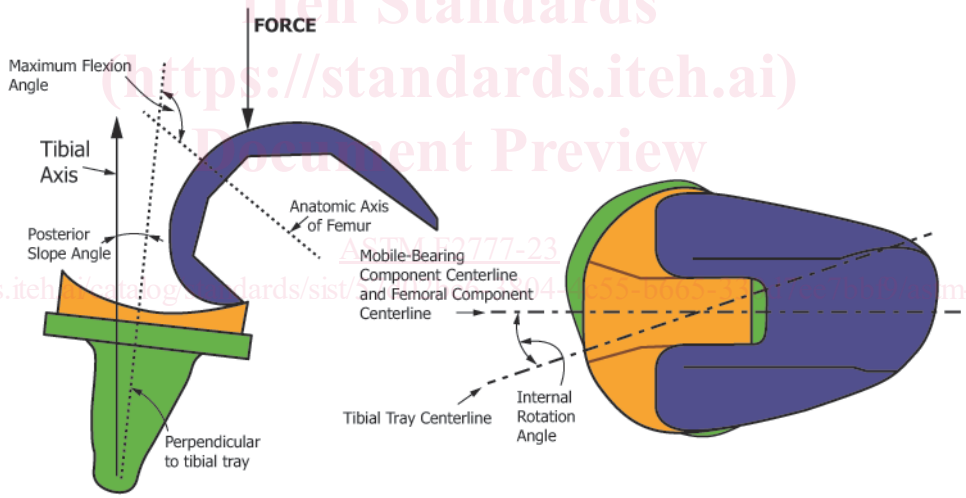

FIG. 5 For a Mobile Bearing Knee Simulate the Internal Rotation for the Tibial Tray, and Load the Femoral Component

of 7.1 on all the samples. Then, repeat the measurements of 7.2 on all samples. The measurements in 7.2 should be conducted on dry samples a minimum of 90 min after testing to allow creep recovery and to permit the sample to reach equilibrium with the 20 ± 2 °C measurement temperature.

8. Reporting Results

8.1 The test report shall include the following information:

8.1.1 Bearing component size, tibial tray size, femoral component size, manufacturer, catalog numbers, and lot numbers.

8.1.2 Bearing component thickness and tolerance specifications for the thickness.

8.1.3 Bearing component material information.

8.1.4 Magnitude and justification (if necessary) of the angle between the bearing component and tibial tray anteroposterior centerlines.

8.1.5 Location and justification for the initial contact points between the femoral and tibial bearing components.

8.1.6 Bearing maximum overhang for mobile bearing systems (in mm).

8.1.7 Preset limits associated with machine shutdown for determining bearing fracture or disassociation.

8.1.8 Description of the UHMWPE bearing in the knee: resin, aged condition (including support for the appropriateness of the aging procedure or justification for not aging), cross-linking method, and sterilization method.

8.1.9 Mode and location of failure.