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.

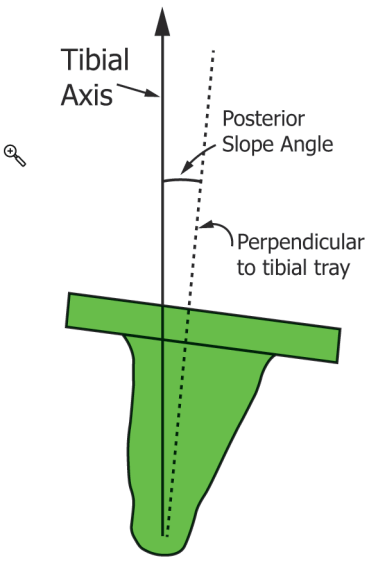

FIG. 1 Incline of the Tibial Tray Relative to the Tibial Axis at the Recommended Angle (Posterior Slope)

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.