Designation: F2723 – 13a

Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation[1]

This standard is issued under the fixed designation F2723; 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 test method describes a laboratory method for evaluating the potential for mobile bearing knee tibial baseplate/bearing disassociation under repeated forces.

1.2 The test described is applicable to any bicompartmental mobile bearing knee with a bearing retention mechanism. With modification, the test can be applied to a unicompartmental mobile bearing knee with a bearing retention mechanism.

1.3 Although the methodology described does not replicate all physiological force conditions, it is a means of *in vitro* comparison of mobile bearing knee designs and the strength of the bearing retention mechanism between the tibial baseplate and bearing components under the stated test conditions.

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

1.5 *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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Terminology

2.1 *Definitions:*

2.1.1 *bearing axis*—the line connecting the lowest points on both the lateral and medial condyles of the superior surface of the mobile bearing.

2.1.2 *bearing retention mechanism*—mechanical means preventing tibial baseplate/bearing disassociation.

2.1.3 *inferior articulating interfaces*—any interface in which relative motion occurs between the underside of the mobile bearing component and the tibial tray.

2.1.4 *limiting position*—the position of the femoral component relative to the bearing at which the shear force is at a maximum with anterior-posterior (AP) movement of the femoral component on the bearing.

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

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

2.1.7 *superior articulating interfaces*—any interface in which relative motion occurs between the topside of the mobile bearing component and the femoral bearing component.

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

2.1.9 *2-axis orthogonal load frame*—a test machine capable of applying forces and displacements that act at 90° to each other.

3. Significance and Use

3.1 This test method includes the use of static and fatigue shear and bending force conditions to evaluate the bearing retention mechanism of a mobile bearing knee design and its ability to prevent disassociation.

3.2 In general, disassociation does not occur during activities where the contact locations are within the boundaries of the bearing surfaces. Disassociation is most likely to occur with forces at the edges of the bearing component or with large AP shear forces on a posterior stabilized knee tibial component post. Extreme bearing rotation, bone/bearing impingement, severe varus or valgus moments, high flexion or any combination of the above can increase the likelihood of disassociation.

3.3 The test method described is applicable to any bicompartmental mobile bearing knee with a bearing retention mechanism. With modification, the test can be applied to a unicompartmental mobile bearing knee with a bearing retention mechanism.

[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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4. Apparatus and Materials

4.1 A 2-axis orthogonal load frame with feedback control on both axes be required for dislocation testing. The machine must be able to record force and displacement in both axes.

4.1.1 *Component Size*—Test specimens should be chosen to maximize the force on the bearing retention mechanism. Considerations should include bearing thickness (a thicker bearing would tend to increase the forces on the locking mechanism, but could also increase the material support for the locking mechanism), bearing profile/size and tibial baseplate profile/size (a large bearing on a small tibial baseplate would tend to increase the overhang with rotation).

4.1.2 *Component Quantity*—The minimum number of test samples shall be five.

4.2 *Component Configurations*—The mobile bearing knee components should be assembled, as they would be for *in-vivo* use.

4.2.1 The femoral component flexion angle should be chosen to maximize the forces on the bearing retention mechanism. An engineering analysis may be necessary to determine the appropriate femoral flexion angle that creates the largest shear and/or bending forces on the retention mechanisms. For example, for a gait congruent design, a 0° flexion angle might distribute forces on both the anterior and the posterior sides of the locking mechanism, minimizing any bending forces. A flexion angle of greater than 90° may maximize the posterior position of the femoral component and consequently increase bending forces on the retention mechanism.

4.2.2 The tibial baseplate should be positioned with the recommended posterior slope. For knee systems where more than one posterior slope is recommended, the largest slope should be used.

4.2.3 *Component Fixtures*—The femoral component is fixed at the desired flexion angle. The tibial baseplate should be fixtured with the appropriate posterior slope. The tibial fixtures must allow the tibial baseplate to be fixed in relative rotation to the bearing and the femoral components. The test specimen coordinate system is shown in Fig. 1. Fixtures should not inhibit free motion of the bearing, even with substantial deformation if it should occur.

4.2.4 *Applied Force*—The vertical axial force should be maintained within ±3 % for the duration of the test. The test apparatus or fixtures should allow the force to be applied through the center of the femoral component (V_c, Fig. 1) to be distributed to the contact points with the tibial component. The peak cyclic horizontal force applied to the tibial baseplate should be maintained within ±3 % for the duration of the test.

4.2.5 *Displacement Measurement*—Displacement sensing devices should be capable of measuring the relative motion between the femoral and tibial baseplate in the anterior-posterior direction.

4.2.6 *Oscillating Frequency*—The cyclic horizontal force should be applied at a frequency of 0.5 to 3.0 cycles per second (0.5 to 3.0 Hz).

4.2.7 *Cycle Counter*—The test apparatus should be equipped with a cycle counter to record the total number of horizontal test cycles.

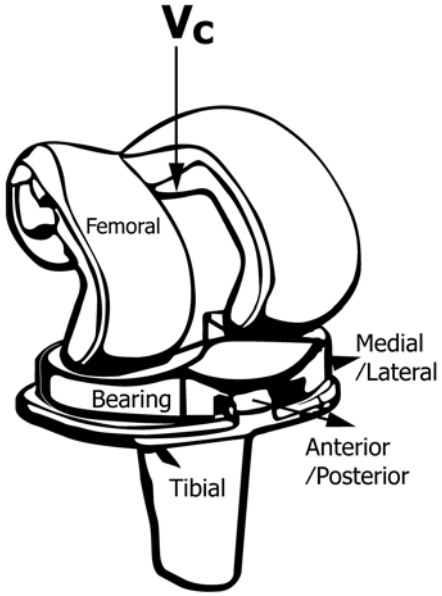

FIG. 1 Coordinate System and Force Locations

5. Test Specimens

5.1 The total knee replacement (TKR) should be the manufacturer's designated "standard" or "medium" size unless the bearing retention mechanism varies with the size of the knee. If the retention mechanism does vary, an engineering analysis should be conducted to justify a "worst case."

5.2 The implant shall be in its original packaging as supplied to the user by the manufacturer.

5.3 If the implant is not available in its package state, the condition of the device shall meet all geometry and material specifications, but may contain slight surface irregularities (that is, "cosmetic rejects") not considered influential in those regions of the device deemed critical to the specific test.

6. Conditioning

6.1 Expose the test specimens to a clean atmosphere at a temperature of 37 ± 2°C for 24 h prior to testing.

6.2 The test shall be run in a bath at 37 ± 2°C that covers the tibial bearing surface. The bath can be either bovine serum, mineral oil, olive oil, or deionized water. Before testing, the implant must be moved cyclically three times in the desired direction before data are acquired. These three repetitions can be performed by hand. This procedure is intended to distribute lubricant between the bearing surface and the tibial component. If the bearing is installed on the tibial component in the presence of lubricant it can be omitted.

7. Procedure

7.1 Assemble the bearing and tibial baseplate.

7.2 Measure vertical distraction (when appropriate for the design) and posterior bearing tilt displacement (Fig. 2). Change in these displacements after testing may be useful as an indicator of damage.