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.

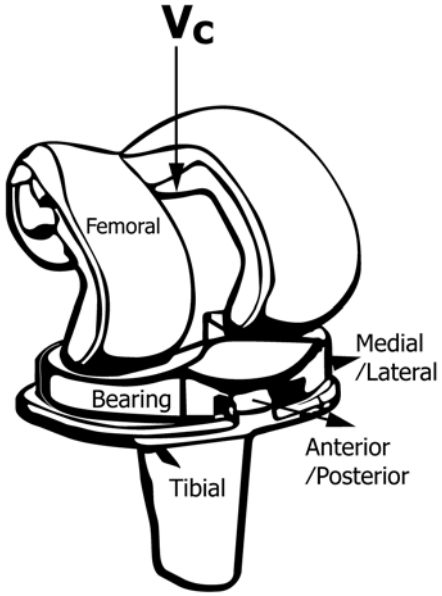

FIG. 1 Coordinate System and Force Locations

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.

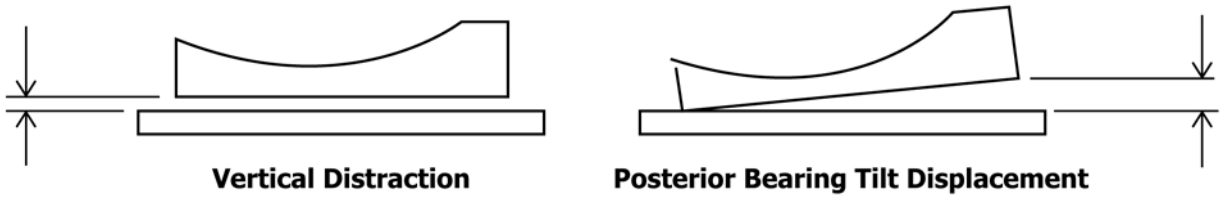

FIG. 2 Vertical Distraction and Posterior Bearing Tilt Displacement

7.2.1 To measure the vertical distraction, use plastic blade-type feeler gauges of an appropriate range to measure the amount of distraction. The gauge blades should be long enough to completely fit under the full length of the bearing. One set shall be placed 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 in the gap without force. The thickness of the feeler gauges is the vertical distraction value.

7.2.2 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 inferior-posterior edge of the bearing and measure the perpendicular distance from that location to the tibial plate. The value of that measurement is the posterior bearing tilt displacement.

7.3 Place test specimens in test apparatus using the appropriate fixtures.

7.3.1 The femoral component should be fixed at the desired flexion angle relative to the tibial baseplate.

7.3.2 The tibial baseplate and bearing should be approximately centered under the femoral component. The tibial baseplate should be axially aligned with the femoral component, that is, 0° of relative rotation. The bearing can be allowed to rotate slightly less than 5° when the force is applied to accommodate the possible variation in the flexion radii of the condyles of the femoral component.

7.3.3 The femoral component should apply the force along the bearing axis of the bearing.

7.4 Apply a compressive force of 2275 N as the vertical axial force, that is, joint reaction force.

7.5 *Limit Measurement Setup:*

7.5.1 Apply a posterior-to-anterior horizontal force to the tibial base plate until the horizontal force reaches 450 N or the femoral component reaches a point where the horizontal force drops because the femur has crossed over the posterior edge of the tibial component. The plot of AP force versus AP displacement is continuously recorded.

7.5.1.1 If the force reaches 450 N, the posterior-to-anterior limit force is 450 N.

7.5.1.2 If the force drops off before 450 N, the posterior-to-anterior limit force is 90 % of the peak force.

7.5.1.3 When dislocation of the femur off the posterior edge of the tibial component is experienced when running the test as specified in 7.7 using the limit force determined in 7.5.1.2, additional preconditioning of the tibial component is required. In that case, perform the procedure of 7.5.1 multiple times, recording the force each time, until the force difference between successive runs falls below 5 %. Use 90 % of the force measured in the last run made as the posterior-to-anterior limit force for the cycle test of 7.7

7.5.2 Apply an anterior-to-posterior horizontal force to the tibial base plate until the horizontal force reaches 450 N or the femoral reaches a point where the horizontal force drops because the femur has crossed over the anterior edge of the tibial component. The plot of AP force versus AP displacement is continuously recorded.

7.5.2.1 If the force reaches 450 N, the anterior-to-posterior limit force is 450 N.

7.5.2.2 If the force drops off before 450 N, the anterior-to-posterior limit force is 90 % of the peak force.

7.6 Using the information from 7.5, apply a cyclic AP horizontal force to the tibial baseplate. The peak force in the anterior to posterior direction will be the limit force for that direction determined in 7.5.2.1 or 7.5.2.2. The peak force in the posterior to anterior direction will be the limit force for that direction determined in 7.5.1.1, 7.5.1.2, or 7.5.1.3, if applicable.

7.7 Run for 110 000 cycles or until failure of the bearing retention mechanism. If dislocation of the femur off the posterior edge of the tibial component is experienced, see 7.5.1.3.

7.8 Record the anterior/posterior displacement for cycles 110 000 and 220 000.

7.9 Measure vertical distraction and bearing tilt (Fig. 2) as in 7.2.

7.10 Repeat the test with the tibial baseplate fixed in relative rotation to the femoral component and the bearing. The rotation should result in bearing overhang. The amount of rotation should be justifiable based on clinical conditions (20° of rotation suggested, but may vary with design). If the mobile bearing design is not symmetrical, the direction (internal or external) of rotation should be chosen in order to maximize the bearing overhang. Run to 110 000 cycles or until failure of the bearing retention mechanism. The cyclic AP horizontal force should be applied in line with the femoral component.

7.11 Record the anterior/posterior displacement for the last cycle.

7.12 Measure vertical distraction and bearing tilt (Fig. 2).

7.13 Replace the test specimens on test apparatus with no relative rotation between bearing and tibial baseplate.

7.14 Apply a steadily increasing anterior-to-posterior force on the tibial baseplate until failure occurs.

7.14.1 Record failure mode, for example, upper bearing disassociation (subluxation/dislocation), lower bearing disassociation, bearing retention mechanism failure, post failure in a posterior stabilized knee design.

7.14.2 Record failure force.

8. Report

8.1 *Materials:*

8.1.1 Record size information and justify the choice of size.

8.1.2 Provide material traceability information for each component. Examples of such information include part number, batch/lot number, material grade, and processing variables.

8.1.3 The method of sterilization should be reported. For irradiation-sterilized specimens, total dose and dose rate should be reported.

8.2 *Test Apparatus and Methodology:*

8.2.1 Describe the mechanisms used to generate the forces, the systems used to measure the forces and displacements, the fixtures, and the lubricant.

8.2.2 Report and justify the femoral flexion angle chosen for the test.

8.2.3 Report and justify the posterior slope of the tibial plate that was used in the test.

8.2.4 Report the number of cycles per second.

8.2.5 Report the horizontal rate of force application.

8.2.6 Report the amount of rotation of the tibial baseplate that was applied per 7.10 with justification for the amount.

8.3 *Outcome:*

8.3.1 Report the anterior and posterior tibial baseplate displacement at the beginning of the test, after 110 000 cycles and after 220 000 cycles.

8.3.2 Report the vertical distraction and the posterior bearing tilt displacement values at the beginning of the test, after 110 000 cycles, and after 220 000 cycles.

8.3.3 Report any bearing disassociation, imminent disassociation, or serious damage to the bearing retention mechanism after 220 000 cycles.

8.3.4 Describe the ultimate failure mode and peak force as a result of the steadily increasing anterior-to-posterior tibial force as applied per 7.14.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 Failure of currently available mobile bearing knee designs by bearing distraction or tilting is not common, as evidenced by the lack of bearing retention mechanism failures reported in the English-language literature.

X1.2 The cyclic portion of this test is representative of low cycle activities of daily living (gait with tibiofemoral contact at the extremes or high flexion). The described test stresses the bearing retention mechanism at the extremes of bearing motion under weight-bearing gait forces. The 450 N AP shear is the maximum AP shear force experienced during the stance phase of gait (**1**).[2] Studies using an implantable telemetry system have shown the peak loads during various activities of daily living are generally lower than historically predicted theoretical values. Current studies have shown joint forces during high flexion activities (> 130° flexion) ranging from 2.5 to 2.9 times the body weight (**2-7**). The 2275 N force used for this study represents 2.9 times a body weight of approximately 80 kg. Acceptance criteria for the test include no bearing disassociation, imminent disassociation, or serious damage to the bearing retention mechanism after 220 000 cycles. This number of cycles represents approximately thirty extreme motions per day for 20 years.

X1.3 The static anterior-to-posterior force after the cyclic testing is representative of less frequent high-force activities (kneeling). This test is especially relevant for posterior stabilized mobile bearing knee designs with posts. For this type of mobile bearing knee, the bearing retention mechanism strength should be subject to the acceptance criteria used for the tibial locking mechanism of a fixed bearing knee (tested in a similar manner). For posterior stabilized knees without posts, dislocation of the upper bearing surface should occur before the bearing retention mechanism fails.

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

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