Designation: F2724 – 08 (Reapproved 2014)

Standard Test Method for Evaluating Mobile Bearing Knee Dislocation[1]

This standard is issued under the fixed designation F2724; 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 is designed to provide a standardized method to determine the dislocation resistance of mobile-bearing knee designs with regard to femoral component disassociation and spin-out/spit-out of the mobile bearing insert.

1.2 Although the methodology described does not replicate all physiological loading conditions, it is a means of *in-vitro* comparison of mobile bearing knee designs and their ability to resist dislocation of the mobile bearing from the femoral or tibial components under stated test conditions.

1.3 The test method applies only to mobile bearing total knee designs.

1.4 The values stated in SI units are regarded as standard. The values given in parentheses are mathematical conversions to inch-pound units that are provided for information only and are not considered 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. Referenced Documents

2.1 *ASTM Standards:*[2]

F1223 Test Method for Determination of Total Knee Replacement Constraint

3. Terminology

3.1 *Definitions:*

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

3.1.2 *centerline axis, n*—a line through the neutral point perpendicular to the bearing axis and in a plane parallel to the plane of the flat portion of the inferior articulating surface of the mobile bearing at 0° posterior tibial slope.

3.1.3 *mobile bearing (insert), n*—the component between fixed femoral and tibial knee components with an articulating surface on both the inferior and superior sides.

3.1.4 *neutral point, n*—midpoint of the bearing axis.

3.1.5 *spin-out, n*—excessive rotation of the bearing component in a rotating platform knee or multi-directional platform knee such that there is dislocation between the femoral or tibial components and the mobile bearing.

3.1.6 *spit-out, n*—escape of the bearing component from beneath the femoral component either anteriorly or posteriorly.

3.1.7 *2-axis orthogonal load frame, n*—a test machine capable of applying forces and displacements that act at 90° to each other.

4. Significance and Use

4.1 This test method is designed to provide a standardized method to determine the constraint of mobile-bearing knee designs with regards to spin-out and spit-out of the mobile bearing.

4.2 Similar to constraint testing of total knees (see Test Method F1223), it is important to note that the test method does not simulate the soft tissues and laxity of the knee joint, which may be key factors related to the occurrence of spin-out or spit-out.[3] For instance, a patient with good soft tissue restraints will perhaps require a lower spin-out/spit-out resistance whereas a patient with major bone loss or destroyed ligamentous structures will likely require an implant with a higher spin-out/spit-out resistance. Therefore, the results from the test should be taken into account along with the condition of the patient's soft tissues to determine the relative safety for the device.

5. Apparatus and Materials

5.1 A engineering analysis should be performed on all sizes of a knee design to justify a "worst case" size for this test. At

[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.

Current edition approved March 15, 2014. Published April 2014. Originally approved in 2008. Last previous edition approved in 2008 as F2724 – 08. DOI: 10.1520/F2724-08R14.

[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] Weale, A. E., et al, "In Vitro Evaluation of the Resistance to Dislocation of a Meniscal-Bearing Total Knee Prosthesis Between 30° and 90° of Knee Flexion," *J. Arthroplasty*, 17(4), 2002, pp. 475–483.

least five mobile bearing inserts of that size should be tested. The tibial tray and knee femoral component may be reused for multiple trials as long as they are not damaged during testing.

5.2 The mobile bearing surfaces shall be lightly coated with bovine serum, olive oil, mineral oil, or deionized water to reduce friction effects during testing.

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

5.4 Fixtures shall be required to allow for an 80 % medial and 20 % lateral load distribution to be applied through the condyles of the femoral component.[4]

5.5 During testing, the tibial tray posterior slope and femoral component degree of flexion should be set according to the recommended surgical alignment.

6. Specimen Preparation

6.1 All components should be inspected prior to testing to ensure that they meet the geometrical and material specifications. The tibial inserts should undergo sterilization as would normally be employed with actual implants.

6.2 The test components should be exposed to a clean atmosphere at a temperature of 25 ± 5°C for 24 h prior to testing.

7. Procedure

7.1 Dislocation testing should be performed at 0°, 60°, and 90° of flexion, as well as the maximum flexion angle that the implant is intended to achieve. The test procedure shall address spin-out and spit-out simultaneously if allowed by the design.

7.2 Either the tibial tray or the femoral component shall be free to translate under actuator control in the anterior and posterior (A/P) directions. A compressive joint reaction force shall be applied to the mobile bearing knee through either the tibial tray or the femoral component along the superior/inferior (S/I) direction. The femoral component should be oriented in the desired flexion angles for the testing. The femoral component shall be constrained in all other translations/rotations.

7.3 The tibial tray should be mounted into fixtures that allow varus/valgus tilt. The pivot axis for the tilt should be selected based on calculations to apply 80 % of the force on the medial condyle and 20 % of the force on the lateral condyle. This can be accomplished by offsetting the pivot axis from the centerline axis in the medial direction by 30 % of total bearing spacing. The posterior slope of the tibial plate should be the slope recommended in the surgical procedure for the device.

7.4 The tibial tray shall be constrained in all other translations/rotations not mentioned in 7.2 or 7.3.

7.5 The components should be adjusted to the zero rotation position prior to testing. A joint reaction force of 710 N (160 lbf) should be applied along the S/I axis and held constant. The femoral component should be positioned on the articulating surface at the same starting location, the approximate low point per design of both the lateral and medial condylar articulating surfaces at zero rotation, under a 50 N load prior to testing. The femoral component should be displaced anteriorly until contact is lost with either of the insert condyles.

7.6 The components will be realigned to the original position. The joint load of 710 N (160 lbf) will be reapplied along the S/I axis and the femoral component should then be displaced posteriorly until contact is lost with either of the insert condyles.

8. Reporting Results

8.1 Report the following information:

8.1.1 Justification for the choice of the knee size tested.

8.1.2 The total femoral displacement relative to the tibial tray and the S/I axis should be reported for each individual trial.

8.1.3 The maximum loads should be reported for each individual trial.

8.1.4 The mode of failure that occurs first, spin-out or spit-out, should be reported for each individual trial.

[4] Hurwitz, D. E., et al, "Dynamic Knee Loads During Gait Predict Proximal Tibial Bone Distribution," *J. Biomechanics*, 31, 1998, pp. 423–430.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 Spin-out and spit-out of mobile bearing inserts has been found clinically to be a mode of failure, with a rate of less than 9.3 % reported in the literature.[5]

X1.2 The applied load of 710 N (160 lbf) was selected based on the applied load in Test Method F1223. The load was selected to provide a relative comparison between devices and is not intended to be related to any physiological load.

X1.3 The 80 % medial/20 % lateral load distribution specified in this test method was selected to represent an extreme case where the majority of the load is applied to a single condyle, increasing the probability that spin-out/spit-out may occur. Based on one study reported in the literature,[4] the most common loading distribution was 60 % medial/40 % lateral, with the majority of patients below the 80 % medial load level

[5] Bert, J. M., "Dislocation/Subluxation of Meniscal Bearing Elements After New Jersey Low-Contact Stress Total Knee Arthroplasty," *Clin. Orthop*., 254, May 1990, pp. 211–215.

that was selected as a worst case for this test method.