Designation: F2724 – 21

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

1.6 *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

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 *total bearing spacing, n*—distance between the contact points as given by Test Method F1223.

3.1.8 *two-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 regard 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

[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 1, 2021. Published March 2021. Originally approved in 2008. Last previous edition approved in 2014 as F2724 – 08 (2014). DOI: 10.1520/F2724-21.

[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*, Vol 17, No. 4, 2002, pp. 475–483.

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 An engineering analysis should be performed on all sizes of a knee design to justify a "worst case" size for this test. At 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 water (for example, reverse osmosis (RO) water, deionized (DI) water, or distilled water) to reduce friction effects during testing.

5.3 A two-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.

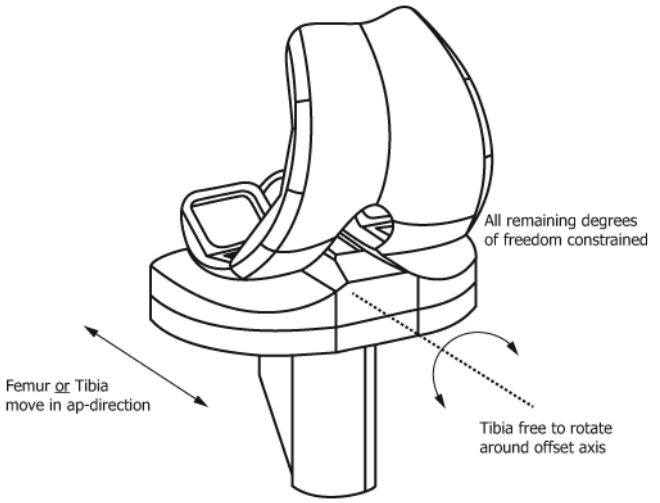
6.2 The test components should be exposed to a clean atmosphere at a temperature of 25 ± 5 °C for 24 h prior to testing.

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 can 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 (see Fig. 1).

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.



NOTE 1—The compressive joint reaction force is applied through either the tibial tray or the femoral component.

FIG. 1 Degrees of Freedom to be Used for Testing

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 100 N load prior to testing. The femoral component should be displaced at a rate of 1 mm⁄s posteriorly until contact is lost with either of the insert condyles. Testing shall be performed at room temperature.

7.6 The components shall be realigned to the original position. The joint load of 710 N (160 lbf) shall be reapplied along the S/I axis and the femoral component should then be displaced anteriorly 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.

9. Precision and Bias

9.1 It is not possible to have a precision statement because there is not a standard implant available to all users of the test

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