Designation: F2722 – 15

Standard Practice for Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops[1]

This standard is issued under the fixed designation F2722; 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 practice covers a laboratory-based *in vitro* method for evaluating the mechanical performance of materials and devices being considered for replacement of the tibio-femoral joint in human knee joint replacement prostheses in mobile bearing knee systems.

1.2 Mobile bearing knee systems permit internal external rotation to take place on one or both articulating surfaces. Some designs place physical limits or stops to the amount of rotation. Other designs may have increases of a resistance force with increases in rotation.

1.3 Although the methodology describes attempts to identify physiologically relevant motions and force conditions, the interpretation of results is limited to an *in vitro* comparison between mobile bearing knee designs and their ability to maintain the integrity of the rotational stop feature and tibial bearing component under the stated test conditions.

1.4 This practice is only applicable to mobile knee tibial systems with a rotational stop.

1.5 The values stated in SI units are regarded as standard.

1.6 *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]

F2083 Specification for Knee Replacement Prosthesis

F2003 Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air

3. Terminology

3.1 *Definitions:*

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

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

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

3.1.4 *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.

3.1.5 *neutral point*—midpoint of the bearing axis.

3.1.6 *rotational stop*—a feature that prevents relative rotation between two articulating joint surfaces beyond a specific angle of rotation or creates resistance to rotation beyond a specific angel of rotation.

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

4. Significance and Use

4.1 Fundamental aspects of this practice include the use of dynamic rotational force and motion representative of the human knee joint during an activity of daily living (deep flexion) and the effect of these forces and motions on the design features which stop or limit rotation in a mobile bearing knee design.

4.2 This test is required if rotational stops are designed to limit motion to ±20° or less; or there are other resistances to rotational motion with this ±20° range. In some instances, the rotational displacement could occur in both the inferior and superior interfaces.

5. Apparatus and Materials

5.1 *Component Configurations:*

[1] This practice 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.

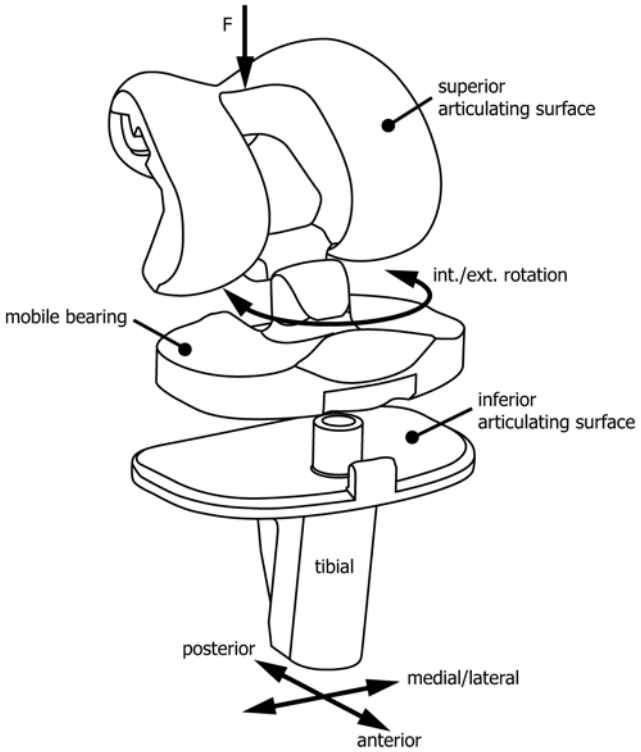

FIG. 1 Schematic of Test Setup

5.1.1 A test construct of the femoral component, mobile bearing component, and tibial tray should be used to provide appropriate interface geometries.

5.1.2 The knee joint tibial and femoral components should be assembled and oriented in a manner similar to that in which they would function *in vivo* as depicted in Fig. 1. The femoral component is mounted at the maximum flexion angle claimed for the device by the manufacturer.

5.1.3 The tibial component is mounted at zero slope. This means that the flat portion of the superior tibial surface will be perpendicular to the force axis.

5.2 *Mechanical Testing Systems:*

5.2.1 *Test Chambers*—Design each chamber entirely of noncorrosive materials, such as acrylic plastic or stainless steel, and ensure that it is easily removable from the machine for thorough cleaning between tests. Design the chambers such that the bearing surfaces are immersed in lubricant throughout the test.

5.2.2 The system should be capable of maintaining an axial force of 2000 N force as illustrated in Fig. 1. (Although this force is representative of a normal range compressive force, it is mainly intended as a uniform force to keep the components in contact during the test.)

5.2.3 The system should be capable of applying under torque control a peak torque of 14 N-m (2× the peak torque measured from a telemeterized knee study (**1**)[3]) and cycling back to near zero torque in both internal and external rotation directions.

5.2.4 If the rotational stop geometries for internal and external rotation are non-symmetrical, both the internal and external rotational stops should be tested. The same sample may be used for both tests if the results of the first test do not cause any damage that could affect the results of the second test.

5.2.5 *Rotational Test Frequency*—Rotate the relative rotational motion at a nominal rate of 0.5 to 3.0 cycles per second (0.5 to 3.0 Hz) per complete cycle to minimize viscoelastic high frequency effects.

5.2.6 *Cycle Counter*—Include with the mechanical testing system a method to monitor and count the number of cycles.

5.2.7 *Lubricant*—Lubricate the specimen by immersion in deionized water, mineral oil, olive oil or other suitable lubricant and maintained at 37 ± 2°C.

6. Specimen Preparation

6.1 The geometry of the parts must be within the specified tolerance ranges of final production designs.

6.2 The metallic components should follow the complete manufacturing process (machining, surface treatment, laser marking, passivation, cleaning, and so forth) until the sterilization stage. Because sterilization has no known effect on the mechanical properties for metallic components, it is not necessary for these to be sterilized. The polymeric components should be sterilized in a manner consistent with the clinical use for such devices, as this may affect the mechanical properties of the material.

6.3 The ultra-high molecular weight polyethylene (UHMWPE) components should be artificially aged according to Practice F2003, except when the mechanical properties of the UHMWPE have been proven not to be detrimentally affected by the aging,

6.4 Because the cold flow of the bearing component depends on its thickness, the thinnest bearing component in the knee system should be used.

6.5 The tibial bearing size, including thickness, shall be explicitly specified and reported, with a rationale of why it was chosen. It is good practice to also explicitly specify and report the sizes and rationale of all other components of the implant specimens used.

7. Procedure

7.1 Rigidly mount the femoral component at the maximum flexion angle of the knee as determined in Specification F2083 to the compressive force axis. The femoral component should contact the mobile bearing component at the bearing axis to allow rotation about the neutral point.

NOTE 1—Although in high flexion the femoral component is more posterior on the bearing, such a position would make it difficult to rotate the bearing around the neutral point.

7.2 The tibial base plate articulating surface (or the flat portion thereof) should be mounted perpendicular to the compressive force axis.

7.3 Mounting of the tibial base plate should not interfere with tibiofemoral rotation.

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

7.4 Either the femoral component or the tibial base plate component may be articulated, based upon the mechanical testing equipment capabilities.

7.5 Place the components in the testing system in zero degrees rotational alignment, add lubricant, apply the axial force, and commence cyclic rotational motions.

7.6 Apply the 2000 N force and maintain it within ±2 %.

7.7 Apply a torque of 14 N-m to force the bearing against the rotational stop. Complete the cycle by decreasing the torque to less than 3 % of the peak torque (0.42 N-m). Peak torque should be maintained within ±3 %. The torque is applied around the neutral point of the mobile bearing component on the tibial base plate. In general, the neutral point should be obvious from the design of the system. If the choice of the rotational axis used in the test is not the neutral point, the choice of the rotational axis should be justified.

7.8 *Test Length*—Due to the high force and large flexion angle deep squatting scenario simulated by this testing protocol, 220 000 cycles shall be used to determine mechanical performance. The number of force cycles should reflect an anticipated implant lifetime of 20 years, unless the device has an alternate expected lifetime. This number of cycles represents approximately thirty deep squatting occurrences per day for 20 years.

7.9 Continue the test until one of the following events occurs:

7.9.1 The bearing component fractures or disassociates.

7.9.2 The testing machine fails to maintain the specified control range.

7.9.3 The 220 000 cycles test duration is achieved.

8. Reporting Results

8.1 The test report shall include the following information:

8.1.1 Bearing component size, tibial baseplate size, and femoral component size.

8.1.2 Bearing component thickness.

8.1.3 Bearing component material information.

8.1.4 Test frequency.

8.1.5 For samples that do not survive 220 000 cycles, the number of cycles completed prior to failure or incipient failure.

8.1.6 All samples should be photographed and the physical condition of the samples noted at the end of the test.

8.1.7 All samples deemed to not have survived the test should have a descriptive failure mode. Detailed examples include: delamination, disassociation from metal backing, fractures, excessive creep resulting in loss of polymeric material articulation, and erratic motion behavior inconsistent with normal physiological motion.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 Limited testing has been performed on mobile-bearing knees where insert damage of the rotational stop was the focus of attention. Multi-gait testing has been conducted on AMTI wear simulators where implants were subjected to four gait cycles (walking, chair descent and rise, stair climbing, and deep squatting) (**2**). The femoral flexion/extension, rotation, anterior/posterior position and tibial internal/external rotations for the deep squat activity were extracted from a gait laboratory subject who performed a double leg rise deep squatting activity (**3**). The damage and deformation of the inserts was observed and examined on an overall basis, resulting from the combination of the four gait cycles, but not from any specific activity. The insert specimens were examined for changes in insert/tray motion and dimensions using an optical microscope, backlighting, and dimensional inspection.

X1.2 The rotation/translation stop features were also examined at the completion of testing where approximately 125 000 deep squat cycles were implemented and showed evidence of slight deformation but no gross damage or failure. Numerous papers have recently been published looking at axial rotation for normal healthy knees, ACL-deficient knees, and total arthroplasty patients and have generally found that maximum tibial axial rotations are reduced for ACL-deficient and TKA patients versus normal intact knees (**4-8**). These studies suggest most patients and activities for mobile bearing ACL-deficient applications require less than 20° of axial rotation and validate the decision to not test for devices that allow more than 20° of rotation. Only during deep squatting activities do internal tibial rotations approach or exceed 20° of rotation. Other recently published studies have specifically focused on the amount of axial rotation that occurs at the superior tibiofemoral insert surface and the inferior insert surface (base plate to insert interface) for mobile bearing total knee applications (**9-14**). Results from these studies suggest that internal rotation of the tibial insert relative to the baseplate is small when compared to the overall rotation of the tibiofemoral interface.

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