Designation: F3143 – 20

Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Replacement Bearings under Standard Conditions Using a Reciprocal Friction Simulator[1]

This standard is issued under the fixed designation F3143; 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 procedure provides a method of determining the frictional torque and friction factor of artificial hip joint bearings used in total hip replacement (THR) systems under laboratory conditions using a reciprocal friction simulator. This test method specifies the angular movement between the articulating components, the pattern of applied force, and the way data can be measured and analyzed.

1.2 Many variables can be investigated using this test method including, but not limited to, the effect of head size, different inclination/version angles, different deformation levels of the acetabular cup, bearing clearances, lubrication, scratched heads, and artificial ageing.

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

1.4 *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.*

1.5 *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]

E4 Practices for Force Verification of Testing Machines

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

2.2 *Other Standards:*[3]

ISO 14242-1 Implants for Surgery—Wear of total hip-joint prostheses, Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test

ISO 14242-2 Implants for Surgery—Wear of total hip-joint prostheses, Part 2: Methods of measurement

ISO 14242-3 Implants for Surgery—Wear of total hip-joint prostheses, Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test

3. Terminology

3.1 *Definitions:*

3.1.1 *friction, n*—the resisting force tangential to the common boundary between two bodies when, under the action of an external force, one body moves or tends to move relative to the surface of the other.

3.1.2 *friction factor, n—in the spherical portions of articular surfaces*, friction factor is defined as an effective (nominal) frictional coefficient, equal to the overall total tangential frictional forces on the hip divided by the overall compressive force on the hip.

3.1.3 *frictional torque, n*—in the case of spherical portions of articular surfaces such as those of a THR, the actual frictional force at any instant varies at different locations on the surfaces. The overall friction can be conveniently characterized as a frictional torque, which represents the overall tangential forces on the bearing surface multiplied by a nominal radius of the spherical articulating surfaces.

[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 Oct. 1, 2020. Published November 2020. DOI: 10.1520/F3143-20.

[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] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.1.4 *overall tangential force, n*—total of all tangential forces on the hip surface equal to the overall frictional torque divided by the nominal radius of the articular surfaces of the THR system.

4. Summary of Test Method

4.1 The total frictional torque under dynamic simulated loading and angular motion regime is determined by using a force transducer and a friction simulator with a low friction bearing with a coefficient of friction less than 0.001 such as a hydrostatic or pneumatic bearing.

4.2 The input profile is a simplified loading cycle and angular motion of the head with respect to the cup.

4.3 Calf serum is used as the base lubricant.

4.4 The frictional torque is determined at the highest force and highest velocity part of the testing cycle.

4.5 The friction factor, f, is calculated using the following equation: $f=\frac{T}{rL}$ where T is the total frictional torque determined, r is the radius of the femoral head, and L is the applied force.

5. Significance and Use

5.1 This test procedure provides a method of evaluating the frictional torque and friction factor of hip replacement bearings.

5.2 The procedure may be used as a standardized method of measuring friction to investigate the effects of specific test parameters such as hip materials, sizes, designs, radial or diametral clearance, different lubricants, different deformation levels of the acetabular cup, clamping (non-uniform sphericity), damaged/scratched bearings, artificial ageing, misalignments during installation, etc.

5.3 Friction torque, and in particular the maximum value, is useful to assess the applicable torques that may compromise fixation, or even risk disassociation of modular components in the acetabular cup or liner/shell assemblies through a lever-out or torsion-out mechanism.

5.4 Friction factor is a useful parameter for comparison of materials and designs, and provides insights into the lubrication regime operating in the implant system. Friction factor measurement may also be able to detect acetabular liner deformation (clamping referred to earlier).

5.5 The loading and motion of a hip replacement *in vivo* differ from the loading and the motion defined in this standard. The amount of frictional forces *in vivo* will, in general, differ from the frictional forces evaluated by this standard test method. The results obtained from this test method cannot be used to directly predict *in vivo* performance. However, this standard is designed to allow for *in-vitro* comparisons for different hip designs, when tested under similar conditions.

5.6 Although this test method can be used to investigate the many variables listed in 1.2 and 5.2, it does not either provide a method to determine beforehand the combination of these variables that will produce the worst-case couple(s) among a range of sizes; the worst-case testing condition(s) for "normal" or "adverse" conditions; or provide specific methods to deform the acetabular cup, simulate Mode 3 wear conditions (for example, third-body particles, scratched heads), or artificially aged materials. As these methods are not included in the standard and if they are to become the subject of the investigation then it is up to the user to justify the couple(s) selected and method(s) used in the test and, if necessary, provide a rationale for how the "worst-case" couple(s) and method(s) were selected to represent clinically relevant "normal" and "adverse" conditions as part of the report.

6. Confounding Variables

6.1 The natural deterioration of the machine can affect the results. Therefore accurate calibration and verification of the equipment used shall be carried out on regular basis to ensure that the measured and the applied forces are correct, repeatable, and reliable.

6.2 Deterioration of the low-friction bearing or oil within the hydrostatic bearing, if used, can lead to generation of friction that can affect the frictional torque of the hip bearing being measured.

6.3 Incorrect fixturing and alignment of the test samples such as the center of the acetabular cup not being concentric with the center of angular rotations of the test machine may result in incorrect friction values and errors in calculating the frictional torque and friction factor.

7. Apparatus

7.1 Testing machine (Fig. 1) capable of producing an angular displacement of ±25° (Fig. 2) and applying a dynamic axial force of a range of 300 N to 2000 N (Fig. 3) while operating at a frequency of 1 Hz.

7.2 Means of aligning and positioning the femoral head so that its center is situated at the center of the axes of rotation of the test machine and so that the same position and orientation may be reproduced following removal for measurement or cleaning if required.

7.3 Means of aligning and positioning the acetabular cup so that its center is situated at the center of the axes of rotation of the test machine and so that the same position and orientation may be reproduced following removal for measurement or cleaning if required.

7.4 Motion control system capable of generating the angular movement of the femoral component given in Fig. 2 with an accuracy of ±3° at the maxima and minima of the motion and ±1 % of the cycle time for phasing.

7.5 Force control system capable of generating a dynamic force and maintaining the magnitude of the maxima of this force cycle to a tolerance of ±5 % of the force value for the cycle and ±5 % of the cycle time for phasing.

7.6 The loading frame should be free to move in the vertical axis allowing the vertical force to be transmitted freely through the center of the femoral head.

7.7 Low friction bearings (machine bearings) capable of providing a low-friction environment under the testing conditions.

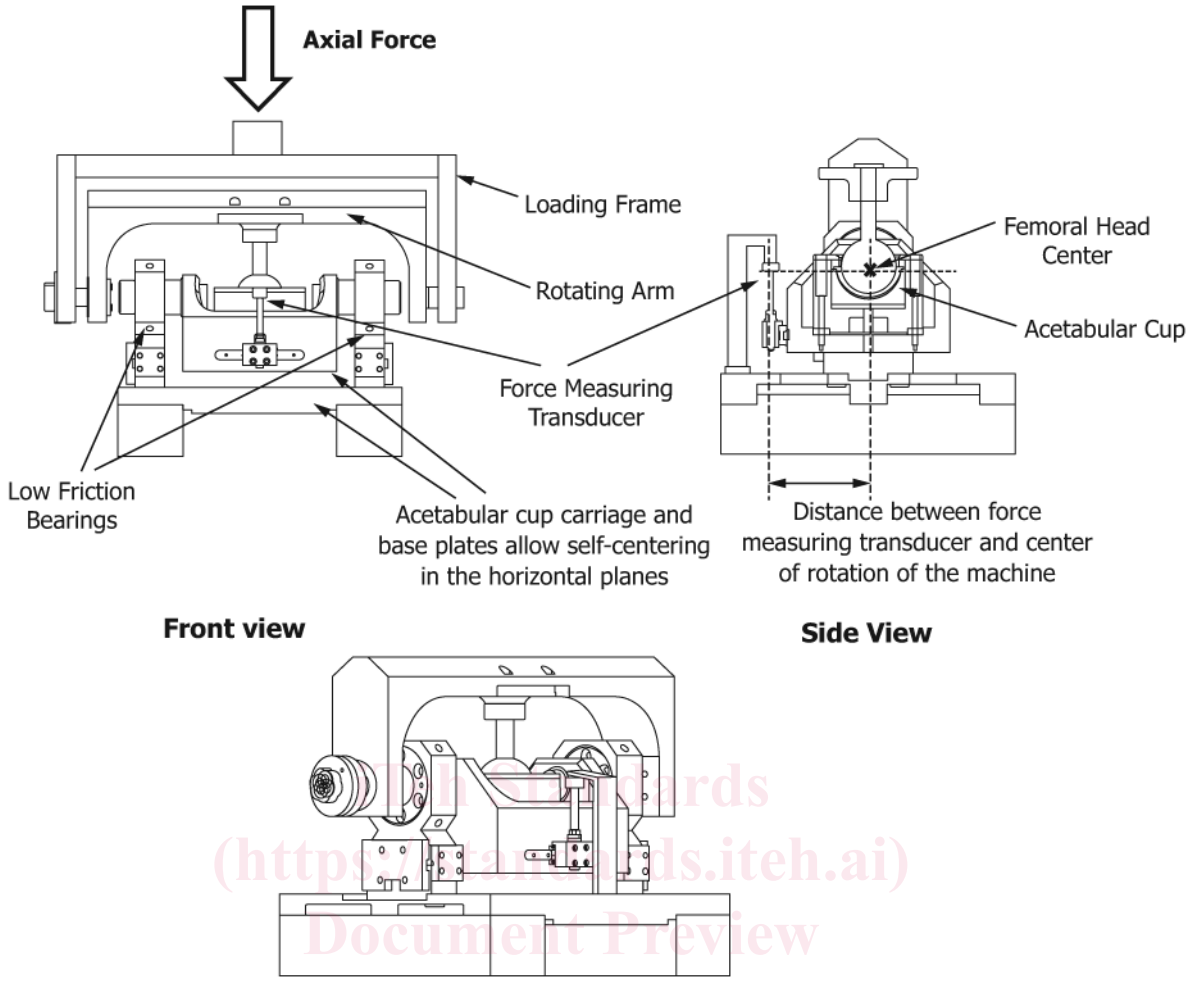

FIG. 1 Conceptual Drawing of a Friction Simulator

7.8 A high sensitivity force sensor connected to the front of friction carriage that can detect the torques within the system by measuring the forces transferred between the fixed frame and the carriage. The force sensor should not constrain the cup translation that allows self-centering. The high sensitivity force sensor should have a range of 200 N (if positioned 100 mm away from center of the machine) with a standard combined error not larger than 1 %.

7.9 Low-friction self-aligning feature for unrestrained motion of the cup in the horizontal plane.

8. Reagents and Materials

8.1 *The Fluid Test Medium*—Fluid test medium shall be as per ISO 14242-1 or ISO 14242-3. Other test fluids may be selected if justified. To minimize microbial contamination, the biological fluid test medium should be stored frozen until required for the test.

8.2 *Test Specimen, Femoral Head, and Acetabular Components*—The test specimens should be fixed in the test cell without causing any unintentional deformation of the bearing surfaces. The test specimens may be partially finished provided that the internal materials, finish, locking mechanism, and geometry are identical to the actual specimens.

8.3 *Control Specimen*—It is recommended that two similar control-bearing couples be kept with the test rig and the friction factor determined on both the control samples (avoid using metal-on-metal bearings). Thereafter, only one of the control samples should be used on a regular basis to make sure that the measuring equipment is producing consistent results and any deviation in the friction factor due to machine deterioration can be detected. Note that the long-term use of control samples can cause wear and roughening or smoothing of the surface, producing higher or lower friction factors than were obtained when they were new. The second control specimen should then

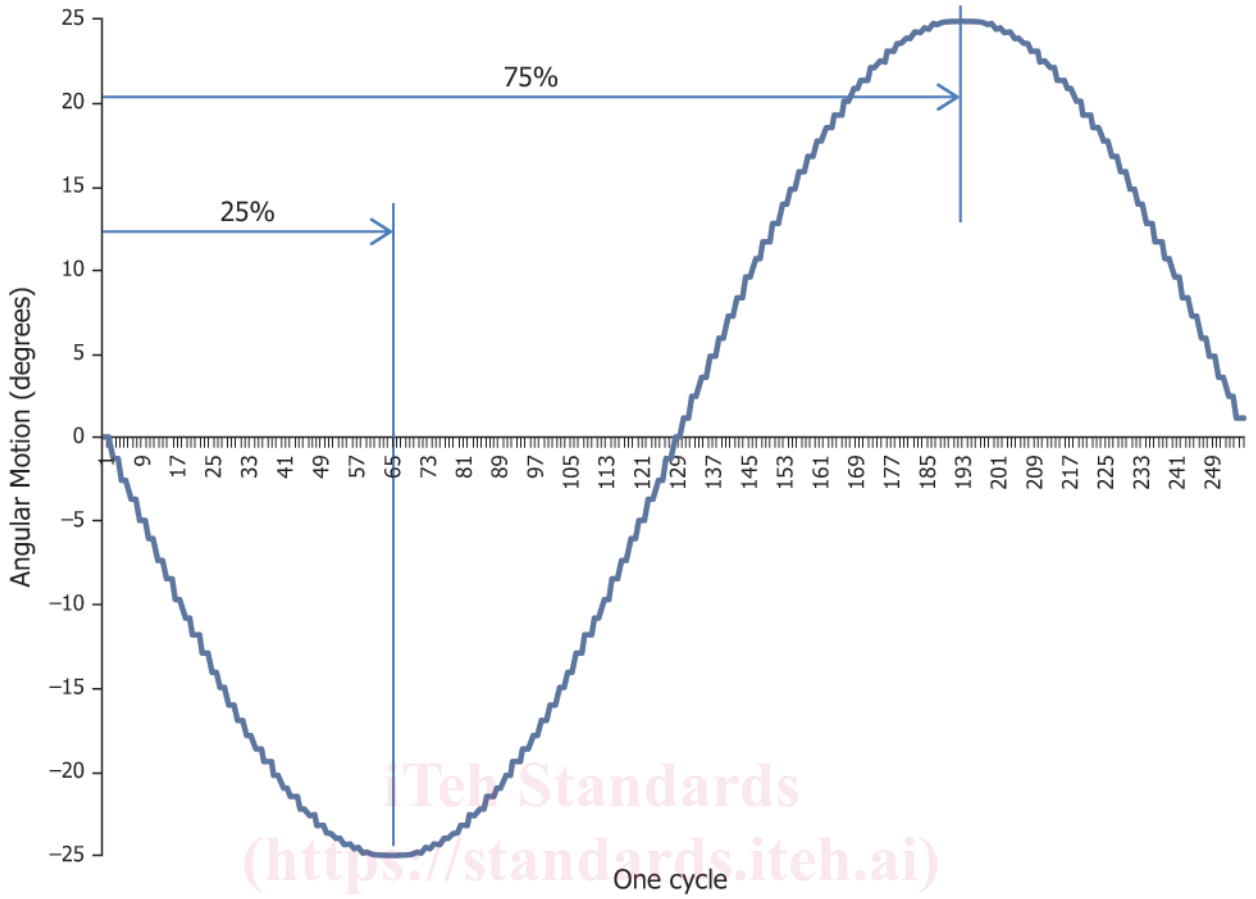

FIG. 2 Angular Rotation Input on the Friction Simulator

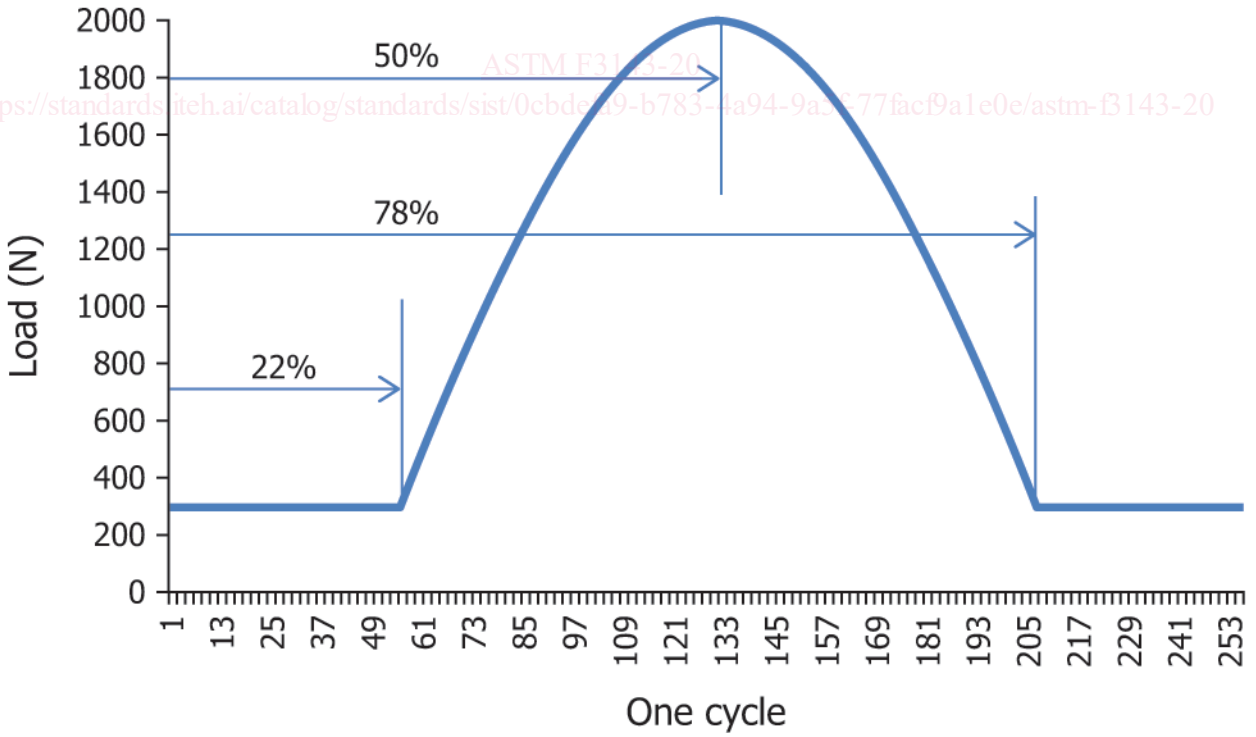

FIG. 3 Force Profile Input on the Friction Simulator

be used for comparison when a new control sample is required. The new control sample then replaces the control specimen that has only been used once. This removes the drift in machine performance that could be seen between the production and test of the control samples.

9. Hazards

9.1 Appropriate personal protective equipment should be used at all times during the operation of the machine.

9.2 Testing results in application of high forces and rapid motion of test parts. Appropriate safeguards should be taken to prevent fingers or other body parts becoming trapped in the test machine.

9.3 The calf serum is considered a biohazard and should be used with care and disposed of responsibly.

10. Sampling, Test Specimens, and Test Units

10.1 The acetabular component shall have the articulating surface attached by its normal immediate backing (for example, bone cement or a machined replica of the inner surface of the backing) unless this is impractical due to physical features of the implant system. If the component forming the articulating surface is fixed to the backing by a rim/snap-fit system, the machined replica shall provide similar fixation conditions.

10.2 The calculation of minimum number of specimens required per testing condition shall follow Practice E122.

11. Preparation of Apparatus and Test

11.1 The governing rule for specimen preparation is that the fabrication process parallels that used or intended for use in the production of actual prostheses, in order to produce a specimen with comparable bulk material properties and surface characteristics (see Practice F86). However, there may be situations where it is desirable to investigate the effects of a specific test parameter, in which case test specimens may be produced with appropriately modified features. For example, the effects of head roughening on friction may be studied by intentionally producing head specimens with artificially roughened articular surfaces.

11.2 Sterilize the specimens in a manner typical of that in clinical use for such devices unless it can be proven that this has no effect on friction properties. Report sterilization processing parameters prior to each test, if known. Sterilization of all test and control specimens within a specific test group should be done simultaneously (ideally in a single container), when possible, to minimize variation among the specimens.

11.3 The femoral head and acetabular cup pairs may be chosen at random, or based on other features such as radial clearance. The rationale for the pairings should be included in the test report.

11.4 It is recommended that a control sample be tested before and after determining the friction on the test specimens, making sure that the friction factor of the control sample has not changed.

11.5 The position of the center of the cup versus the force sensor (see 7.8) shall be known within ±0.2 mm. The position of the femoral head in respect to the machine axis is not as critical; however, larger offsets shall be avoided as they result in greater motion of the cup in the horizontal plane.

11.6 It is advisable to have alignment marks on the test specimens in case it is necessary to repeat the test.

12. Calibration and Standardization

12.1 Accurate calibration and verification of the equipment used shall be carried out on a regular basis to ensure that the measured and the applied forces are correct, repeatable, and reliable.

12.2 The replacement control sample(s) should be validated against a previous control sample as described in 8.3.

13. Procedure

13.1 It is recommended that the samples are preconditioned as per ISO 14242-2.

13.2 It is recommended that the test components be cleaned thoroughly and that alignment marks be engraved prior to the start of the test. If engraving alignment marks are used, then care should be taken to avoid damage to the bearing surfaces. It should be noted that cleaning may affect the measured friction factor.

13.3 It is recommended that the roughness on the bearing surfaces of the femoral head and acetabular cup or liner be measured prior to the start of the test and included in the report to facilitate comparisons.

13.4 It is recommended that the clearance of the bearing couple be determined and included in the report to facilitate comparisons.

13.5 Mount the acetabular cup in a cup holder in such a way that the center of rotation of the acetabular cup matches the center of rotation of the friction simulator.

13.6 Make sure that the fixation method used causes minimum deformation of the acetabular cup unless this is the purpose of the investigation. The fixation method should not deform the inner acetabular cup surface by more than 50 microns for a polyethylene liner and more than 10 microns for a ceramic or a metal liner. Mount the femoral head on the head holder.

13.7 Mount both the cup holder (containing the acetabular cup) and the head holder (with the head attached) on the machine.

13.8 When mounting the test components in the simulator, it may be necessary to consider the contact area between the components, especially if they have been subject to wear in a wear simulator.

13.9 Add the lubricant, heated to 37 ± 2 °C, making sure that the contact area between the head and the cup is fully immersed. If possible, the lubricant temperature should be maintained at 37 ± 2 °C.

13.10 Start the equipment and the measuring transducer.