



Designation: F3446 – 20

Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Implants Using an Anatomical Motion Hip Simulator¹

This standard is issued under the fixed designation F3446; 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 evaluating the frictional torque and friction factor of artificial hip joint bearings used in Total Hip Replacement systems. The method presented here was based on a published study, first as a conference paper in 2008 (1)² and then as a peer-reviewed journal paper (2). The method is compatible with and is capable of being carried out during actual wear testing of total hip replacement implants on wear simulators equipped with multiple degrees of freedom force and moment sensors.

1.2 Although the methodology described does not replicate all physiological loading conditions, it is a means of *in-vitro* comparison of the frictional torque and friction factor of artificial hip joint bearings used in Total Hip Replacement systems under the stated test conditions.

1.3 *Units*—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.*

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

2. Referenced Documents

2.1 ASTM Standards:³

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F732 Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses

F2025 Practice for Gravimetric Measurement of Polymeric Components for Wear Assessment

G40 Terminology Relating to Wear and Erosion

2.2 ISO Standards:⁴

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 4287 Surface Texture: Profile Method—Terms, Definitions and Surface Texture Parameters

ISO 4288 Surface Texture: Profile Method—Rules and Procedures for the Assessment of Surface Texture

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 coefficient, n*—usually, friction force divided by the applied compressive load.

3.1.3 *friction factor, n*—in the spherical portions of articular surfaces, this factor is defined here for use as an effective frictional coefficient, equal to the overall total tangential

³ 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.

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

frictional forces on the hip femoral head component divided by the overall compressive load on that hip component.

3.1.4 *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 of the surfaces. The overall friction can be conveniently characterized as a frictional torque, which represents the overall tangential forces on all of the femoral head component surface multiplied by a nominal radius of that spherical articulating surface.

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

3.1.6 *THR system, n —total hip replacement implant system*, typically comprising a femoral stem, femoral head, and either a bearing liner and an acetabular shell, or a one-piece acetabular cup.

3.2 For definitions relating to erosion and wear, refer to Terminology G40.

4. Principle and Summary of the Test Method

4.1 The femoral and acetabular components of a test specimen are placed in position in their normal configuration simulating a THR system used *in vivo*.

4.2 The test apparatus, of which a schematic example is shown in Fig. 1(a), transmits a specified time-varying compressive force between the components, together with specified relative angular displacements to simulate a physiological activity such as walking as simulated in ISO 14242-1.

4.3 All forces and moments (see Fig. 1) on the specimens are measured by one (six degrees of freedom) or multiple load cells capable of measuring: (1) axial force along the femoral (z) axis, F_z ; (2) moment about the z -axis, M_z ; (3 and 4) forces along orthogonal axes, F_x and F_y ; (5 and 6) moments about orthogonal axes, M_x and M_y . The nature of these forces and moments and how they interact are described in (2).

4.4 By conducting vertical and horizontal linear force equilibrium as well as moment equilibrium on a free-body diagram (FBD) that includes all significant net forces and moments, calculation of the frictional torque and friction factor is achieved, as described in detail in (2).

5. Significance and Use

5.1 This test procedure provides a method of evaluating the frictional torque and friction factor of artificial hip joint bearings under the stated *in-vitro* test conditions.

5.2 Friction is not simply a materials property. The specimen system and the effects on its friction are multi-factorial, including the materials and processing of the components, the design and assembly of the components, the test parameters, and environmental factors (lubricant, temperature, etc.).

5.3 The procedure may be used as a standardized method of measuring friction for a particular system, or as a method of investigating the effects of specific test parameters such as hip

sizes, designs, radial clearance, different lubricants, clamping (nonuniform sphericity), misalignments during installation, etc.

5.4 The procedure may be used to study the variation of friction with time as the specimens wear, which is particularly useful for samples that undergo a transition from “run-in” to “steady-state” wear behavior. Since the motion and load waveforms are identical to those specified in ISO 14242-1:2014, standardized friction and wear measurements may be combined and viewed in the correct perspective where they affect each other.

5.5 Frictional torque, and in particular the maximum value, are useful to assess the torques that may compromise fixation, or cause disassociation of modular components in acetabular cup or liner/shell assemblies through a lever-out or torsion-out mechanism.

5.6 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).

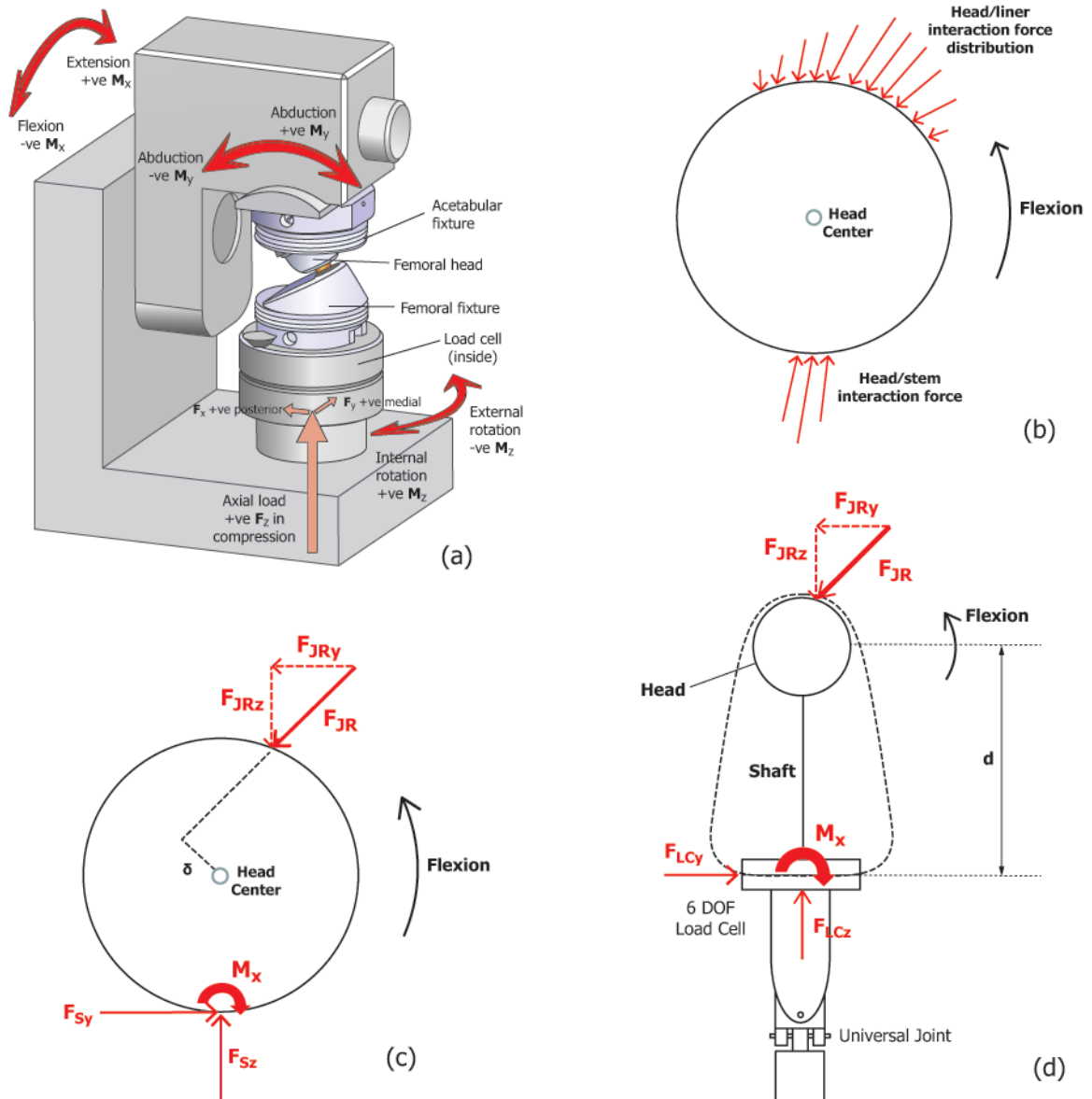
6. Interferences

6.1 Incorrect fixturing and alignment of the test samples, such as the center of the femoral head not being concentric with the centers of angular rotations of the test machine, will not affect the analysis or results when using the simulator and load cell configuration shown in Fig. 1(a) (full analysis was published in (2)). However, if the femoral head is not centered with the load cell system axis to within 0.25 mm, it may result in exaggerated or attenuated friction values and errors in calculating the frictional torque reaching over 0.75 Nm. The effects of such misalignment were also analyzed (2) and some estimates as the above were provided for its effects and simple ways to check and correct for it were also described. One way to reduce (for example, halve) such errors is to center the femoral head more closely to the load cell center, to within 0.13 mm. In this example, the 130 μ m alignment accuracy is very practical and even more alignment accuracy for two rigidly fastened mechanical components can be targeted.

7. Apparatus

7.1 Testing machine, capable of producing the relative angular displacements and corresponding forces as shown schematically in Fig. 1(a) and based on the wear test procedure ISO 14242-1, operating at a frequency of 1.0 ± 0.1 Hz. The flexion/extension, abduction/adduction, and internal/external rotations may be applied to either the acetabular cup or the femoral head in order to create the relative rotations shown in Fig. 1(a).

7.2 Means of mounting and enclosing the test specimen, using a corrosion-resistant material, capable of holding the femoral and acetabular components using attachment methods comparable to the intended anatomical fixation. An enclosure which is capable of isolating the test specimen to prevent third-body contamination from the test machine and the atmosphere shall be provided. When mounting two hip



- (a) Schematic of the test setup configuration for the analysis in (2).
 (b) Schematic depicting the force and stress distribution on the femoral head in the y-z plane.
 (c) Resultant forces and moments on the femoral head.
 (d) Free-body diagram in the y-z plane around the femoral assembly including the 6-DOF load cell upon which the analysis in (2) was based.

FIG. 1 Schematic Configuration of the Test Setup

designs or materials or sizes, the same type, material, and size of the enclosure seal (for example, section of an intravenous (IV) bag) should be used.

NOTE 1—An enclosure seal, such as a section of a compliant IV bag, sealed at its ends using seamless hose clips, is often used to contain the lubricant attached to the femoral component and the acetabular component fixture assemblies. However flexible, the resistance to deform the enclosure seal would be confounded with the friction from the articular surface contact. To minimize this error, the stiffness of the enclosure seal should be minimized to add least to the friction, and the enclosure seal type should not be changed when comparing two hip test specimens.

7.3 Means of aligning and positioning the acetabular component of the test specimen, so that its spherical center is

situated at the center of the axes of rotation of the test machine. The same position and orientation may be reproduced following removal for measurement or cleaning, if required.

7.4 Means of aligning and positioning the femoral component of the test specimen so that its spherical center lies along the z-axis of the machine which should pass through the center of the force-sensing system of single or multiple load cells. Aligned thus, the assembly of the femoral head and the load cells should be rigid and able to be fully seated in contact with the acetabular component. The same position and orientation may be reproduced following removal for measurement or