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Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Implants Using an Anatomical Motion Hip Simulator[1]

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.*

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

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

[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).

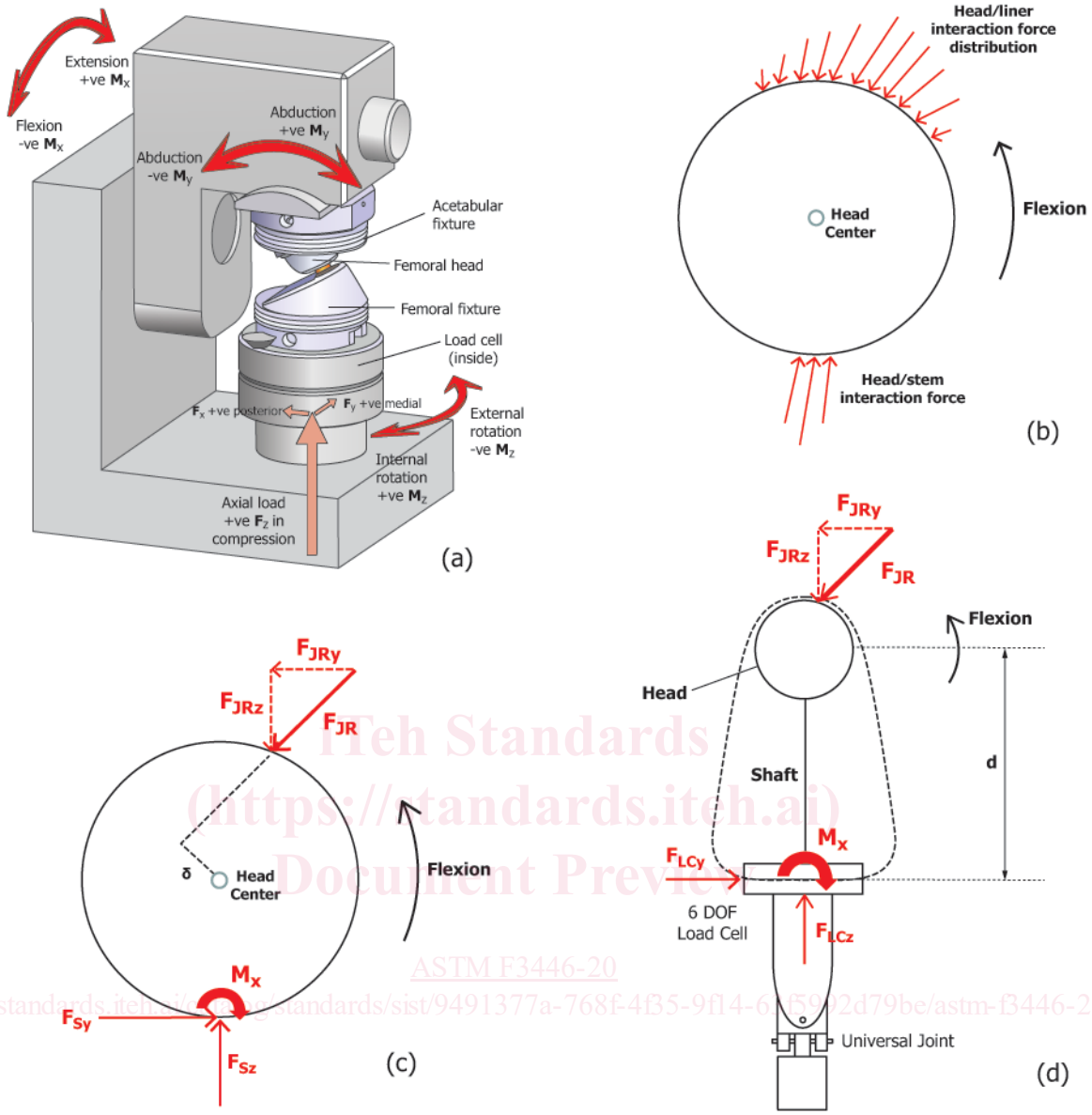
6. Interferences

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 µm 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 comparing 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

cleaning, if required. The importance of this alignment and estimates of errors resulting from misalignments in the configuration shown in Fig. 1(a) were described in a published study (**2**).

NOTE 2—Other simulator machine configurations where the load cell is positioned on the acetabular side will require accurate alignment of the femoral head and need similar assessment.

NOTE 3—Any self-aligning mechanisms utilized in the above (7.3 or 7.4) need to be verified to be frictionless unless they are outside the hip specimen/load-cell assembly, as they may introduce errors in the frictional forces and moments measured. For example, the universal joint used for self-alignment shown in Fig. 1(d) is below the 6-degree of freedom load cell, and so its friction (if any) does not introduce errors in the measurements or the analysis (**2**). Different configurations from that shown in Fig. 1(a) and (d) should be given similar considerations with regard to such potential errors.

7.5 Motion and force control system, capable of generating and measuring the compressive axial force and relative rotations based on ISO 14242-1 and measuring the forces and torques described in the publication (**2**) with a 6-degree of freedom load cell.

NOTE 4—Multiple degrees of freedom load cells can exhibit "cross-talk" where a force or moment in one axis can cause an artifact of extra measured force or moment in another axis. Optionally, one could consider estimating such error effects by applying an axial compressive force (for example, 3kN) at the neutral alignment of the hip system (flexion-extension angle = 0°, abduction-adduction angle = 0°, and internal-external angle = 0°) while measuring all the resulting forces (F_x, F_y) and torques (M_x, M_y, M_z). These (unintended) forces and torques resulting from "cross-talk" and/or some implant misalignment can be processed to estimate potential frictional errors.

7.6 Lubrication system, capable of maintaining the contact surfaces immersed in the fluid test medium. The use of sealed enclosures may reduce or prevent evaporation.

7.7 Temperature control system, capable of maintaining the temperature of the fluid test medium at 37 ± 2 °C.

8. Fluid Test Medium (Lubricant)

8.1 The fluid test medium shall be the same as what is specified in ISO 14242-1. To minimize microbial contamination, the fluid test medium shall be stored frozen until required for testing. An antimicrobial reagent (such as sodium azide) can be added. A complete description of the lubricating solution, dilution, and protein concentration should be included in the test report. **Warning—**Antimicrobial reagents are potentially hazardous.

9. Hazards

9.1 Antimicrobial reagents (such as sodium azide) are potentially hazardous.

9.2 Testing results in application of high loads and rapid motion of test parts. Appropriate safeguards should be taken to prevent fingers or other body parts becoming trapped in the test machine, and use of safety glasses is highly advisable.

10. Sampling, Test Specimens, and Test Units

10.1 *Femoral Head and Acetabular Component Test Specimens:*

10.1.1 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 the same fixation conditions. If it is not practical to use the normal backing or cement fixation due to physical features of the implant system, the support system for the acetabular component should represent normal design features and conditions of use but should preferably allow removal of the component for cleaning or measurement of wear without destruction.

10.2 Femoral heads should be mounted on test spigots having the same materials, dimensions, and surface finishes as the stem tapers they are designed to mate with. The spigot should mount the femoral head such that its center is located as prescribed in 7.3 and 7.4.

11. Test Preparation

11.1 *Specimen Preparation:*

11.1.1 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 desired 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.

NOTE 5—Pre-test and post-test measurements of surface roughness can optionally be made for all femoral heads and acetabular cups such as: spherical radius, maximum peak-to-valley deviation from sphericity, and surface finish (R_a, R_q, and R_{sk}). Definitions of these parameters are given in ISO 4287 and measurement procedures in ISO 4288.

11.1.2 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.

11.2 *Sterilization:*

11.2.1 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 *Specimen Marking:*

11.3.1 If it is necessary to remove the test specimens during the test (for example, for cleaning or wear measurements), then reference marks should be made on a non-articulating surface of each specimen and on the fixtures, if required. Optionally, manufacturing features such as engraved lot numbers may be used instead of reference marks, but the orientation of each specimen relative to the test fixtures should be recorded and maintained upon reassembly.

11.4 *Specimen Cleaning:*

11.4.1 Prior to friction testing, careful cleaning of the specimens is important to remove any contaminants that would not normally be present on an actual prosthesis. During the test, the specimens may need to be re-cleaned and dried before each wear measurement (if made) or it may be desirable to clean the components at each lubricant change in order to minimize microbial growth. The required procedure for cleaning and drying of polymeric specimens is defined in Practice F2025.

12. Conditioning

12.1 Polymeric and polymer composite specimens should be pre-soaked in deionized water or wear test lubricant to minimize fluid sorption during the friction test. Without pre-soaking, specimens made from very low-wear polymers such as ultra-high molecular weight polyethylene (UHMWPE) could show a net increase in weight or volume during the initial portion of the test due to fluid sorption. There may be an effect of this on friction which is not yet known.

12.2 No attempt should be made to "run the parts in" prior to the test. Rather, friction should be measured at periodic intervals in order to determine how friction changes as the parts "run in."

13. Procedure

13.1 If wear is to be measured during the test, make any initial measurements required to determine the subsequent amount of wear of the specimens (see ISO 14242-2 for the gravimetric measurement method for polymeric materials).

13.2 Place the specimens in their test chambers, add the lubricating fluid, and ensure that all the articulating surfaces are fully immersed.

13.3 Activate on each station the loads and motions of ISO 14242-1.

13.4 The first measurement of forces and moments shall be made within 1000 cycles of the start of the test. The six degrees of freedom (DOF) load cell or similar sensor(s) on each test station shall be used to measure: (*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. These forces and moments are to be logged along with or against a time stamp that corresponds with the input kinematics of flexion angle, abduction-adduction angle, and internal-external angle. On each station, all force and moment measurements should be made either simultaneously from all stations or in a sequence, one test station at a time, for a duration of five test cycles. It is important, however, that all the variables/signals from a given test station are logged at the same time.

13.5 Make a note of any evidence of audible noise (such as squeaking) coming from the samples.

13.6 Make force/moment measurement at the desired intervals (see 13.9).

13.7 In the event of fluid loss by evaporation, de-ionized water should be added to maintain a constant fluid volume throughout the test.

13.8 Optionally, lubricating fluid may be changed at regular intervals in order to minimize microbial activity. If the test specimens are removed for cleaning or wear measurements, care should be taken to re-install them in the same orientation each time.

13.9 The appropriate test duration depends on the objective of the specific test, the duration of run-in effects, and the potential for transitions in friction/wear mechanism. It is recommended that the testing (number of test cycles) be continued until calculated frictional torques and friction factors have stabilized such that no monotonic trends of increasing friction remain evident. The total testing period can vary depending on the purpose of the test, and can last up to the total duration (for example, 5 million cycles) of a whole wear test. The first measurement should be made within 1000 cycles of the start of the testing and frictional measurements should be logged at least every 100 000 cycle interval. Friction measurements may be combined with wear measurements (for example, ISO 14242-1) during the same test in order to provide a more complete picture of the tribological behavior of the specimens.

14. Calculation and Interpretation of Results

14.1 In general, the method aims to estimate the frictional torque about the hip system femoral head component. It requires measurement of an orthogonal set of forces and moments on at least three of each type (for example, design, material, and size combination) of specimens tested. By conducting vertical and horizontal linear force equilibria as well as moment equilibria on a free-body diagram (FBD) which encompasses the specimen and the load cell, estimates of the frictional torque (about the hip system femoral head component) and friction factor may be calculated. Example derivations of expressions for frictional torque and friction factor with an example hip specimen and load cell configuration are provided in (**2**) for a given anatomical mounting setup. In the example provided, the acetabular cup is superior and the femoral head is inferior. The flexion/extension and abduction/adduction rotations are applied to the cup, and the internal/external rotations are applied to the head. The compressive load is applied from below to the femoral head component and the load cell is mounted on the load actuator and internal-external rotation shaft.

14.2 Force/torque measurements shall be made continuously or at discrete intervals during the test. The overall frictional torque and friction factor shall be calculated as a function of time over five consecutive loading cycles. For each force/moment measurement, at least 100 data points per loading cycle should be acquired and processed. The five waveforms cycles for overall frictional torque and friction factor should be plotted as a function of time without any signal filtering (for example, Figs. 2 and 3).

14.3 The calculated friction factor is often found to be relatively high and unstable over the swing phase portion of the cycle (for example, Fig. 3), where the applied load is small, thus the friction factors can be spuriously elevated due to amplified experimental errors resulting from dividing by small