Designation: F2582 – 20

# Standard Test Method for Dynamic Impingement Between Femoral and Acetabular Hip Components[1]

This standard is issued under the fixed designation F2582; 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 covers a procedure to simulate dynamic impingement between femoral and acetabular components in a hip replacement; the subsequent qualitative assessment of damage modes (as outlined in 8.2); and, if necessary, quantitative assessment of changes in modular component attachment strength.

1.2 This test method can be used to evaluate impingement between femoral components and the following: single-piece, modular, semi-constrained, bipolar, constrained, or dual mobility acetabular components, manufactured from polymeric, metallic, or ceramic materials.

1.3 The values stated in SI units are regarded as the 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

F1820 Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices

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

F2009 Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses

F2033 Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials

F2091 Specification for Acetabular Prostheses

2.2 *ISO Standards:*[3]

ISO 7206-1 Implants for Surgery – Partial and Total Hip Joint Prostheses – Part 1: Classification and Designation of Dimensions

ISO 7206-6 Implants for Surgery – Partial and Total Hip Joint Prostheses – Part 6: Endurance Properties Testing and Performance Requirements of Neck Region of Stemmed Femoral Components

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 21535 Non-Active Surgical Implants – Joint Replacement Implants – Specific Requirements for Hip-Joint Replacement Implants

2.3 *FDA Document:*[4]

21 CFR 888.6 Degree of Constraint

## 3. Terminology

3.1 *Definitions:*

3.1.1 *femoral head*—convex spherical bearing member for articulation with the natural acetabulum or prosthetic acetabulum.

3.1.2 *impingement*—the point at which two opposing components collide to restrict motion.

3.1.3 *locking mechanism*—the pieces of various components that contribute to the fixing of one component to another.

[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] 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.

[4] Available from U.S. Food and Drug Administration (FDA), 10903 New Hampshire Ave., Silver Spring, MD 20993, http://www.fda.gov.

3.1.4 *range of motion*—the effective pattern of motion limited by impingement. In one plane this is measured from one impingement point to the opposite impingement point.

3.1.5 The following classification by degree of constraint is suggested for all total joint prostheses, including total hip replacement systems based on the concepts adopted by the U.S. Food and Drug Administration (21 CFR 888.6; see 2.3).

3.1.5.1 *Constrained*—A "constrained" joint prosthesis is used for joint replacement and prevents dislocation of the prosthesis in more than one anatomic plane and consists of either a single, flexible, across-the-joint component or more than one component linked together or affined.

3.1.5.2 *Semi-Constrained*—A "semi-constrained" joint prosthesis is used for joint replacement and limits translation and rotation of the prosthesis in one or more planes via the geometry of its articulating surfaces. It has no across-the-joint linkage.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *compressive load*—the force directed normal to the entry diameter of the acetabular prosthesis (see ISO 7206-1).

## 4. Summary of Test Method

4.1 Femoral and acetabular components are evaluated for fatigue fracture, deformation, delamination, wear, and chipping (ceramic components) under dynamic impingement conditions. Modular acetabular prosthesis designs should be evaluated for additional damage mechanisms affecting any component or locking mechanism. Examples of damage modes for modular acetabular prosthesis designs include dissociation and loosening of any component or locking mechanism, or both.

4.2 This test method can be used to evaluate dynamic characteristics. Various joint reaction forces and impingements can be applied in order to simulate known clinical conditions.

## 5. Significance and Use

5.1 This test method should be used to evaluate and compare different femoral and acetabular prosthesis designs to assess the damage tolerance under controlled laboratory conditions.

5.2 Although the methodology described attempts to identify physiologically relevant motions and loading conditions, the interpretation of results is limited to an *in-vitro* comparison between different femoral and acetabular prosthesis designs regarding their ability to resist impingement damage modes (defined in 8.2) under the stated test conditions.

## 6. Apparatus for Impingement

6.1 One axis shall be capable of applying a constant compressive load force for static loading.

6.2 Three motion axes shall be capable of controlling and monitoring angular displacement.

6.3 The equipment may be electromechanical, servohydraulic, or other, as long as it meets the requirements of Practices E4 for force verification.

6.4 The compressive load shall be applied through fixturing that allows for the separation of the acetabular prosthesis from the femoral prosthesis during the impingement test. See Fig. 1 for the test principle. The acetabular prosthesis is allowed to move freely in the horizontal plane but is constrained for rotation around the load axis. For hip simulators that do not meet these requirements, the deviations from the standardized test setup shall be justified.

NOTE 1—For dual mobility components, the mobile component might be fixated by means of a rotational stop to allow for impingement testing.

## 7. Sampling and Test Specimens

7.1 All acetabular and femoral components shall be representative of implant quality products. This shall include any sterilization processes if the sterilization may affect the results.

7.2 Worst-case specimen(s) shall be determined and justified for all conditionally acceptable damage modes (see 8.2). The worst-case specimen(s) may vary by damage mode. Ensure all components in the test are considered, including aspects like head offset, stem geometry, surface finish, and material and acetabular component(s) geometry, surface finish, and material. Deformation and wear of components may occur during testing, and if so, will be continually changing with the potential of accentuated change at the times of component repositioning. In consideration of the unknown geometries, calculation of contact stresses and other stresses in the components (for example, stress in locking mechanism region) that are needed for worst-case analysis should consider the as-manufactured (not deformed) geometry of the components. Consideration of overall worst case for each damage mode should consider how deformation and wear will contribute to

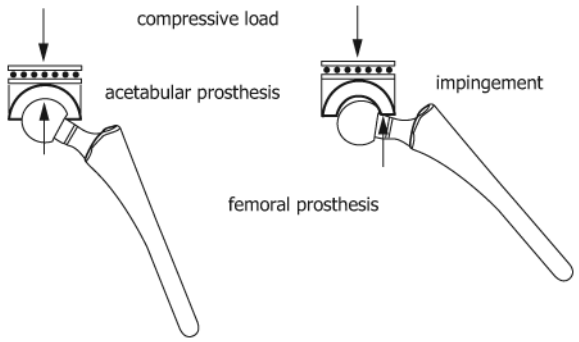


**FIG. 1 Principle of the Test Setup**

overall worst case, and will likely need to be based on evaluation or experience.

NOTE 2—Modeling the neck-rim contact using a Finite Element Method (FEM) to determine maximum stress configuration is one possible technique to support the worst-case analysis.

NOTE 3—Worst-case considerations may include contact geometry, material finish, thinnest acetabular component(s), components with lowest initial locking strength, components exhibiting direct metal-on-metal contact, and component materials with lowest strength.

7.3 A minimum of three samples shall be tested.

7.4 Precondition the polymeric specimens according to Practice F2003 (artificial aging) unless there is evidence that the polymeric specimens are generally resistant to aging.

NOTE 4—The acetabular and femoral prostheses should have freedom to move relative to each other in the plane perpendicular to the compressive load. Flexion-extension (FE), abduction-adduction (AA), and internal-external (IE) rotations are relative motions between the acetabular and femoral prostheses. Implant in regular (left) and impingement (right) position.

NOTE 5—Rotation around the load axis is constrained. This can be achieved by a xy-table.

NOTE 6—Some simulator designs may allow for xy-translation of the femoral prosthesis. In principle this setup is sufficient for testing according to this standard, but great care must be taken to achieve the correct loading conditions.

## 8. Procedure

8.1 *Test Procedure:*

8.1.1 Assemble the acetabular prosthesis according to Test Method F1820 (if applicable) and the femoral prothesis according to Test Method F2009 (if applicable).

8.1.2 See Fig. 1 for a schematic representation of the test setup.

NOTE 7—A worst-case test setup for bipolar components is one in which the outer bipolar component articulation is locked in rotation (A/P, M/L, and polar axes) to simulate soft tissue impeding component mobility, such that there is restricted relative motion between the outer articulation and the acetabulum.

NOTE 8—Worst-case test setups for dual mobility components include both (*1*) locking the outer dual mobility articulation to AP and ML rotations; and (*2*) allowing the outer dual mobility articulation to freely move around all axes to achieve impingement contact between the femoral head (skirted) or neck of the femoral stem and the acetabular liner or shell. For (*2*), impingement at the outer dual mobility articulation is not intended. This component can be locked to avoid impingement if necessary. Include in the report which worst-case test setup(s) were evaluated and, if one is omitted, a rationale should be provided.

8.1.3 Mount the acetabular prosthesis with the entry diameter plane orthogonal to the direction on the main compressive load imposed by the simulator.

8.1.4 Mount the femoral prosthesis separately, such that the simulator actuators allow for relative motion with the acetabular component, providing flexion/extension, abduction/adduction, and internal-external rotation. The femoral component assembly shall consist of a femoral head and stem neck region for the minimum length that may contact the acetabular component.

8.1.5 See Fig. 2 for the definition of the coordinate system. The rotation axis is aligned with the neck of the femoral component and the extension axis is in the frontal plane as shown in Fig. 2 (see X1.8). The coordinate system is stationary in relation to the acetabular component. The sequence of

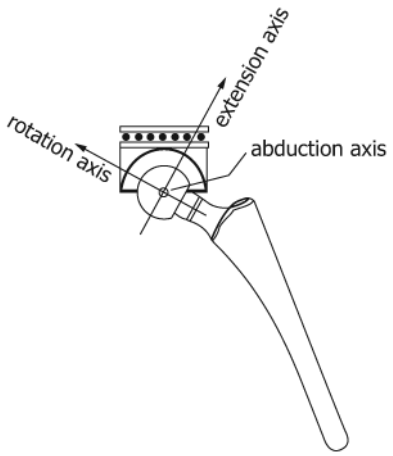


**FIG. 2 Coordinate System at the Reference Position**

angular transformation (Euler angles) is abduction-extension-rotation. For a test frame that does not generate the Euler sequence by its mechanical setup (that is, the extension actuator is moved by the abduction frame and the rotation actuator is moved by the extension frame), the motions described in Fig. 3 have to be transformed.

NOTE 9—The alignment of the cup versus the compressive load is intended to be constant. The impingement forces generated by simulators that do move the cup versus the compressive load force must be analyzed to ensure that the loading conditions as described by this standard are generated.

NOTE 10—The use of quaternions has been found helpful for coordinate transformation.

8.1.6 Adjust the simulator actuators for the hip assembly to have zero internal/external rotation and zero flexion/extension.

NOTE 11—Computer analysis as well as range of motion testing as described by ISO 21535 might support the adjustment of the reference position.

8.1.7 Apply a constant compressive load of 600 N.

8.1.8 Rotate the test assemblies around the center of the femoral head under angular displacement control in abduction motion until impingement in the direction of rotation of these test samples occurs. With this starting point and the abduction motion described in Fig. 3, impingement will occur throughout the entire first test cycle.

NOTE 12—The contact conditions shall represent the worst-cast *in-vivo* situation. Internal/external rotation or flexion/extension of the stem, or both, shall be considered.

NOTE 13—Computer models may be used to evaluate the worst-case impingement.

NOTE 14—Testing of constrained prostheses will require additional mechanical or electronic systems, or both, to limit the test load to the compressive load of 600 N.

NOTE 15—If a multi-station test frame with mechanically linked abduction/adduction is being used, ensure that all liners are meeting impingement conditions when setting up at each interval of testing.

8.1.9 The test fluid and test chamber shall be in accordance with ISO 14242-1.

8.1.10 The relative motion between the femoral stem and the acetabular cup about the reference position (see 8.1.7 and 8.1.8) shall be 0 to 5° for abduction, –5 to 5° for internal/

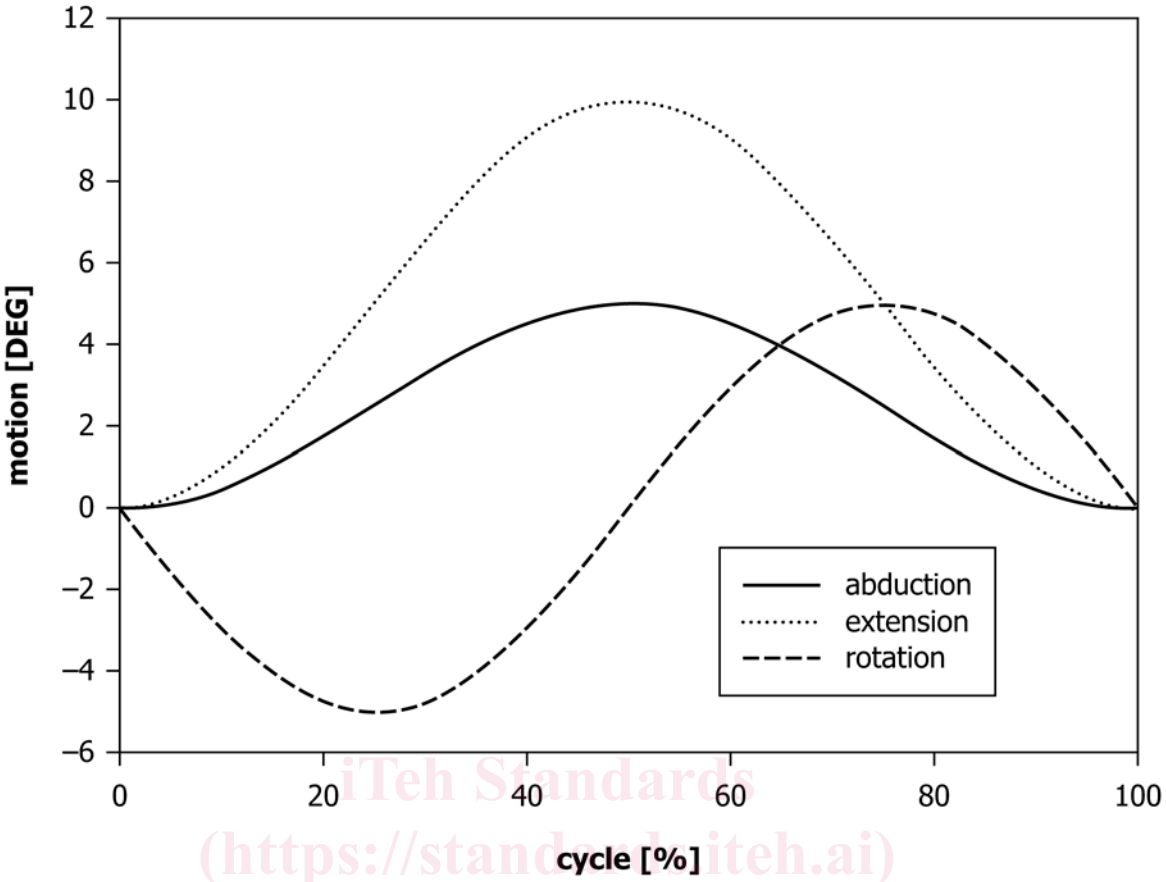


FIG. 3 Motions for Impingement Wear Testing



external rotation, and 0 to 10° for extension. See Fig. 3 for phasing of the individual motions.

8.1.11 The maximum test frequency shall be 1 Hz. Each test interval is 0.2 million cycles.

8.1.12 Ensure that the test specimens are in contact with the acetabular component at each test interval starting point. Readjustment of the reference position is necessary due to wear and deformation of the components.

8.1.13 Inspect the components, especially in the area of impingement, for any signs of fracture, deformation, delamination, wear, or chipping (ceramic components) at a magnification of equal or better than 8× for any signs of dissociation or loosening of modular components. Document findings (including photographic documentation) if there are signs of a conditionally acceptable damage mode at each test interval. Acceptable and conditionally acceptable damage modes are defined in 8.2.

8.1.14 Test for one million cycles.

8.2 *Definition of Acceptable and Conditionally Acceptable Damage Modes:*

8.2.1 Acceptable and conditionally acceptable damage modes may include, but are not limited to, the following:

8.2.1.1 Acceptable: Plastic deformation, abrasive wear, and delamination at the rim of the acetabular liner. These damage modes are regarded as a common finding for impingement loading and are regarded as acceptable for semi-constrained acetabular components. These damage modes are considered conditionally acceptable for constrained, bipolar, and dual mobility components (see 8.2.1.6).

8.2.1.2 Conditionally acceptable: Dissociation or loosening (that is, compromised liner/shell attachment strength) of a modular acetabular liner from an acetabular shell. These damage modes must be justified using either an analysis of the number of cycles until complete dissociation or an analysis of the reduction in attachment strength between the liner and modular acetabular shell. To demonstrate that the attachment strength has not been compromised, testing of the impingement samples per Test Method F1820 should be performed before and after impingement testing. A justification of the type of test performed or not performed (axial disassembly, offset pullout disassembly, lever out disassembly, torque out disassembly) should be provided. Justification for the results must be provided.

NOTE 16—Disassembly testing may be destructive for the locking mechanism. Initial Test Method F1820 testing may be performed on new components identical to those used for impingement testing.

8.2.1.3 Conditionally acceptable: Cracks in polyethylene acetabular components are regarded as a common finding for impingement loading and might be regarded as acceptable if the damage does not compromise the attachment strength between the polyethylene liner and modular acetabular shell (that is, the cracks do not propagate through the locking mechanism), or the articulating wear properties (that is, the cracks do not propagate through the articulations), or fracture