Designation: F2582 – 14

Standard Test Method for Impingement of Acetabular Prostheses[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 evaluate acetabular component fatigue, deformation, and wear and femoral head assembly dislocation under dynamic impingement conditions.

1.2 This test method can be used to evaluate single-piece acetabular prostheses, modular prostheses, and constrained prostheses 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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E4 Practices for Force Verification of Testing Machines

E467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System

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

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

3. Terminology

3.1 *Definitions:*

3.1.1 *component separation*—the disruption of a connection between components. May be stable or unstable.

3.1.2 *dislocation*—the loss of normal physical contact between opposing components, usually indicated by large separation and a loss of stability.

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

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

3.1.5 *joint reaction force*—the force directed normal to the entry diameter of the acetabular prosthesis (see ISO 7206-1).

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

3.1.7 *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.

3.1.8 *subluxation*—partial dislocation.

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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 International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland, http://www.iso.org.

4. Summary of Test Method

4.1 Acetabular prostheses are evaluated for fatigue, deformation, and wear under repeated impingement conditions. Modular acetabular prostheses should be evaluated for additional failure mechanisms including separation, loosening, fracture, and deformation 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 acetabular prostheses to assess the relative degree of constraint for the prosthesis and 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 acetabular prosthesis designs regarding constraint and their ability to resist impingement fatigue, wear, deformation, and dislocation under the stated test conditions.

6. Apparatus for Impingement

6.1 One axis shall be capable of applying a constant joint reaction 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, servo-hydraulic or other, as long as it meets the requirements of Practices E4 and E467 for force verification.

6.4 The joint reaction force shall be applied through unconstrained fixturing that allows for the separation of the acetabular prosthesis from the femoral prosthesis during the impingement and dislocation test. See Fig. 1 for the test principle.

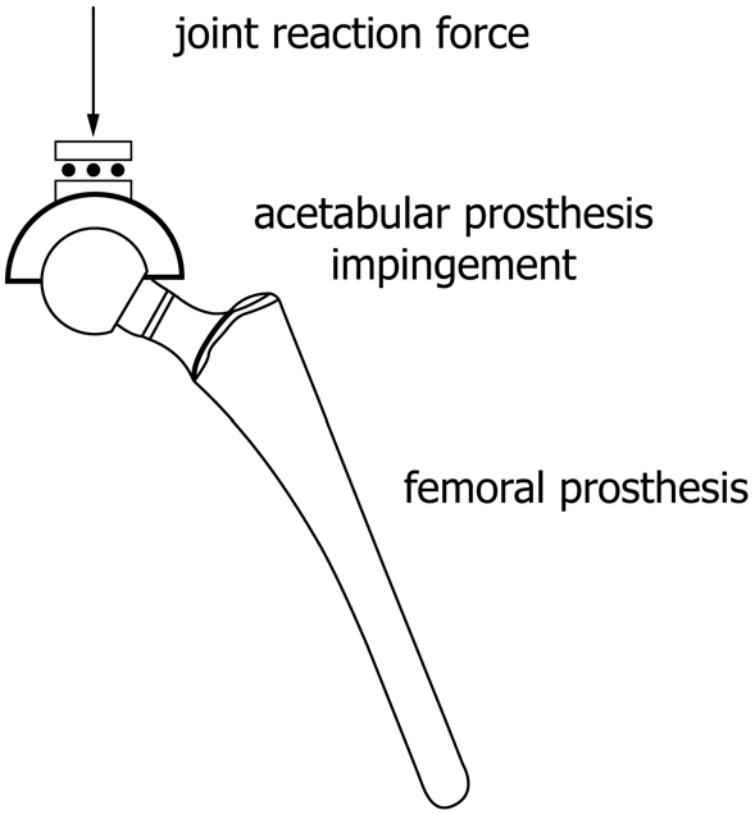
7. Sampling and Test Specimens

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 A minimum of three samples shall be tested to determine the impingement wear. Three additional samples should be used as reference samples without impingement in order to provide a comparison to the amount of mode 1 wear[4] that would otherwise occur if the primary samples were not impinging.

7.3 Precondition the specimens according to Practice F2003 (artificial aging).

[4] McKellop, H. A., "The Lexicon of Polyethylene Wear in Artificial Joints," *Biomaterials*, Vol 28, 2007, pp. 5049–5057 (Definition of wear modes).



NOTE 1—The acetabular and femoral prostheses should have freedom to move relative to each other in the plane perpendicular to the joint reaction force. Flexion-extension (FE), abduction-adduction (AA), and internal-external (IE) rotations are relative motions between the acetabular and femoral prostheses.

FIG. 1 Principle of the Test Set-Up

7.4 Precondition the specimens according to ISO 14242-2 (soaking).

8. Procedure

8.1 *Test Procedure:*

8.1.1 Weigh the acetabular inserts as described by ISO 14242-2.

8.1.2 Measure the original (unworn) geometry of the impingement section of the acetabular insert.

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

8.1.4 Mount the acetabular prosthesis with the entry diameter plane orthogonal to the direction on the main joint reaction force imposed by the simulator.

8.1.5 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.

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

NOTE 1—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 joint reaction force of 600 N.

8.1.8 Rotate a subset of three 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. 2, impingement will occur throughout the entire test cycle.

8.1.9 Adjust the other subset (optional) of three assemblies (control samples) in a position which allows for a minimum of 5° of abduction motion before contacting the acetabular component.

NOTE 2—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 3—Computer models may be used to evaluate the worst-case impingement.

NOTE 4—Testing of constrained prostheses will require additional mechanical or electronic systems, or both, to limit the test load to the joint reaction force of 600 N.

NOTE 5—Soak control samples (loaded or unloaded) might be used to correct wear measurements for fluid absorption of the specimens.

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

8.1.11 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/external rotation, and 0 to 10° for extension. See Fig. 2 for phasing of the individual motions.

8.1.12 The maximum test frequency shall be 3 Hz.

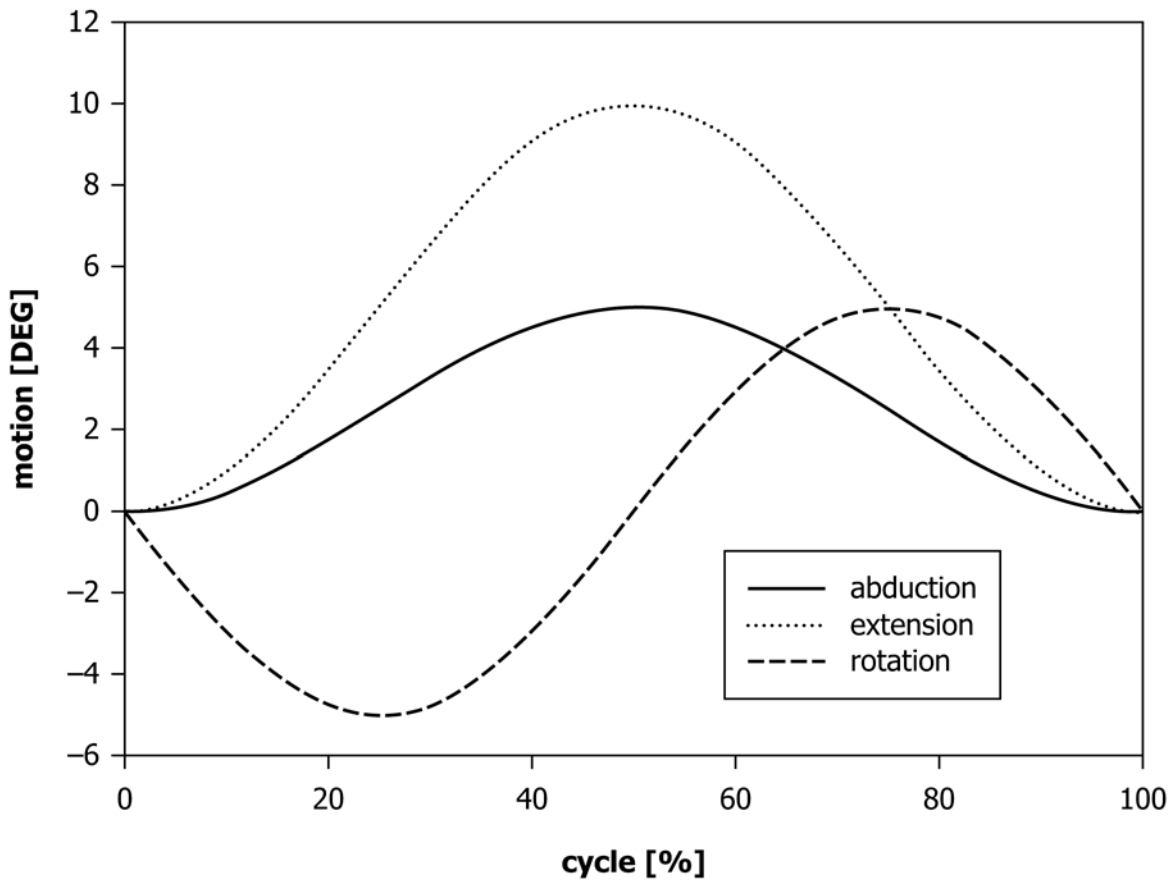


FIG. 2 Motions for Impingement Wear Testing

8.1.13 Determine the acetabular component weight as described by ISO 14242-2 at 0.2 million cycle intervals.

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

8.1.15 Test for a maximum of one million cycles or failure, whichever comes first. Failure is defined in 8.2.

8.1.16 Measure the final surface geometry of the worn impingement section of the acetabular insert and determine the volume difference between the original and the final geometry.

8.2 *Definition of Failure:*

8.2.1 Potential failure modes may include, but are not limited to, the following:

8.2.1.1 Dislocation of the femoral component from the acetabular component.

8.2.1.2 Separation or loosening of a modular acetabular liner from an acetabular shell.

8.2.1.3 Fracture of any prosthetic component.

8.2.1.4 Gross deformation of any prosthetic component.

8.2.1.5 Fracture or failure, or both, of a locking mechanism between modular components.

9. Report

9.1 The report shall include the following information:

9.1.1 Product codes, lot numbers, and special processes that might influence the test results should be noted.

9.1.2 Product sizing, style and specific dimensions (Specifications F2091 and F2033) relative to the performance of the test shall be recorded including the specific or simulated neck region of the femoral prosthesis.

9.1.3 Test environment.

9.1.4 Description of failure mechanisms.

9.1.5 Reference position at each test interval and at the end of the test.

9.1.6 Joint reaction force.

9.1.7 Description of the damage to the femoral and acetabular prosthesis incurred over the course of the entire test.

9.1.8 Photographic documentation of the damage to the femoral and acetabular prostheses incurred over the course of the entire test.

9.1.9 Change in the angular displacement of the acetabular prosthesis at the end of the dynamic test compared to the beginning of the test.

9.1.10 Wear data of the test specimens and reference specimens (optional) for the impingement wear test.

9.1.11 Volume difference between the original geometry and the final geometry.

10. Precision and Bias

10.1 A precision and bias statement does not exist for this test method because round robin testing has not been performed.

11. Keywords

11.1 acetabular prosthesis; dislocation; impingement; range of motion

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 This test method was developed to provide a standardized means for assessing the functional performance of an acetabular prosthesis under laboratory conditions. This test method may be used to evaluate the range of motion, impingement and dislocation of acetabular prostheses, and locking mechanism characteristics.

X1.2 It is recognized that there are several clinical failure modes for acetabular prostheses and that this test method may or may not be capable of reproducing them. This test method does not purport to accurately recreate *in-vivo* conditions.

X1.3 Although surgical placement may be the largest factor influencing dislocation between femoral and acetabular prostheses, the design allowances for range of motion (ROM), impingement tolerance, and resistance to dislocation will contribute and therefore should be assessed using a standardized method.

X1.4 There are several references that may be useful in understanding this test method and the clinical rationale for this test method. Some are listed in the Bibliography of this test method.

X1.5 A constant load of 600 N was chosen for the impingement wear method which equals about 10 Nm for average acetabular components.

X1.6 A maximum cycle count of one million was chosen for the dynamic testing with the belief that many failure mechanisms can be elicited in this time frame. Testing may be continued to a higher number.

X1.7 It is recognized that there are other methods for testing acetabular prostheses. Based on various goals, investigators may choose to deviate from the test method defined here.

X1.8 Due to the lack of data, the motions defined for impingement wear are based on worst-case assumptions. The

maximum abduction is in coincidence with the maximum speed of relative motion generated by rotation. The maximum extension motion is reached at the same point of the cycle. This motion is assumed to generate worst-case condition contact for stems having a non-symmetric cross section at the neck region.

X1.9 Because of the range of motion in this test being smaller than that of ISO 14242-1, a higher test frequency of up to 3 Hz is allowed.

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