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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.

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

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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).

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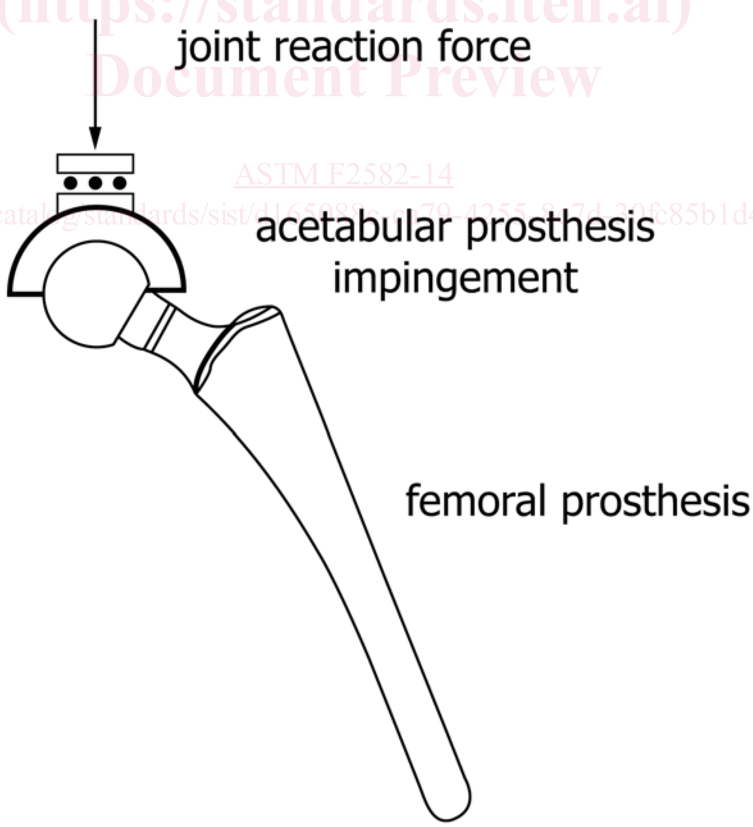

NOTE 1—The acetabular and femoral prostheses should have freedom to move relative to each other in the plane perpendicular to the joint reaction force. Flexion-extension (FE), abduction-adduction (AA), and internal-external (IE) rotations are relative motions between the acetabular and femoral prostheses.

FIG. 1 Principle of the Test Set-Up