Designation: F2582 – 08

StandardTest 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 for measuring the range of motion, impingement, and dislocation of a femoral head assembly and acetabular prosthesis.

1.2 This test method covers the procedure for static and cyclic fatigue tests.

1.3 This test method may be used to evaluate single piece acetabular prostheses, modular prostheses, and constrained prostheses manufactured from polymeric, metallic, or ceramic materials.

1.4 The values stated in SI units are regarded as the standard.

1.5 *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

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

F2091 Specification for Acetabular Prostheses

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 *dislocation moment*—the maximum torsional moment (N-m) measured at the point of dislocation. See Fig. 6.

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

3.1.5 *impingement*—the point at which two opposing components collide to restrict motion, usually indicated by a sharp change in force or moment. See Fig. 3 and Fig. 6.

3.1.6 *impingement moment*—the moment (N-m) measured or applied at the point of impingement.

3.1.7 *joint reaction force*—the force directed normal to the contacting surfaces between two opposing articulating components.

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

3.1.9 *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.

3.1.10 *subluxation*—partial dislocation.

4. Summary of Test Method

4.1 Acetabular prostheses are evaluated for range of motion until impingement. The impingement behavior is measured up to a dislocation or failure point. Modular acetabular prostheses may 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 may be used to evaluate static or dynamic characteristics. Various joint reaction forces and impingements may be applied in order to simulate known clinical conditions.

5. Significance and Use

5.1 The test method may 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.

[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.

FIG. 1 Representative Unconstrained Planar Bearing Fixture for Femoral Component

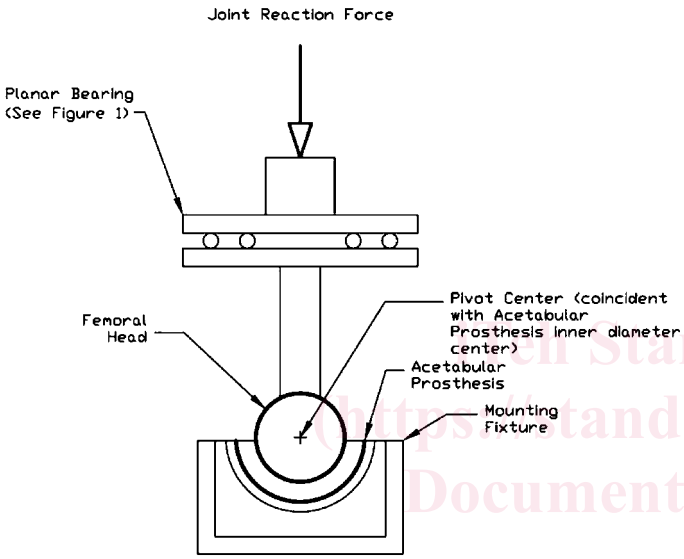

FIG. 2 Schematic Representation of the Test Setup

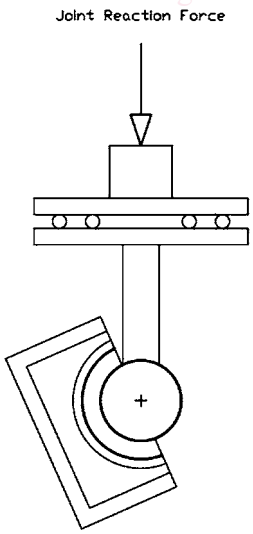

FIG. 3 Schematic Representation of the Test Setup at the Point of Impingement

5.2 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.

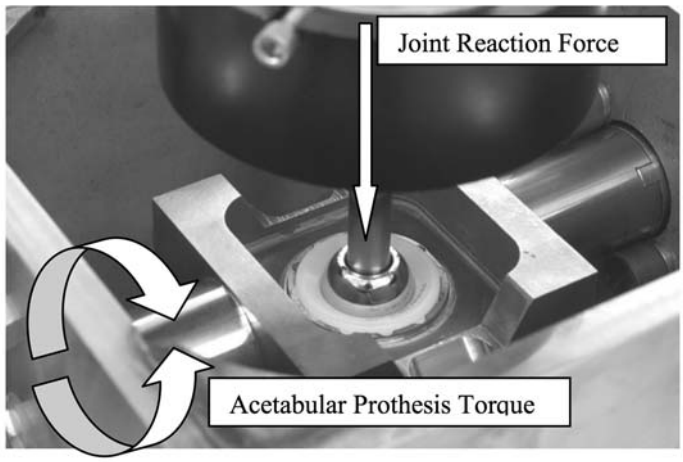

FIG. 4 An Example Test Setup

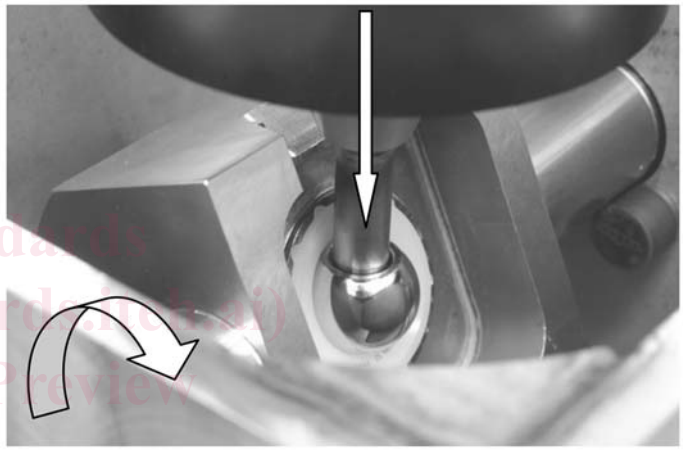

FIG. 5 An Example Test Setup Showing the Point of Impingement

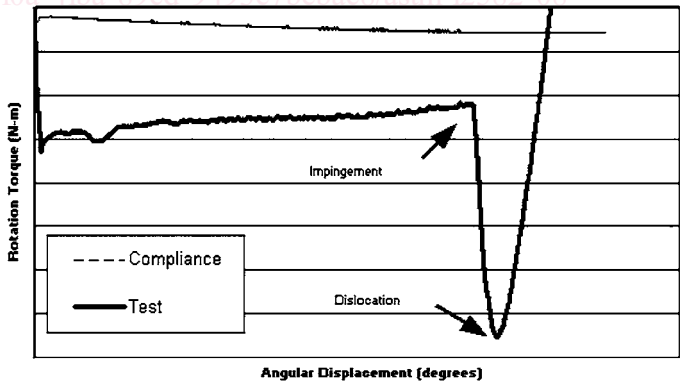

FIG. 6 Representative Moment versus Angular Displacement Result Obtained for the Static ROM and Dislocation Test

6. Apparatus

6.1 One axis must be capable of applying either a constant joint reaction force for static and dynamic loading or a physiological waveform for dynamic loading.

6.2 A second axis must be capable of controlling and monitoring angular displacement and torque.