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Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation[1]

This standard is issued under the fixed designation F 2028; 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 These test methods measure how much a prosthetic glenoid component rocks or pivots following cyclic displacement of the humeral head to opposing glenoid rims (for example, superior-inferior or anterior-posterior). Performance is judged by the tensile displacement opposite each loaded rim after dynamic rocking.

1.2 The same setup can be used to test the locking mechanism of modular glenoid components, for example, for disassociation.

1.3 These test methods cover shoulder replacement designs with monolithic or modular glenoid components for cemented fixation.

1.4 The values stated in SI units are to be regarded as the standard. The values given in parentheses are provided for information purposes only.

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]

E 4 Practices for Force Verification of Testing Machines

F 1378 Specification for Shoulder Prostheses

F 1839 Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments

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3. Terminology

3.1 *Definitions:*

3.1.1 *glenoid*—the prosthetic portion that replaces the glenoid fossa of the scapula and articulates with a prosthetic replacement of the humeral head. It may consist of one or more components from one or more materials, for example, either all-polyethylene or a metal baseplate with a polymeric insert.

3.1.2 *humeral head*—the prosthetic portion that replaces the proximal humerus or humeral head and articulates with the natural glenoid fossa or a prosthetic replacement.

3.1.3 *glenoid plane*—see Fig. 1. In symmetrical glenoids, the glenoid plane is defined by joining the two articular edges; in planar and asymmetric glenoids, it is defined by the back surface.

3.1.4 *axial load; axial translation*—the force and displacement, respectively, perpendicular to the glenoid plane; the axial load simulates the net compressive external and muscle forces (see Fig. 1).

3.1.5 *shear load; shear translation*—the force and displacement, respectively, parallel to the glenoid plane, applied, for example, in the superior/inferior or anterior/posterior direction (see Figs. 1 and 2); the shear load simulates the net shear external and active and passive soft tissue forces.

3.1.6 *subluxation load*—the peak shear load required for subluxation, for example, the peak resistive force at the glenoid articular rim opposing movement of the humeral head.

3.1.7 *subluxation translation*—the distance from the glenoid origin (see Fig. 2), parallel to the glenoid plane, to the point at which the subluxation load occurs.

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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.

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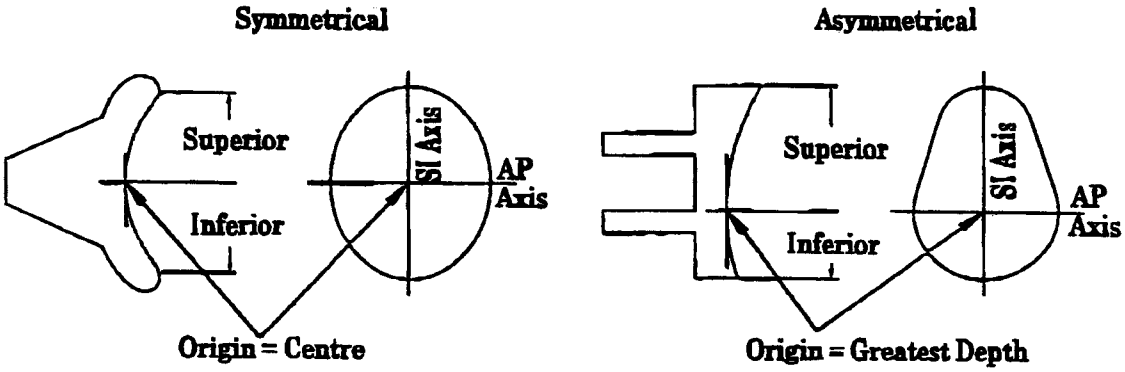

FIG. 2 Glenoid Axes and Origin

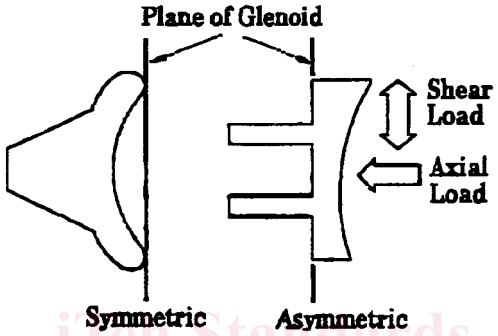

FIG. 1 Glenoid Plane and Load Directions

3.1.8 ~~*superior/inferior (SI), anterior/posterior (AP)*—the SI axis is the longest dimension and the AP axis the widest dimension of the glenoid (see~~ superior/inferior (SI)—the SI axis is the longest dimension of the glenoid (see Fig. 2).

3.1.9 *anterior/posterior (AP)*—the AP axis the widest dimension of the glenoid (see Fig. 2).

3.1.10 *edge displacements*—the translation, perpendicular to the glenoid plane, of a specific point on the outside edge of the glenoid, when subjected to loading (see Fig. 3).

GLENOID LOOSENING TEST METHOD

4. Summary of Test Method

4.1 The prosthetic glenoid component is fixed with bone cement into a bone substitute using the normal surgical technique.

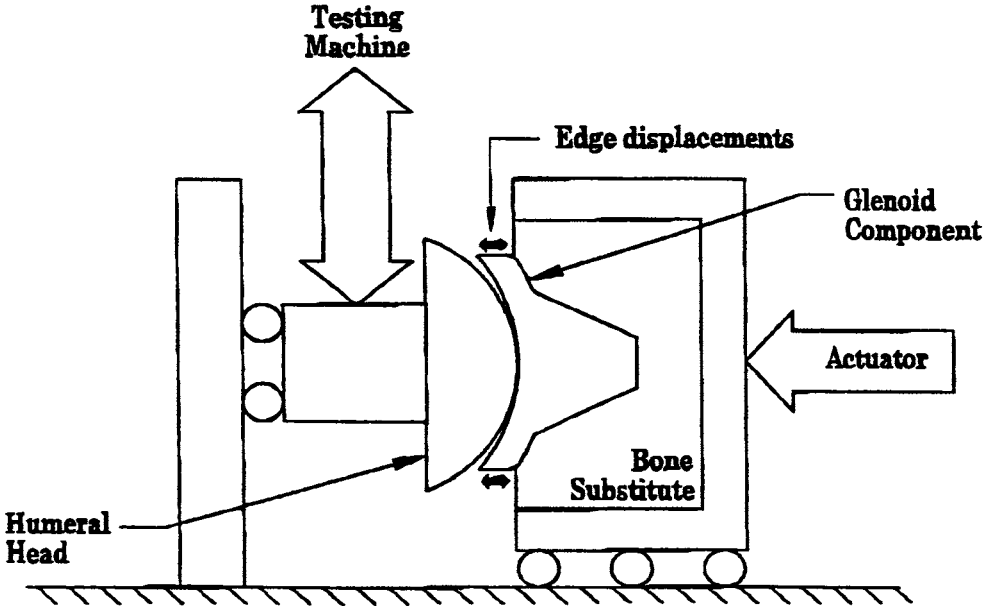

FIG. 3 Biaxial Testing Apparatus

4.2 The subluxation translation is determined experimentally on additional components. This is accomplished, using a biaxial apparatus (see Fig. 3) by applying an axial load perpendicular to the glenoid, then translating the humeral head parallel to the glenoid plane until encountering a peak shear load. This is performed in both directions, corresponding to the direction of intended rocking (for example, superior-inferior, anterior-posterior, or an alternative angle).

4.3 The edge displacements of the glenoid are measured before cycling: a given axial load is first applied perpendicular to the glenoid, then the edge displacements are measured with the humeral head in three positions: at the glenoid origin, and positioned to 90 % of the subluxation translation (see X1.2), in both directions, as defined in 4.2. (Cycling to 90 % of the subluxation load would be acceptable, but is not ~~practically feasible as a result~~practical because of the large displacements, quick speeds, and deformable polyethylene.)

4.4 The humeral head is cycled to 90 % of the subluxation distance for a fixed number of cycles.

4.5 The edge displacements (4.3) are either repeated following the cycling or measured continuously during the cycling.

5. Significance and Use

5.1 This test method is intended to investigate the resistance of a glenoid component to loosening. Glenoid loosening is the most common clinical complication in total shoulder arthroplasty (see X1.1). The method assumes that loosening occurs because of edge loading, often called the rocking-horse phenomenon.

5.2 This test method can be used both to detect potential problems and to compare design features. Factors affecting loosening performance include articular geometry, flange geometry, materials, fixation design, bone quality, and surgical technique.

6. Apparatus and Equipment

6.1 The test apparatus shall be constructed such that an axial load is applied perpendicular to the glenoid plane and a shear load is applied parallel to the glenoid plane (see Fig. 1). Fig. 3 shows the axial load to be horizontal and the shear load to be vertical; however, this arrangement may be reversed.

6.2 A bone substitute representing the strength or glenoid cancellous bone (see X1.5) shall be used. If a polyurethane foam is used, it shall conform to Specification F 1839.

6.3 The glenoid and humeral head shall be enclosed in a chamber with water heated to 37 ± 2°C (98.6 ± 3.6°F), at least for the dynamic portion of the test (see X1.6). A buffer may be added, if the tester deems this necessary.

6.4 A means to measure the axial load, shear load, shear translation, and glenoid edge displacements is required. A means to measure the axial translation is desirable.

6.5 The tests ~~win~~shall be performed on either mechanical or hydraulic load frames with adequate load capacity and shall meet the criteria of Practices E 4.

7. Sampling and Test Specimens

7.1 A minimum of three samples shall be tested. At least two additional components should be used to determine the subluxation translation. The test may be conducted along the superior-inferior axis, the anterior-posterior axis, or another axis of interest to the user.

7.2 All glenoid components shall be in the final manufactured condition. All plastic components shall be sterilized according to the manufacturer-recommended specifications for clinical use.

7.3 The humeral head shall include the identical radius or radii and material as the actual implant. Other features of the humeral component such as the shaft may be omitted. The same head may be used for all tests unless the surface becomes damaged.

7.4 Glenoid and humeral components ~~axe~~are used in total shoulder arthroplasty and should conform to the criteria specified in Specification F 1378.

8. Procedure

8.1 The following steps are common to both the subluxation (4.2) and rocking (4.3-4.5) tests:

8.1.1 Secure the glenoid component in a bone substitute with bone cement using the normal surgical procedure and instrumentation. Do not perform tests until the cement has ~~properly cured.~~ cured properly.

8.1.2 Position the path of the humeral head on the glenoid within ±0.5 mm (sideways) of the desired path, for example, by using a dye to locate the contact point of the humeral head; a dye is unnecessary for congruent prostheses. Locate the center of the path (for the subluxation test, this need not be exact; for the rocking test, the peak loads at each rim during cycling should be within ±10 % of each other for symmetrical designs).

8.1.3 Perform the static measurements (subluxation and edge displacements) either in air at room temperature or in water at 37°C. The cyclic testing must be performed in 37°C water (see 6.3, X1.3, and X1.6).

8.1.4 Apply a given axial load to the glenoid, for example, 750 N (169 lb) ± 7.5 N (see X1.4).

8.2 Determine the subluxation translation experimentally on separate components (see X1.2):

8.2.1 After applying the axial load, displace the humeral head at a constant rate to a given displacement ensuring that a peak load is achieved in both directions. A rate of 50 mm/min (2 in./min) is recommended to avoid polyethylene creep.

8.2.2 Yielding is expected at the recommended load and does not constitute a failure. The test shall be terminated if the insert of a modular glenoid disassociates.

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