Designation: F2028 – 14

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

This standard is issued under the fixed designation F2028; 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 anatomic glenoid component rocks or pivots following cyclic displacement of the humeral head to opposing glenoid rims (for example, superior-inferior or anterior-posterior). Motion is quantified by the tensile displacement opposite each loaded rim after dynamic rocking. Similarly, these test methods measure how much a prosthetic reverse glenoid component rocks or pivots following cyclic articulation with a mating humeral liner. Motion is quantified by the magnitude of displacement measured before and after cyclic loading.

1.2 The same setup can be used to test the locking mechanisms of modular glenoid components, for example, disassociation of both anatomic and reverse shoulder components.

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

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this 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

F1378 Specification for Shoulder Prostheses

F1839 Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments

3. Terminology

3.1 *Definitions:*

3.1.1 *anatomic total shoulder arthroplasty, n*—shoulder implant that has a concave glenoid component and a convex humeral component design.

3.1.1.1 *anatomic glenoid, n*—the concave prosthetic portion that replaces the glenoid fossa of the scapula and articulates with a convex prosthetic replacement of the humeral head in anatomic total shoulder arthroplasty applications. 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.

3.1.1.2 *humeral head, n*—the convex prosthetic portion that replaces the proximal humerus or humeral head and articulates with the natural glenoid fossa or an anatomic prosthetic replacement.

3.1.2 *reverse total shoulder arthroplasty, n*—shoulder implants that have a convex glenoid component and a concave humeral component design.

3.1.2.1 *glenoid baseplate, n*—the nonarticular portion of the reverse glenoid component that modularly connects to the glenosphere and is usually fixed to the glenoid fossa of the scapula using bone screws without the use of cement.

3.1.2.2 *glenosphere, n*—the convex prosthetic articular portion of the reverse glenoid component that articulates with the concave prosthetic replacement of the proximal humerus or humeral head (for example, the humeral liner).

3.1.2.3 *glenosphere thickness, n*—the height of the truncated section of the sphere which composes the glenosphere. Note that the difference between the glenosphere articular radius and thickness defines the medial/lateral position of the glenoid center of rotation (see Fig. 1). The glenosphere thickness could also be affected by the geometric relation between the glenosphere and the glenoid baseplate.

3.1.2.4 *humeral liner, n*—the concave prosthetic portion of the reverse humeral component that replaces the proximal

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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.

humerus or humeral head and articulates with the convex prosthetic replacement of the glenoid (for example, the glenosphere).

3.1.2.5 *reverse glenoid, n*—the convex prosthetic portion that replaces the glenoid fossa of the scapula and articulates with a concave prosthetic replacement of the humeral head in reverse total shoulder arthroplasty applications. The reverse glenoid may consist of one or more components from one or more materials; most commonly, the reverse glenoid is composed of a metal glenosphere that is modularly connected to a metal glenoid baseplate which is fixed to the glenoid fossa.

3.1.3 *anterior/posterior (AP), n*—the AP axis is the widest dimension of the glenoid component (see Fig. 2 and Fig. 3).

3.1.4 *axial load; axial translation, n*—the force and displacement, respectively, perpendicular to the glenoid plane. The axial load simulates the net compressive external and active and passive soft tissue forces (see Fig. 4).

3.1.5 *edge displacements, n*—the translation, perpendicular to the glenoid plane, of a specific point on the outside edge of the glenoid, when subjected to loading (see Fig. 5, Fig. 6 and Fig. 7).

3.1.6 *glenoid plane* (see X1.9), *n*—in symmetrical anatomic glenoids, the glenoid plane is defined by joining the two articular edges; in planar and asymmetric anatomic glenoids, it is defined by the back (medial) surface. For a reverse shoulder it is defined as the plane created by the face of the glenoid baseplate (see Fig. 4).

3.1.7 *runout, n*—a predetermined number of cycles at which the testing on a particular specimen will be stopped, and no further testing on that specimen will be performed.

3.1.8 *shear load; shear translation, n*—the force and displacement, respectively, parallel to the glenoid plane, applied, for example, in the superior/inferior or anterior/posterior direction. The shear load simulates the net external shear and active and passive soft tissue forces (see Fig. 4).

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

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

3.1.11 *superior/inferior (SI), n*—the SI axis is the longest dimension of the glenoid component (see Fig. 2 and Fig. 3).

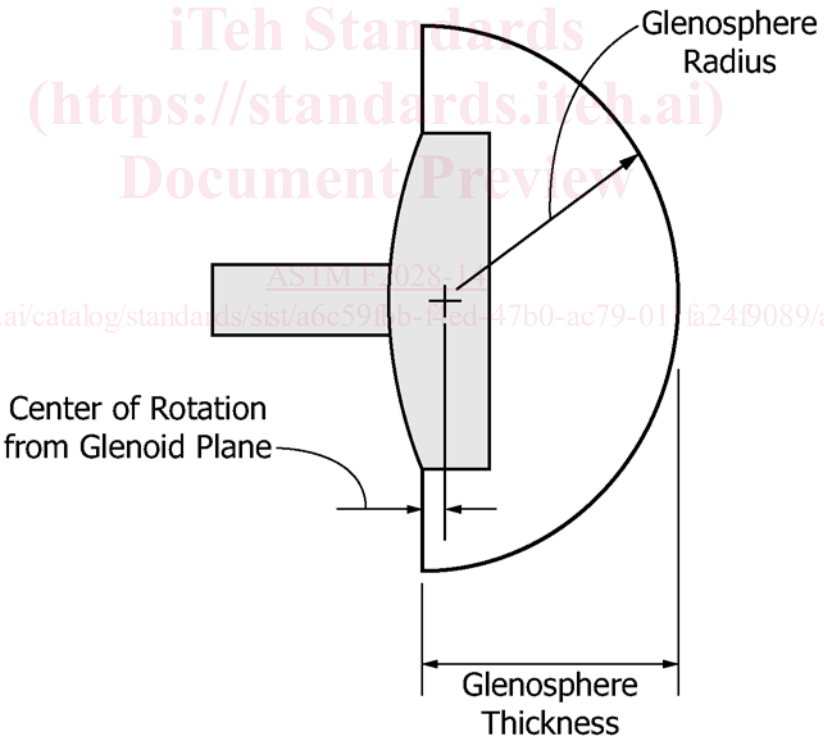

FIG. 1 Glenosphere Thickness

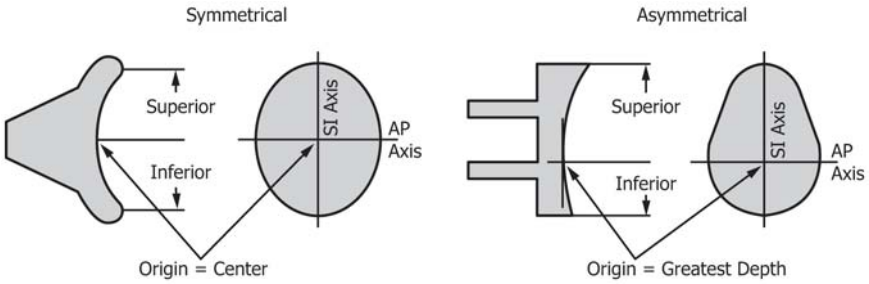

FIG. 2 Anatomic Glenoid Axes and Origin

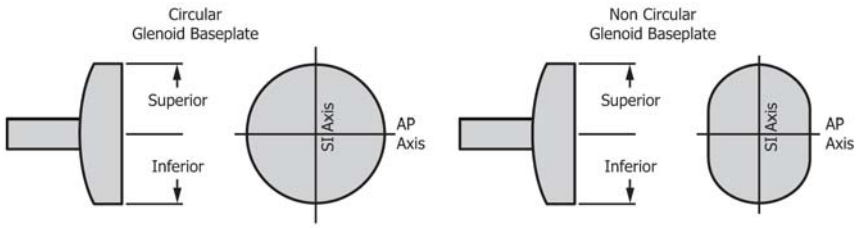

FIG. 3 Reverse Glenoid Baseplate Axes

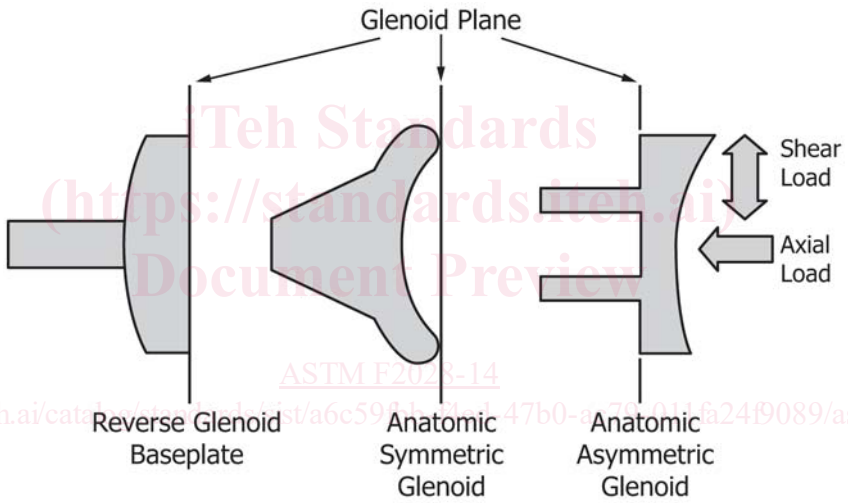

FIG. 4 Glenoid Plane and Load Directions

ANATOMIC SHOULDER 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.

4.2 The subluxation translation is determined experimentally on additional components. This is accomplished using a biaxial apparatus (see Fig. 5) 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 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.

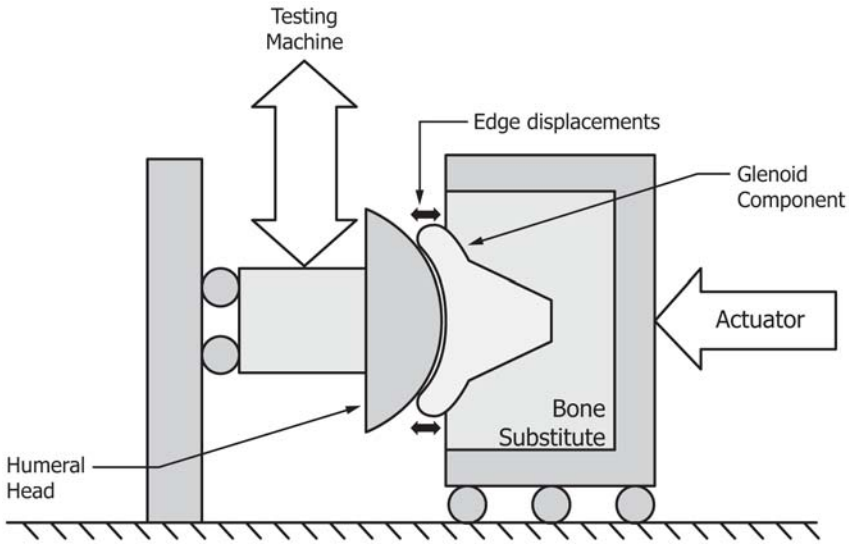

FIG. 5 Biaxial Testing Apparatus for Anatomic Shoulders

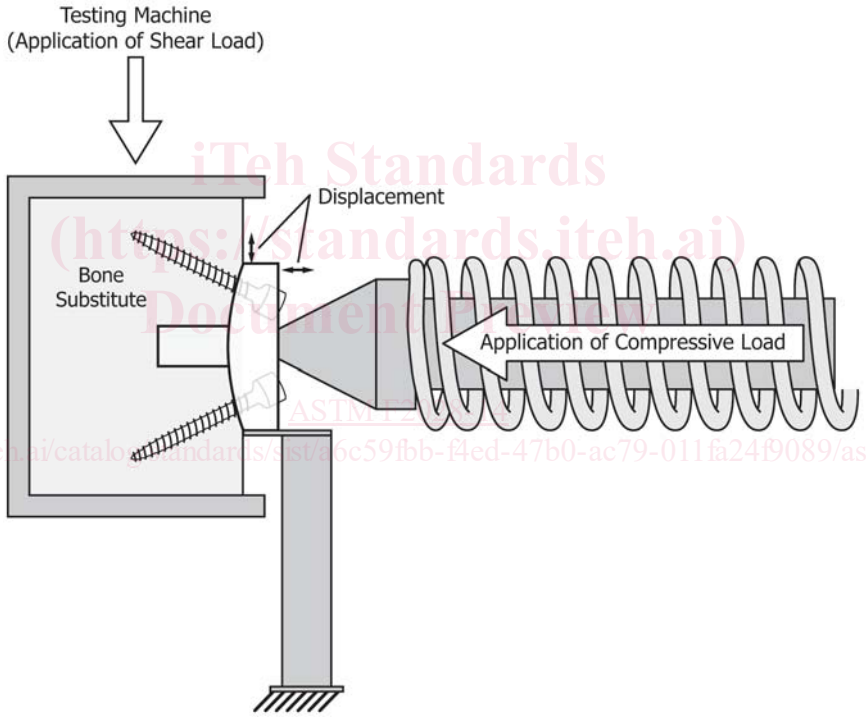

FIG. 6 Displacement Test Configuration

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. 4). Fig. 5

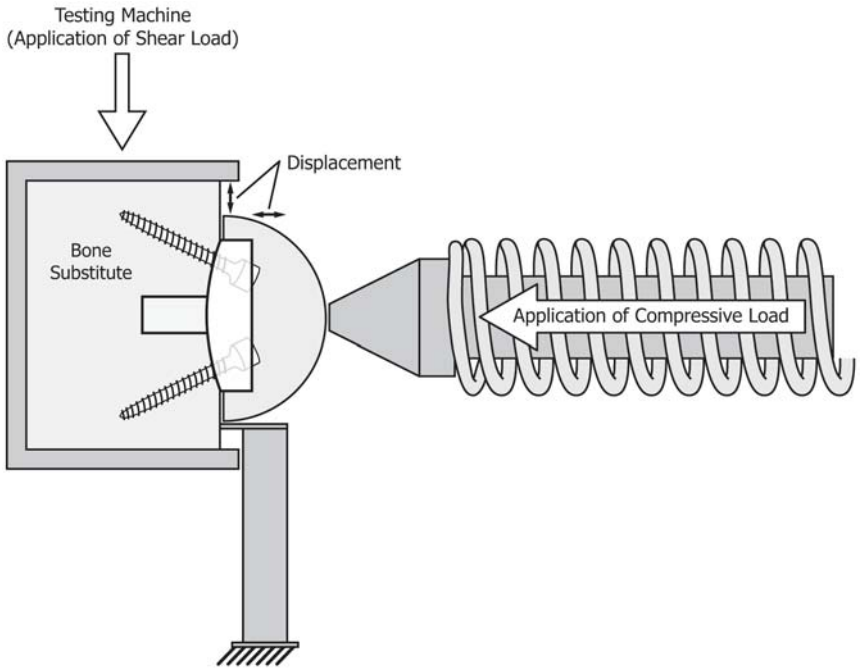

FIG. 7 Alternative Displacement Test Configuration

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 F1839.

6.3 The glenoid and humeral head shall be enclosed in a chamber with water heated to 37 ± 2°C, 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 shall be performed on either mechanical or hydraulic load frames with adequate load capacity and shall meet the criteria of Practices E4.

7. Sampling and Test Specimens

7.1 A minimum of three samples shall be tested. Additional samples may be used to reflect test variability. 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 are used in total shoulder arthroplasty and should conform to the criteria specified in Specification F1378.

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 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 shall 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 ± 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 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.

8.2.3 Record the axial load, subluxation load, and subluxation translation.

8.3 Measure the edge displacements before rocking:

8.3.1 Create a foundation for measurements at both ends of the glenoid at a similar distance from the back surface of the glenoid for all prostheses. One possibility is to insert 2-mm-diameter screws into the outside edge at each end of the glenoid prosthesis, parallel to the articular surface (to avoid exiting either into the articular surface or into the bone substitute). Flatten the screw head parallel to the glenoid plane. Alternative methods are acceptable (see X1.8).

8.3.2 Rest a displacement measuring device, for example, a linear variable differential transformer (LVDT), differential variable reluctance transducer (DVRT), or dial gauge, on each foundation to measure the displacements perpendicular to the glenoid plane (see X1.8). Continuous measurement is desirable, but measurement at the beginning and end of the rocking is sufficient.

8.3.3 Condition the prosthesis/bone substitute system, for example, for ten cycles at 0.25 Hz.

8.3.4 Measure the edge displacements with the humeral head located at the glenoid origin (see Fig. 2 and Fig. 3).

8.3.5 Translate the humeral head parallel to the glenoid plane to 90 % of the subluxation translation determined previously (8.2) in one direction. Measure both edge displacements.

8.3.6 Translate the humeral head to 90 % of the subluxation translation in the opposite direction and measure both edge displacements.

8.3.7 Repeat the three readings at least once to ensure repeatability.

8.4 Cyclically translate the humeral head to 90 % of the subluxation translation to cause a rocking motion of the glenoid at a given frequency (for example, 2 Hz as a result of the large translations, or up to a maximum of 6 Hz) to a maximum number of cycles (for example, 100 000) (see X1.7). Maintain the axial load and specified displacement.

8.5 Terminate the test when either the maximum number of cycles has been reached or a modular glenoid insert disassociates.

8.6 Repeat the glenoid edge displacement measurements (8.3) if measurements were not taken continuously.

8.7 Testing may be continued to a higher number of cycles if desired.

9. Report

9.1 The test report shall include the following:

9.1.1 All details relevant to the particular implants tested including type, size, and lot number as well as the glenoid radius, humeral head radius or radii, and the prosthesis material.

9.1.2 The axis and direction of testing (for example, central-superior-inferior).

9.1.3 *Subluxation Test*—The subluxation load and translation for each specimen, as well as the axial load and displacement rate. A chart plotting the load versus displacement with the 90 and 100 % subluxation loads clearly marked should be included.

9.1.4 *Rocking Test*—The axial load, cyclic displacement, maximum number of cycles, testing frequency, and cause of test termination. Testing parameters that differ from those recommended shall be justified.

9.1.5 *Displacement Test*—The edge displacements before and following cycling, highlighting the tensile displacement on the unloaded side following rocking (for example, the displacement opposite the loaded side minus the value with the head at the glenoid origin).

9.1.6 If the amplitude of the axial translation decreases suddenly during the test (indicating a tilt of the glenoid and the probable onset of loosening), the number of cycles at which this occurred should be recorded.

10. Precision and Bias

10.1 *Precision*—The precision of this test method was established by an interlaboratory comparison among four laboratories, with each laboratory testing three specimens. The specimens tested were commercially available UHMWPE glenoid components and cobalt chrome humeral heads. The population mean micromotion before and after testing was 368 ± 330 µm and 496 ± 275 µm, respectively. Each laboratory utilized different methods for measuring the edge displacements, and one laboratory performed the test using a lubricant at the contact surface instead of performing the test in solution (see X1.8).

10.1.1 *Repeatability*—For replicate results obtained by the same laboratory on nominally identical test specimens, the repeatability standard deviation (s_r) was 72.3 µm before testing and 268.0 µm after testing. All laboratories were within the critical k values for the before and after testing conditions.

10.1.2 *Reproducibility*—For replicate results obtained by the same laboratory on nominally identical test specimens, the reproducibility standard deviation (s_R) was 335.9 µm before testing and 359.4 µm after testing. One laboratory exceeded the critical h value for the before testing condition (h=1.50 versus h_{crit}=1.49). All laboratories were within the critical h values for the after testing condition.

10.2 The above round robin data represent initial efforts at establishing a precision and bias statement for this test method and have been published before documentation of full lab participation was completed (4 out of 6). Additionally, some labs experienced difficulty with measurement of micromotion resulting in test method variances. Further testing is warranted and a revised precision and bias statement incorporating participation by additional labs with reduced methodology variances is intended for future publication.

11. Keywords

11.1 arthroplasty; glenoid; loosening; subluxation; total shoulder replacement

MODULAR DISASSOCIATION TEST METHOD

12. Summary of Test Method

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