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).

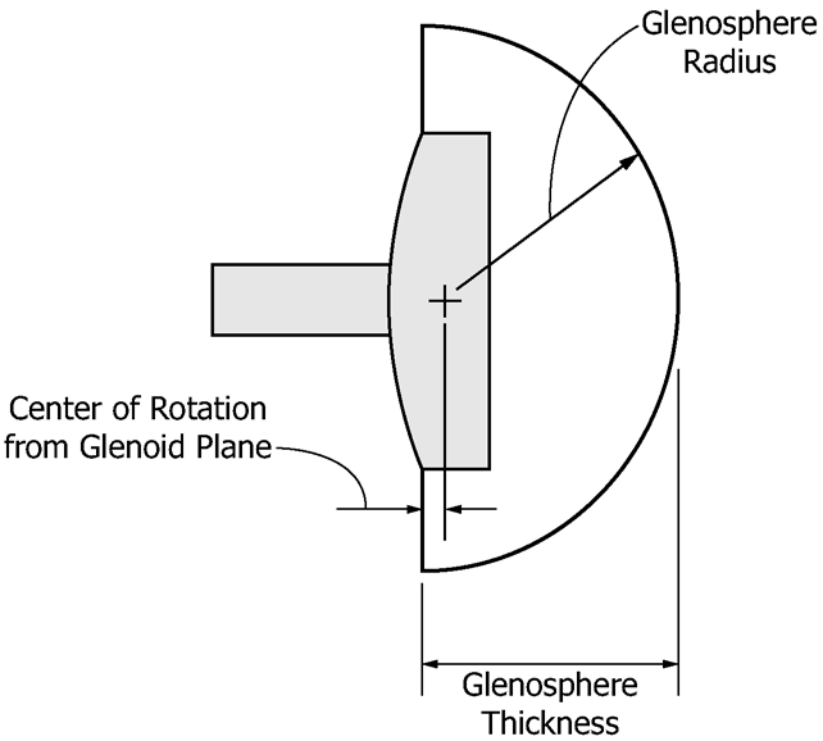

FIG. 1 Glenosphere Thickness

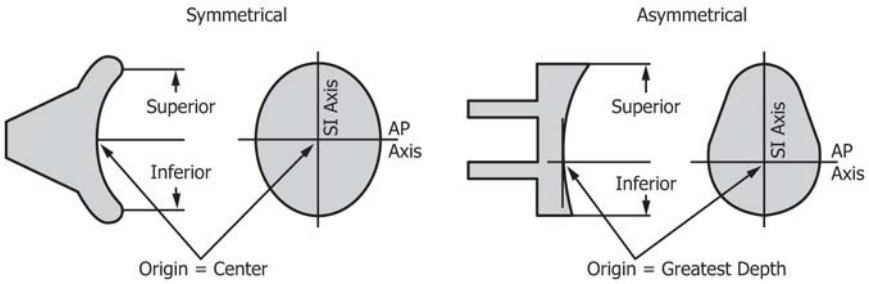

FIG. 2 Anatomic Glenoid Axes and Origin

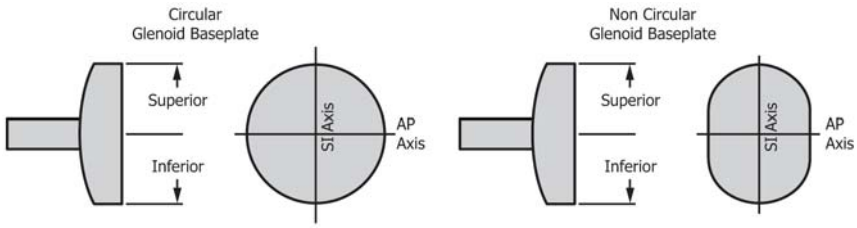

FIG. 3 Reverse Glenoid Baseplate Axes

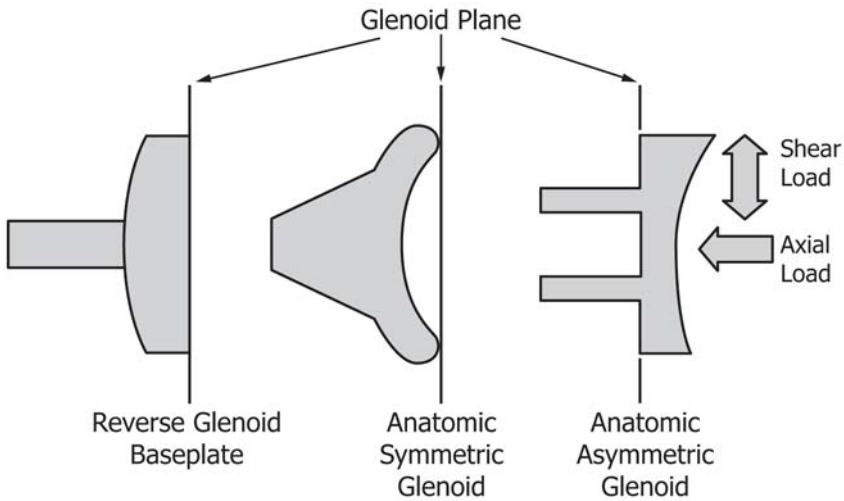

FIG. 4 Glenoid Plane and Load Directions

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.

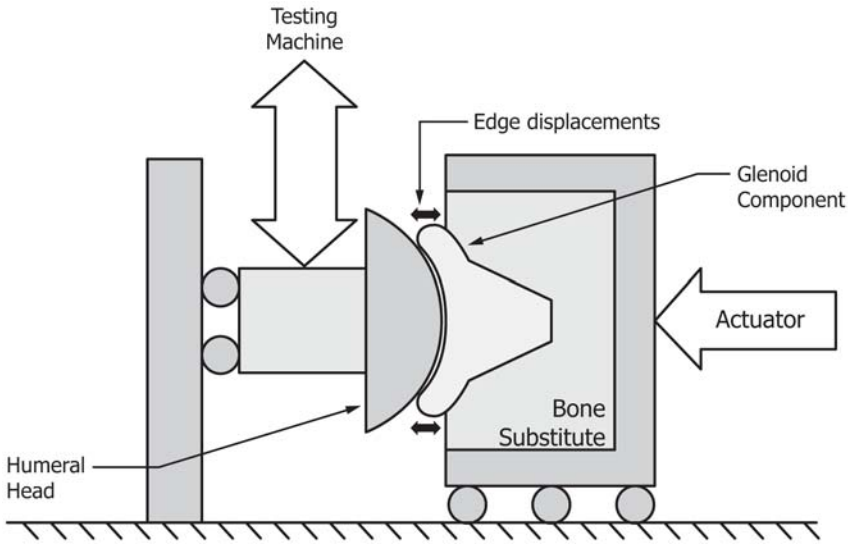

FIG. 5 Biaxial Testing Apparatus for Anatomic Shoulders

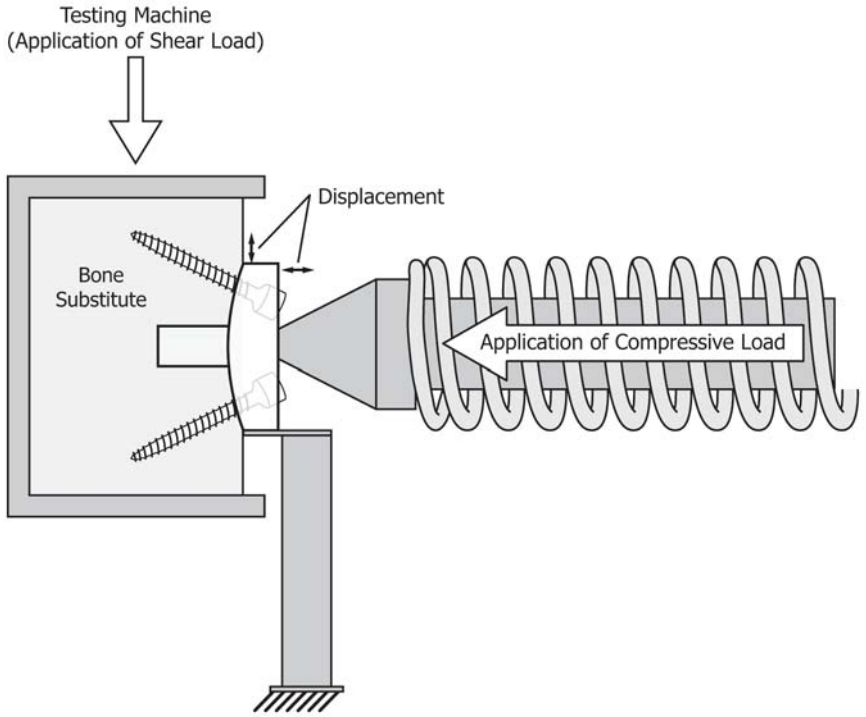

FIG. 6 Displacement Test Configuration

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

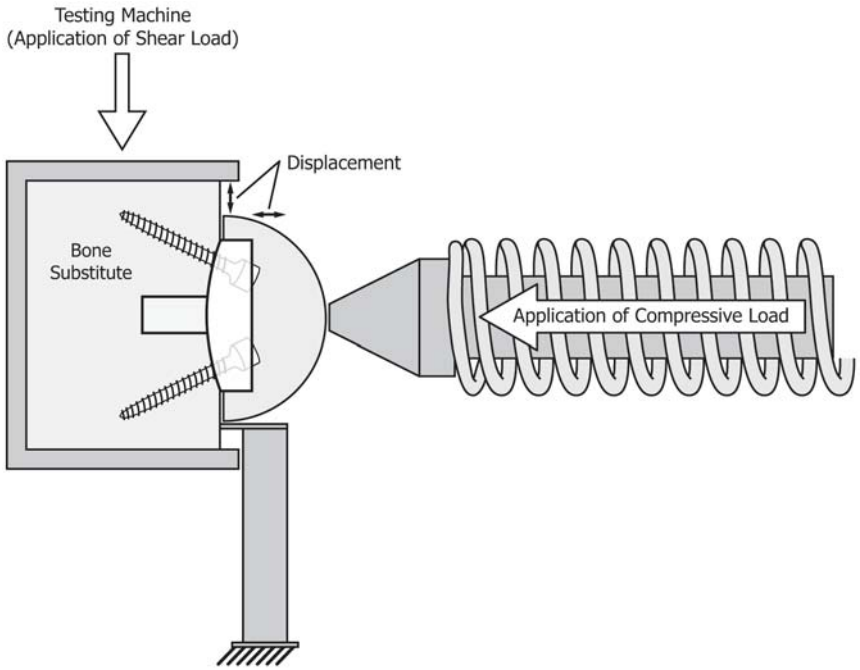

FIG. 7 Alternative Displacement Test Configuration

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.

12.2 The subluxation translation is determined experimentally on the intended test samples or additional components. This is accomplished using a biaxial apparatus (see Fig. 5), by first 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).

12.3 The humeral head is cycled to 90 % of the subluxation distance for a fixed number of cycles (see X1.2). (Cycling to 90 % of the subluxation load would be acceptable, but is not practical because of the large displacements, quick speeds, and deformable polyethylene).

13. Significance and Use

13.1 This test method is intended to investigate the locking mechanism of a modular glenoid. Disassociation of the insert is the greatest issue in modular glenoid components. This test method can be used either to detect potential problems or to compare design features.

14. Apparatus and Equipment

14.1 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 shows the axial load to be horizontal and the shear load to be vertical; however, this arrangement may be reversed.

14.2 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.

14.3 A means to measure the axial load and shear translation is required.

14.4 The tests shall be performed on either mechanical or hydraulic load frames with adequate load capacity and shall meet the criteria of Practices E4.

15. Sampling and Test Specimens

15.1 A minimum of three samples shall be tested. Additional samples may be used to reflect test variability. The test may be conducted along the superior-inferior axis, the anterior-posterior axis, or another axis of interest to the user. The initial shear displacement or load should be set just below the subluxation displacement or load. Each test will result either in a failure or, if no disassociation occurs within the set number of cycles, a runout. The load should be progressively stepped down until at least one runout occurs.

15.2 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.

15.3 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.

15.4 Glenoid and humeral components are used in total shoulder arthroplasty and should conform to the criteria in Specification F1378.

16. Procedure

16.1 The following steps are common to both the subluxation (12.2) and rocking (12.3) tests:

16.1.1 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.

16.1.2 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 run during cycling should be within ±10 % of each other for symmetrical designs).

16.1.3 Perform the measurements in 37°C water (see 14.2, X1.3 and X1.6).

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

16.2 Determine the subluxation translation experimentally on the intended test specimens or separate components (see X1.2):

16.2.1 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.

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

16.2.3 Record the axial load and subluxation translation. The subluxation load is not required for the rocking test, but may be of interest to characterize the prosthesis.

16.3 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 or higher, see X1.7). Maintain the axial load and specified displacement.

16.4 Terminate the test when either the maximum number of cycles has been reached or the glenoid insert disassociates. The load should be set high enough to produce a failure, then reduced to produce at least one runout.

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

17. Report

17.1 The test report shall include the following:

17.1.1 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 materials.

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

17.1.3 *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.

17.1.4 *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.

18. Precision and Bias

18.1 The precision and bias of this test method has not been established. Test results that could be used to establish precision and bias are solicited.

19. Keywords

19.1 arthroplasty; disassociation; glenoid; subluxation; total shoulder replacement

REVERSE SHOULDER GLENOID LOOSENING/ DISASSOCIATION TEST METHOD

20. Summary of Test Method

20.1 The prosthetic reverse glenoid baseplate is fixed with bone screws into a bone substitute using the normal surgical technique.

20.2 The initial glenoid baseplate fixation to the bone substitute is measured before cyclic loading. Fixation can be measured directly from the glenoid baseplate or with the glenosphere assembled. Fixation is measured as an axial compressive load is applied approximately through the center of rotation, perpendicular to the glenoid plane as a shear load is applied parallel to the glenoid plane. The induced displacement of the glenoid baseplate or glenoid baseplate/glenosphere assembly in the directions of the shear and axial compressive loads should be measured. If the glenoid baseplate is noncircular in shape (see Fig. 3), then the shear load should be applied (and the associated displacements measured) along the device's major and minor axes, typically in the superior/inferior and anterior/posterior directions (see X2.10).

20.3 The glenosphere is connected to the glenoid baseplate (if not already assembled), mated with the reverse humeral component, and the assembly is secured to a biaxial apparatus.

20.4 Using the biaxial apparatus, the reverse glenoid component is rotated about the humeral liner for a fixed number of cycles as an axial compressive load is applied through the humeral liner into the glenoid component (see Fig. 8 and X2.6).

20.5 The glenoid fixation is measured after cyclic loading according to the method described in 20.2.

20.6 As this cyclic test loads the reverse shoulder assembly in a physiologically relevant manner, the cyclic test is also applicable to evaluate the resistance of a modular reverse shoulder design to disassociation or dislocation.

21. Significance and Use

21.1 This test method is intended to investigate the resistance of a reverse shoulder glenoid baseplate to loosening, disassociation of modular components, and/or dislocation. Glenoid loosening is a common clinical complication of reverse total shoulder arthroplasty. The method assumes that loosening occurs because of the cyclic loading of conforming articular curvatures and not due to edge loading of nonconforming articular curvatures common to anatomic total shoulder arthroplasty (see X2.2, X2.3, X2.6).

21.2 This test method can be used to detect potential problems and compare design features. Factors affecting loosening performance include the type of screw (for example,

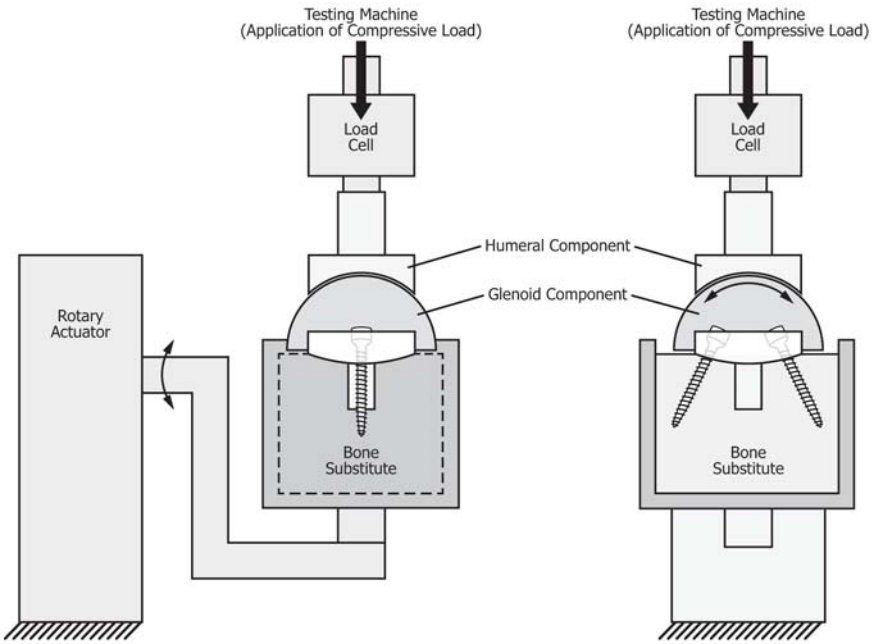

FIG. 8 Biaxial Testing Apparatus for Cyclic Test of Reverse Shoulders

compression versus locking), screw length and diameter, screw angulation, screw positioning or configuration, glenoid baseplate contact area, glenoid baseplate backside geometry (for example, flat or curved), glenoid baseplate fixation post geometry (for example, cylinder, taper, or screw), the amount of the glenoid baseplate pressfit, glenosphere thickness, glenosphere diameter, glenoid component center of rotation (for example, medialized, lateralized, or inferiorly shifted), articular geometry, materials, surface roughness, bone quality, and surgical technique (see X2.4).

21.3 This test method is intended to investigate short-term fixation only and does not evaluate the contribution of biological fixation.

22. Apparatus and Equipment

22.1 The biaxial test apparatus shall be constructed such that an axial compressive load is applied approximately through the center of rotation as the glenoid component is rotated about the humeral liner in the cyclic test (see Fig. 8). Fig. 9 depicts the axial compressive load being applied through the humeral liner as the glenoid component is cyclically rotated in the superior/inferior direction (see X2.6 and X2.7).

22.2 The test apparatus should also permit the application of a shear load approximately parallel to the glenoid plane as an axial compressive load is applied perpendicular to the glenoid plane in the displacement test. Fig. 6 depicts the shear and axial compressive loads applied directly to the glenoid baseplate. The point of application of loading should be chosen to minimize the creation of a moment on the baseplate. Fig. 7 depicts an alternative method in which the shear and axial compressive loads are applied through the glenosphere/glenoid baseplate assembly (see X2.10).

22.3 A bone substitute representing the strength of glenoid cancellous bone shall be used. If a polyurethane foam is used, it shall conform to Specification F1839 (see X2.5).

22.4 The cyclic loading of the reverse components can be performed in air at room temperature; however, the post-cyclic displacement measurements should be made only after the tested components have cooled to room temperature following cyclic loading (for example, 18 to 25°C). A fan or air jet may be used to cool the test components during cyclic loading or the test may be performed in a lubricated environment, if the tester deems this necessary.

22.5 A means to measure the axial compressive load and the angle of rotation during cyclic loading is required during the cyclic test. A means to measure the axial compressive load, shear load, and the glenoid baseplate displacement (or glenosphere/glenoid baseplate assembly displacement) in the directions of both the shear and axial compressive loads is required during the displacement test (see Fig. 5, Fig. 6, Fig. 7, and X2.4).

22.6 The tests shall be performed on either electromechanical or servohydraulic load frames with adequate load capacity and shall meet the criteria of Practices E4. A loading frequency of 0.5 Hz is recommended; however, a faster or slower rate of rotation may be used if desired though it should not exceed 1.0 Hz (see X2.9).

23. Sampling and Test Specimens

23.1 A minimum of three samples shall be tested. Additional samples may be used to reflect test variability. The reverse glenoid component should be cyclically rotated about the humeral liner along the superior-inferior glenoid axis as

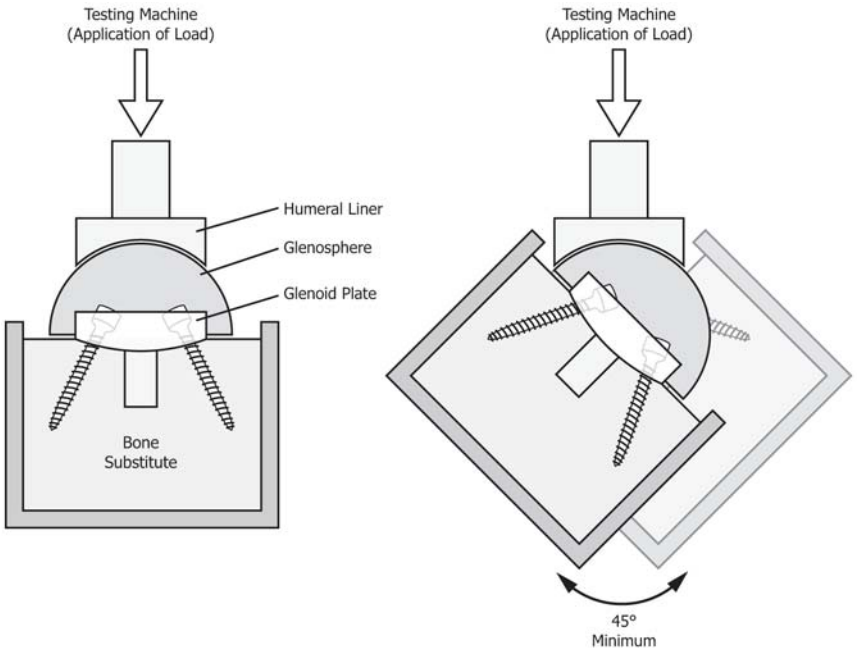

FIG. 9 Cyclic Test Configuration

this simulates humeral abduction, the primary motion generated by the deltoid. The displacement test should be conducted such that displacement is measured in the directions of both the applied shear and axial compressive loads; however, this shear load may be applied along the superior-inferior axis, the anterior-posterior axis, or another axis of interest to the user. If the glenoid baseplate is noncircular in shape (see Fig. 3), then the shear load should be applied (and the associated displacements measured) along the devices major and minor axes (see X2.10).

23.2 All reverse glenoid components shall be in the final manufactured condition. The same glenosphere may be used for all tests unless the surface or locking mechanism becomes damaged.

23.3 The humeral liner shall include the identical radius or radii and material as the actual implant. If the test is also being used to assess the resistance of the humeral component design to disassociation, the mating locking mechanisms shall also be in the final manufactured condition. Other features of the humeral component such as the shaft/stem may be omitted. A new humeral liner should be used in each test.

23.4 All plastic components shall be sterilized according to the manufacturer-recommended specifications for clinical use.

23.5 Glenoid and humeral components used in reverse total shoulder arthroplasty should conform to the criteria specified in Specification F1378.

24. Procedure

24.1 Method to measure the initial glenoid baseplate (or glenosphere/glenoid baseplate assembly) displacement (see Fig. 6 and Fig. 7).

24.1.1 Secure the glenoid baseplate to the bone substitute with bone screws using the normal surgical technique and instrumentation.

24.1.2 Position the glenoid component in the testing apparatus so that a shear load can be applied parallel to the glenoid plane as an axial compressive load is applied perpendicular to the glenoid plane, approximately through the center of rotation (see Fig. 6 and Fig. 7).

24.1.3 Apply a shear load of 350N ± 15N as an axial compressive load of 430N ± 15N is applied perpendicular to the glenoid plane, the rate of the shear and compressive loads should not exceed 200N/sec (see Fig. 6, Fig. 7, and X2.10). A smaller magnitude compressive load may be applied if desired.

24.1.4 Record the applied shear and axial compressive loads.

24.1.5 Use a dial indicator or similar device to measure the initial (pre-cyclic loading) displacement of the glenoid component in the directions of both the applied shear and axial compressive loads. Static measurements can be performed at room temperature. A measurement accuracy of at least 5 μm is required.

24.1.6 Record the glenoid baseplate (or glenosphere/glenoid baseplate assembly) displacement in the directions of both the applied shear and axial compressive loads at the peak shear/compression loads.

24.1.7 Unload the specimen and repeat sections 24.1.2 through 24.1.6 with the same specimen for a total of at least three displacement measurement sets.

24.2 Method to cyclically load the reverse glenoid components (see Fig. 8 and Fig. 9).

24.2.1 Secure the glenosphere to the glenoid baseplate and position the components in the biaxial testing apparatus.

24.2.2 Secure the humeral liner component in the biaxial testing apparatus and align the center of the humeral liner with the reverse glenoid component.

24.2.3 Apply an axial compressive load of 750N ± 15N to the back of the humeral liner through the center of rotation. A larger magnitude compressive load may be applied if desired (see Fig. 8 and X2.8).

24.2.4 Rotate the glenoid component about the humeral liner along the superior-inferior axis for 10,000 cycles at a rate of 0.5 Hz; the glenoid component should be rotated at least 45° (see Fig. 9, X2.7, and X2.9). The angular position of the glenoid component may be biased at any position along the superior/inferior axis, if the tester deems this necessary.

24.2.5 Testing may be conducted in air at room temperature; a fan or air jet may be used to cool the test components during cyclic loading or the test may be performed in a lubricated environment, if the tester deems this necessary.

24.2.6 Record the axial load and the magnitude of glenoid component rotation. The test shall be terminated if the construct dislocates, disassociates, or fails in any way.

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

24.3 Method to measure the post-cyclic glenoid baseplate (or glenosphere/glenoid baseplate assembly) displacement (see Fig. 6 and Fig. 7).

24.3.1 Dislocate the glenoid component from the humeral liner.

24.3.2 Position the glenoid component in the testing apparatus so that a shear load can be applied parallel to the glenoid plane as an axial compressive load is applied perpendicular to the glenoid plane approximately through the center of rotation (see Fig. 6 and Fig. 7).

24.3.3 Apply a shear load of 350N ± 15N as an axial compressive load of 430N ± 15N is applied perpendicular to the glenoid plane, the rate of the shear and compressive loads should not exceed 200N/sec (see Fig. 6, Fig. 7, and X2.10). A smaller magnitude compressive load may be applied if desired.

24.3.4 Record the applied shear and axial compressive loads.

24.3.5 Use a dial indicator or similar device to measure the post-cyclic loading displacement of the glenoid component in the directions of both the applied shear and axial compressive loads. Static measurements can be performed at room temperature.

24.3.6 Record the glenoid baseplate (or glenosphere/glenoid baseplate assembly) displacement in the directions of both the applied shear and axial compressive loads at the peak shear/compression loads.

24.3.7 Unload the specimen and repeat sections 24.3.2 through 24.3.6 with the same specimen for a total of at least three displacement measurement sets.

25. Report

25.1 The test report shall include the following:

25.1.1 All details relevant to the particular implants tested including type, size (for example, glenosphere radius and glenosphere thickness), and lot number as well as the number/location of screws used, the orientation of the glenoid components, and the density of polyurethane bone substitute used.

25.1.2 The axis and direction of cyclic testing, for example, superior-inferior.

25.1.3 The axis and direction of displacement testing, for example, superior-inferior, anterior-posterior, or another axis of interest to the user.

25.1.4 Environmental temperature during testing.

25.1.5 Use of lubricant or cooling of the bearing surface during testing.

25.1.6 *Cyclic Test*—The axial load, amount of glenoid component rotation, maximum number of cycles, testing frequency, and cause of test termination. Testing parameters that differ from those recommended shall be justified (see X2.6).

25.1.7 *Displacement Test*—The glenoid component displacements before and after cycling and the magnitude of axial compressive and shear loads associated with each displacement measurement (see X2.10).

26. Precision and Bias

26.1 The precision and bias of this test method has not been established. Test results that could be used to establish precision and bias are solicited.

27. Keywords

27.1 arthroplasty; glenoid loosening; reverse total shoulder replacement; subluxation

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE FOR ANATOMIC SHOULDER GLENOID LOOSENING TEST

X1.1 These test methods characterize the dynamic loosening of a glenoid component or the locking mechanism of a modular glenoid component. Glenoid loosening is the most common clinical complication in total shoulder arthroplasty (**1, 2**),[3] and modular disassociations have been reported clinically. Many surgeons consequently limit the indications for implanting a glenoid prosthesis (**2**) despite improvements in pain relief, range of motion, and patient satisfaction associated with glenoid replacement (**3**). Although glenoid loosening is multifactorial (**2, 4**), some designs showed high failure rates (**1, 2**). Thus, a test that can compare the physical performance of different glenoid prostheses is valuable.

X1.2 The cyclic displacement was chosen to be close (for example, 90 %) to the subluxation translation because loosening is suggested to be due to eccentric loading on the glenoid rim (**1, 2, 4**). Neither testing to a fixed translation nor testing to a fixed load would lead to rim loading for all shapes and sizes (imagine the very smallest, very largest, most constrained, and least constrained prostheses). Therefore, a translation relative to the subluxation distance was chosen as the consistent criterion. Highly constrained prostheses have shown higher loosening rates (**2**) because all shoulder loads were transferred via the prosthesis to the bone. In less constrained designs, active and passive soft tissues carry a greater load. Thus higher loads for a more constrained design are justified. Cycling relative to the subluxation load would be justifiable, but is not practical because of the large displacements, quick speeds, and deformable polyethylene. The subluxation translation shall be determined experimentally because, as a result of polyethylene deformation, it cannot be predicted from rigid-body theory (**5**). For example, the vertical rigid-body-predicted subluxation translation for a conforming prosthesis would be zero.

X1.3 Dynamic testing is necessary because the ranking of all-polyethylene prostheses cannot be predicted from the initial static prerocking measurements (**6**).

X1.4 Although normal loading on the glenohumeral joint is low, even daily living activities can exert several times body weight across the joint. An axial load of 750 N, as recommended in these test methods, leads to resultant loads of between about 800 and 1000 N, depending on the glenoid geometry or about one to one-and-a-half times body weight. This represents carrying a 5- to 8-kg object at the side or lifting a 2- to 4-kg load to shoulder height and is even less than that exerted while getting out of a chair or walking with a cane (**7**). Higher loads could be justified for component strength testing but do not represent typical performance.

X1.5 Glenoid loosening normally occurs at the bone-cement interface. Since this represents a system failure rather than component failure, the mechanical properties of the bone substitute are important (**8**). Rigid polyurethane bone substitute (compressive modulus (E) = 193 MPa and strength (σ_u) = 7.6 MPa) provides a suitable substitute for glenoid bone (**5, 6**). Although it is advantageous to use a consistent bone substitute, and cancellous bone represents the worst-case condition, the user is permitted to use a different bone model. At the load and cycle numbers used in these test methods, a gap between the prosthesis and bone substitute typically does not occur. The substrate is not important when testing for modular disassociation.

[3] The boldface numbers in parentheses refer to the list of references at the end of this standard.

X1.6 The dynamic tests shall be performed in water because testing in air resulted in disintegration of the bone substitute, extrusion of the cement, and component breakage. The water acts both as a lubricant and a temperature controller. A modular locking mechanism should be tested at 37°C since the properties of polyethylene change with temperature. Circulation of the water is recommended, but not required because of the relatively short duration of the test.

X1.7 The number of cycles is currently suggested to be 100 000 because the test does not investigate component strength; activities causing higher loads at the shoulder occur much less frequently than in the lower limb; and people with shoulder prostheses would be expected to load their arms even less frequently. This number of cycles would represent approximately 25 higher-load activities a day for 10 years. Testing may be continued to a higher number of cycles if desired, especially when testing a modular locking mechanism.

X1.8 Various methods were used to measure the edge displacements during the precision and bias round robin testing. While the suggested method is to use DVRTs or LVDTs in contact with screws placed within the glenoid component, one laboratory reported using DVRTs that were mounted directly to the glenoid component. One laboratory ran the test with a surface lubricant, noting that the LVDTs could not be operated in the fluid environment dictated in the standard. Other laboratories reported problems with using screws placed in the glenoid component, as the humeral head articulating over the glenoid surface resulted in local deformation that caused displacement of the screw relative to the glenoid component itself. One laboratory mitigated this effect by placing the screws within the glenoid at an angle to reduce the proximity of the screw to the articulating surface.

X1.9 Although the glenoid fossa is not truly a planar structure, the terms “plane of the glenoid” and “glenoid plane” have both been used in the scientific literature to describe the anatomic orientation of the glenoid.

X2. RATIONALE FOR REVERSE SHOULDER GLENOID LOOSENING/DISASSOCIATION TEST

X2.1 Reverse shoulder arthroplasty has been demonstrated to be a viable treatment option for patients suffering from cuff tear arthropathy and other degenerative diseases of the glenohumeral joint in which the fixed fulcrum created by the inverted articular curvatures (that is, the convex glenoid and the concave humerus) provide the stability necessary for shoulder function (**9**, **10**, **11**, **12**, **13**, **14**). Because of these significant improvements in both pain and function for certain patients in which there is no other treatment option, reverse shoulders are also commonly used in revision and salvage procedures in the elderly in which both the soft and hard tissue are sometimes severely compromised (**9**, **13**, **14**, **15**, **16**, **17**, **18**, **19**).

X2.2 Short and mid-term clinical outcome studies have reported aseptic glenoid loosening rates between 0 and 12 %, with an average rate of approximately 5 % (**10**, **11**, **12**, **13**, **14**, **19**).

X2.3 Recent biomechanical studies in the literature demonstrate a widespread desire to reduce the glenoid loosening rate (**20**, **21**, **22**, **23**, **24**, **25**, **26**, **27**, **28**, **29**). This dynamic test method is intended to simulate the physiological loading conditions typical of a reverse shoulder (see X2.6). And as such, this method is appropriate to quantify the displacement describing the initial fixation of the reverse shoulder glenoid component and for evaluating the locking mechanisms of the reverse shoulder modular components. This test method has been utilized to demonstrate significant differences in displacement between different screw configurations, medialized/lateralized center of rotation, glenoid baseplate designs, scapular defects and wear patterns, and different densities of bone substrates (**25**, **26**, **27**, **28**, **29**). This test method does not address the long-term effects of impingement on glenoid loosening nor does it assess biologic fixation.

X2.4 The factors influencing the reverse shoulder glenoid loosening rate are numerous: the loosening rate is expected to increase with time, with poorer quality bone, and when secured to structurally compromised/worn bone. Because the reverse shoulder glenoid component is uncemented, glenoid loosening can occur due to an insufficient initial fixation to promote osseous integration, the absence of this long-term fixation is likely to result in screw fatigue failure and aseptic glenoid loosening (**10**). For this reason, this test method recommends quantifying glenoid plate displacement before and after the application of a dynamic physiologically relevant load. While this method does not judge performance based upon any particular displacement magnitude, it is worth noting that 150 µm is the generally accepted displacement threshold to promote osseous integration and long-term fixation in bone (**30**, **31**, **32**). The relevance of this 150 µm displacement threshold to this method is limited by the density of the substrate used to perform the test.

X2.5 This test method recommends the use of a rigid polyurethane bone substitute conforming to Specification F1839. Due to the predominately older and female recipient population for reverse shoulders, a 0.24 or 0.32 g/cm^3 (15 or 20 lb/ft^3) density polyurethane block is recommended. A substrate of this type provides a suitable substitute for the density, strength, and modulus of glenoid cancellous bone in the recipient patient population for reverse shoulders (**8**, **33**, **34**, **35**). Although it is advantageous to use a consistent bone substitute, and cancellous bone represents the worst-case condition, the user is permitted to use a different bone model.

X2.6 The method of dynamic rotation was chosen to simulate the primary motion of a reverse shoulder, the motion generated by the deltoid (for example, abduction) (**9**, **36**). Initial static measurements at a given angle are insufficient to

simulate this physiologic loading pattern. This reverse shoulder test method differs from that of the anatomic glenoid test method. The reverse shoulder glenoid and humeral articular components are semiconstrained and conforming, and only permit rotation; whereas, the anatomic glenoid and humeral components are unconstrained and nonconforming and permit both rotation and translation. Additionally, the deltoid forces subjected to the reverse shoulder fixed fulcrum are transmitted into rotation; whereas, those subjected to the anatomic shoulder manifest themselves in humeral head migration/glenoid edge loading.

X2.7 The arc of rotation selected is design-dependant and a function of the articulating geometry of the humeral liner and glenosphere; specifically, the magnitude of rotation is expected to change based upon the curvature and constraint of the humeral liner, the curvature and thickness of the glenosphere, and the center of rotation of the glenoid component (be it lateralized, medialized, or inferiorly shifted) (**37**, **38**, **39**, **40**). This rotation simulates the motion of the glenoid component relative to a fixed humeral component; therefore, a humeral/scapula rhythm is not simulated in this method. This method recommends rotating the glenoid component relative to a fixed humeral component to ensure a shear load is transmitted to the glenoid component during cyclic loading. This method recommends a minimum arc of rotation of 45°, Forty five degrees is considered a minimum threshold that is achievable for even the most constrained humeral liner designs; (**41**) additional rotation may occur if desired.

X2.8 The magnitude of cyclic loading was selected to reflect that typical of a normal shoulder in order to simulate a worst-case scenario for the reverse shoulder. We recognize worst-case loading for reverse shoulders is expected to be less than that for normal shoulders (for example, 0.89*body weight (BW) (**42**, **43**, **44**) due to the impaired rotator cuff muscles, its predominate use in older patients with limited needs, and due to features inherent to the design of the reverse shoulder itself, such as the modified muscle moment arms (which improves the efficiency of the deltoid and requires less force for a given motion) (**9**, **43**, **45**, **46**, **47**, **48**). In order to simulate the worst-case loading scenario for the assumed body weight of 86kg, this test method recommends a 750N ± 15N (0.89*86kg) axial compressive load during the cyclic test, though additional load may be applied if desired.

X2.9 The number of cycles is recommended to be 10,000. Although 10,000 cycles is low relative to hip and knee testing and less than that recommended for the Test Methods F2028 anatomic total shoulder glenoid loosening test, this value is justified because the test does not simulate prosthesis wear related failure modes, high-load activities are less likely with the reverse shoulder, and finally, because the reverse glenoid component is uncemented (**6**, **7**, **23**). Testing may be continued to a higher number of cycles if desired. The rate of rotation is recommended to be 0.5 Hz to reduce the heat generated from the articulation; a faster or slower rate of rotation may be used if desired though it should not exceed 1.0 Hz.

X2.10 The method to quantify glenoid component displacement was selected in order to quantify the displacement in a worst-case loading configuration, when the maximum shear load is expected to be experienced. The maximum shear load in a normal shoulder was described by Poppen and Walker, to occur at 60° abduction and is approximately 0.42*BW (**44**). Poppen and Walker described the corresponding axial compressive load at this shear load to be approximately 0.51*BW (**44**). These shear and compressive loading values describing a normal shoulder were assumed to follow the same pattern for a reverse shoulder. For the assumed body weight of 86kg, the peak shear force assumed for the reverse shoulder is approximately 350N ± 15N (0.42*86kg, rounded down from 354N) and the corresponding axial compressive force assumed for the reverse shoulder at that shear load is approximately 430N ± 15N (0.51*86kg).

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