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AMERICAN SOCIETY FOR TESTING AND MATERIALS
100 Barr Harbor Dr., West Conshohocken, PA 19428
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Standard Test Method for Static Evaluation of the Glenoid Locking Mechanism in Shear[1]

This standard is issued under the fixed designation F 1829; 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 practice covers a method for determining the static shear disassembly force of modular glenoid components used in shoulder prostheses. It is intended to be used as a design validation and for comparison with other prostheses.

1.2 This test method covers modular glenoid components comprised of a separate articular insert and backing. The insert and backing can be fabricated from any combination of the following materials: metal alloys, polymeric materials, composite 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:*

E 4 Practices for Force Verification of Testing Machines[2]

F 1378 Specification for Shoulder Prosthesis[3]

3. Terminology

3.1 *Definitions:*

3.1.1 *articular insert*—the polymeric prosthetic portion of a multiple piece glenoid component that articulates with the humeral head.

3.1.2 *"d"*—offset distance from the edge of the glenoid backing locking mechanism to the centerline of the point of load application on the articular insert as shown in Fig. 1 and Fig. 2.

3.1.3 *glenoid backing*—the metallic or composite material prosthetic portion of a multiple piece glenoid component that attaches to the scapula.

3.1.4 *glenoid component*—the prosthetic portion that replaces the glenoid fossa of the scapula and articulates with the natural humeral head or a prosthetic replacement.

4. Significance and Use

4.1 This test method can be used to describe the effects of materials, manufacturing, and design variables on the performance of metal backed glenoid prostheses locking mechanisms to resist static shear loading.

4.2 The glenoid component is used in shoulder replacements and should conform to the criteria specified in Specification F 1378.

4.3 The loading of metal backed glenoid prostheses in vivo will, in general, differ from the loading defined in this test method. The results obtained here can not be used to directly predict in vivo performance. However, this test method is designed to allow for comparisons between different metal backed glenoid locking mechanism designs, when tested under similar circumstances.

4.4 This test method may not be appropriate for all types of implant applications. The user is cautioned to consider the appropriateness of the method in view of the materials being tested and their potential application.

4.5 In order for the test data on metal backed glenoid components to be comparable, reproducible, and capable of being correlated among laboratories, it is essential that uniform procedures be established.

5. Apparatus

5.1 The test fixture shall be constructed so that the line of load application is parallel to the intended axis of the implant (that is, inferior to superior or anterior to posterior).

6. Equipment

6.1 The tests will be performed on either mechanical or hydraulic load frames with adequate load capacity and that meet the criteria of Practices E 4.

7. Sampling

7.1 A minimum of five samples with the load oriented in the inferior to superior direction shall be tested per device.

7.2 A minimum of five samples with the load oriented in the

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[2] *Annual Book of ASTM Standards*, Vol 03.01.

[3] *Annual Book of ASTM Standards*, Vol 13.01.

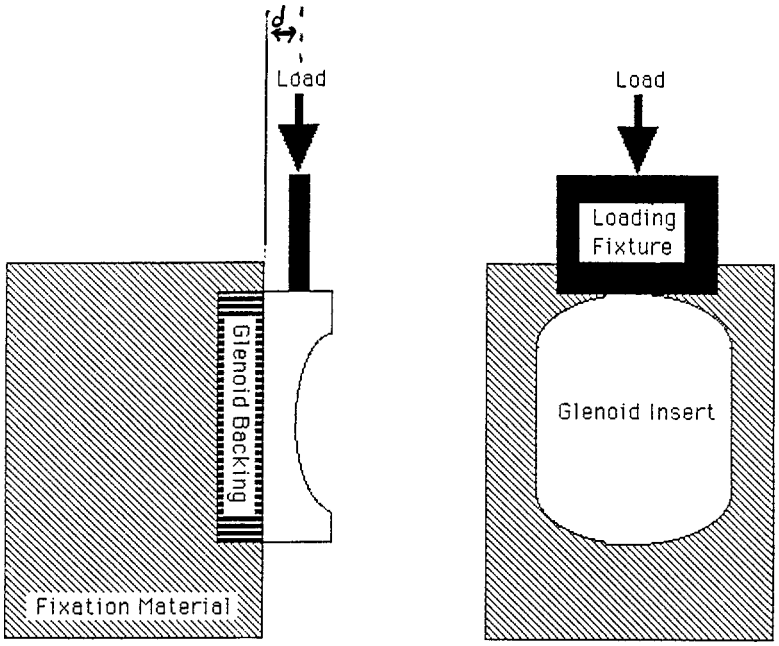

FIG. 1 Schematic of Static Glenoid Locking Strength Inferior to Superior Direction

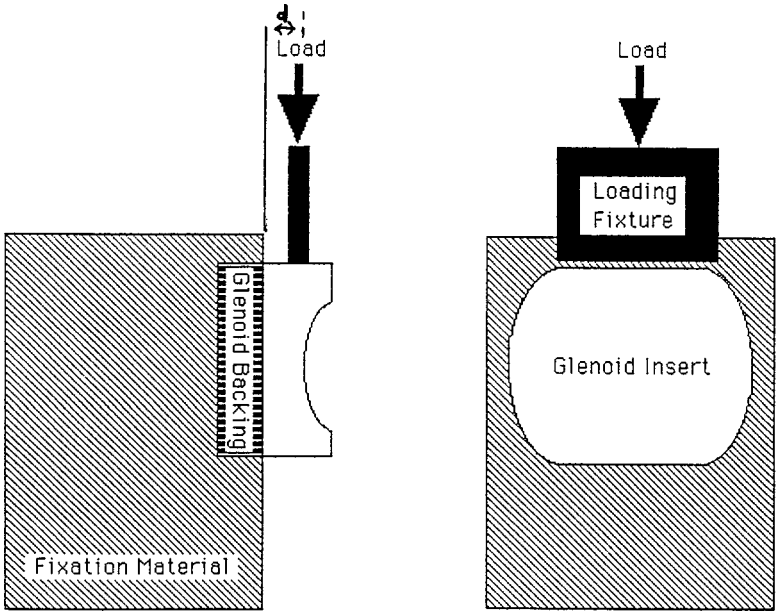

FIG. 2 Schematic of Static Glenoid Locking Strength Anterior to Posterior Direction

anterior to posterior direction shall be tested per device.

8. Sample and Test Specimen

8.1 All articular insert test components shall be representative of final manufactured implant quality products.

8.2 Glenoid backing test components may either be in the form of the final implant or may be a simplified model with the exact locking mechanism to be used on the final implant. The materials and surface shall be representative of implant quality products. All manufacturing processes (including heat treatment) should be followed.

8.3 All components should be sterilized according to manufacturer recommended specifications for clinical use, if this process could affect the results.

8.4 A new articular insert should be used for each test.

9. Procedure

9.1 Following proper assembly of an insert into a backing, the assembly is attached to the test machine such that the load is applied in an inferior to superior direction (see Fig. 1).

9.2 This test is to be performed in air at room temperature. It is permissible to perform this test in simulated physiological environment if the conditions of the test environment are recorded (that is, temperature, humidity, fluid).

9.3 Apply a vertical load to the assembly offset at a specified distance from the locking mechanism.

9.4 Load should be applied to the articular insert with a blunt edge loading applicator.

9.5 A constant displacement rate should be used and recorded (for example, 25.4 mm/min).

9.6 Testing of samples shall be terminated when one of the following occurs:

9.6.1 The articular insert disengages from the glenoid backing,

9.6.2 The disengagement force has reached a maximum and continues to decrease, and

9.6.3 Gross deformation of the insert occurs without dislocation of the insert.

9.7 Record load versus displacement and the failure mode. The glenoid backing should be visually inspected for damage after each test run.

9.8 Repeat the procedure with a new insert and with the load applied in an anterior to posterior direction (see Fig. 2).

10. Report

10.1 The test report shall include the following:

10.1.1 All details relevant to the particular implants tested (that is, size, thickness, materials). If the glenoid component is not symmetric then details of the non-symmetry and its relation to the test configuration should be specified,

10.1.2 The distance, "*d*", between the top of the locking mechanism and the centerline of the point of load application (see Fig. 1),

10.1.3 The displacement rate,

10.1.4 The maximum load to failure,

10.1.5 The failure mode,

10.1.6 The indentor loading applicator configuration.

10.1.7 Number of glenoid backing test components used.

11. Precision and Bias

11.1 The precision and bias of this test method needs to be established. Test results that can be used to establish precision and bias are solicited.

12. Keywords

12.1 arthroplasty; disassembly; glenoid; modular; orthopaedic medical devices; shoulder arthroplasty

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 A minimum of five test specimens is recommended for this test method. The investigator should determine if additional specimens are required. Statistical methods that take into account variability in the components being tested may be used to achieve the desired level of significance.

X1.2 This test method is intended to allow the investigator to compare different glenoid locking mechanism designs as subjected to shear loading. This test method is not intended to test for all modes of failure or loading to which the component may be subjected. The investigator should determine if additional test conditions are necessary. It is believed that fatigue, particularly in a rocking motion, is more likely to cause disassembly of the glenoid locking mechanism clinically and will provide further insight into the glenoid components behavior.

X1.3 The size of the glenoid component shall be determined by the investigator. In general, the worst case size should be chosen based on evaluation or experience. There may also be a reason why an investigator wishes to test a size that is not worst case. This test method may also be used for this purpose.

X1.4 Worst case loading of the glenoid component may vary depending on material, design, and clinical indications. The investigator shall evaluate the possible clinical and design-related failure modes and attempt to determine a worst case condition.

X1.5 It is recognized that for some materials the environment may have an effect on the response to loading. The test environment used and the rationale for that choice shall be described in the test report.

X1.6 The loading of metal backed glenoid prostheses in vivo will, in general, differ from the loading defined in this test method. The results obtained here cannot be used to directly predict in vivo performance. The results obtained from this test method do not imply that the prosthesis will be clinically successful.