Designation: F 2028 – 02

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 The test method covers shoulder replacement designs with both monolithic and modular humeral and glenoid components with either cemented or noncemented 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.

2. Referenced Documents

2.1 *ASTM Standards:*

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

F 1378 Specification for Shoulder Prostheses[3]

F 1839 Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments[3]

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 symmetric glenoids, the plane is defined by joining the two articular edges; in planar and asymmetric glenoids, it is defined by the back surface.

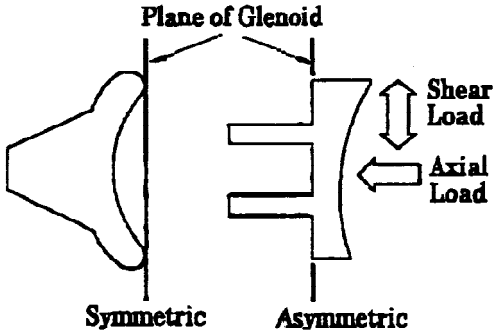

FIG. 1 Glenoid Plane and Load Directions

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.

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 Fig. 2).

3.1.9 *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).

---

[1] These test methods are under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and are the direct responsibility of Subcommittee F04.22 on Arthroplasty.

Current edition approved Nov. 10, 2002. Published December 2002. Originally approved in 2000. Last previous edition approved in 2000 as F 2028 – 00ε1.

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

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

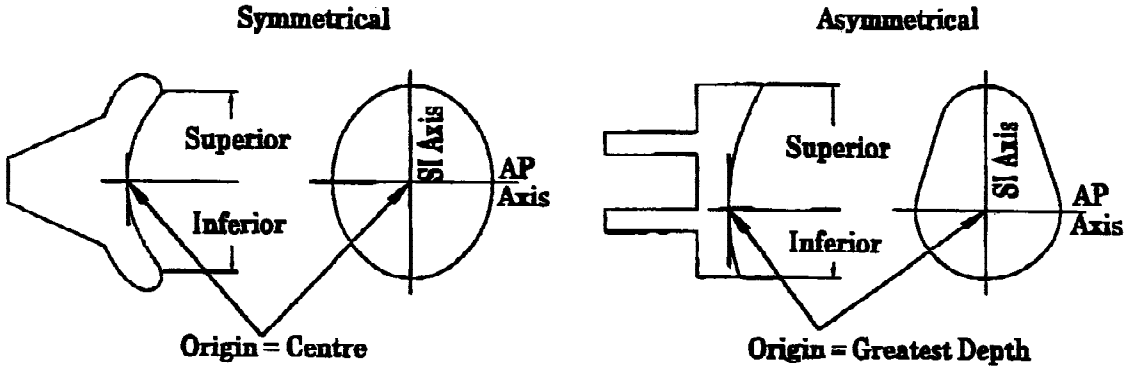

FIG. 2 Glenoid Axes and Origin

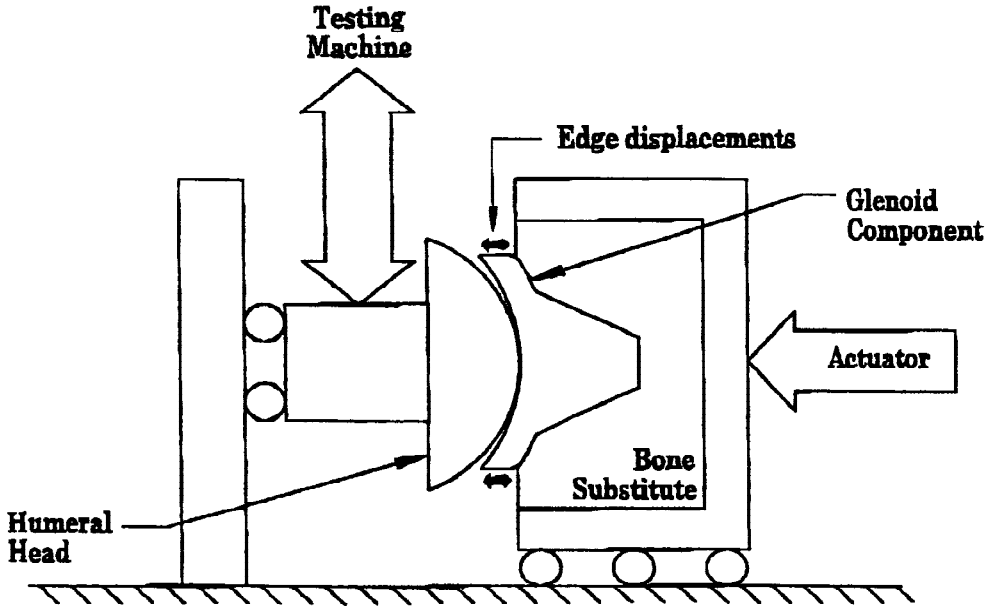

FIG. 3 Biaxial Testing Apparatus

GLENOID LOOSENING TEST METHOD

4. Summary of Test Method

4.1 The prosthetic glenoid component is fixed 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. 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 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 The 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 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 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 using the normal surgical procedure and instrumentation using bone cement for cemented components and mechanical fixation for noncemented components. Do not perform tests until the cement has properly cured.

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.

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.

8.3.2 Rest a displacement measuring device, for example, an LVDT, DVRT, or dial gauge, on each foundation to measure the displacements perpendicular to the glenoid plane. 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).

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 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.

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 in to a bone substitute or grouting agent 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. 3), 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 practically feasible 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. The 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. 1). Fig. 3 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 (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.

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

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

15. Sampling and Test Specimens

15.1 A minimum of three samples shall be tested. 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 specified in Specification F 1378.

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 using the normal surgical procedure and instrumentation, using bone cement for cemented components and mechanical fixation for noncemented components. Do not perform tests until the cement has properly cured.

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 N (169 lb) ± 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 (2 in./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

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

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)**, 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 to (for example, 90 %) 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), thus 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 practically feasible because of the large displacements, quick speeds, and deformable polyethylene. The subluxation translation must 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 does not typically occur between the prosthesis and bone substitute. The substrate is not important when testing for modular disassociation.

X1.6 The dynamic tests must 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.

REFERENCES

(**1**) Cofield, R.H. and Edgerton, B.C., "Total shoulder arthroplasty: complications and revision surgery," *Inst. Course Lect*., 39:(1990)449-462.

(**2**) Wirth, M.A. and Rockwood, C.A., Jr., "Current concepts review: complications of total shoulder replacement arthroplasty," *J. Bone Joint Surg [Am.]*, 78A(4):(1996)603-616.

(**3**) Boyd, A.D., Thomas, W.H., Scott, R.D., et al, "Total shoulder arthroplasty versus hemiarthroplasty," *J. Arthroplasty*, 5(4):(1990)329-336.

(**4**) Franklin, J.L., Barrett, W.P., Jackins, S.E., and Matsen, F.A. III, "Glenoid loosening in total shoulder arthroplasty: association with rotator cuff deficiency," *J. Arthroplasty*, 3(1):(1988)39-46.

(**5**) Anglin, C., Wyss, U.P., and Pichora, D.R., "Shoulder prosthesis subluxation: theory and experiment," *J. Shoulder Elbow Surgery* (2000).

(**6**) Anglin, C., Wyss, U.P., and Pichora, D.R., "Mechanical testing of shoulder prostheses and recommendations for glenoid design," *J. Shoulder Elbow Surgery* (2000).

(**7**) Anglin, C., Wyss, U.P., and Pichora, D.R., "Glenohumeral contact forces," *Proc. Instn. Mech. Engrs. [H]* (2000).

(**8**) Anglin, C., Tolhurst, P., Wyss, U.P., and Pichora, D.R., "Glenoid cancellous bone strength and modulus," *J. Biomechanics*, 32(10):(1999)1091-1097.