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Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion[1]

This standard is issued under the fixed designation F 1440; 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 describes a method for the fatigue testing of metallic stemmed femoral components used in hip arthroplasty. The described method is intended to be used to evaluate the comparison of various designs and materials used for stemmed femoral components used in the arthroplasty. This practice covers procedures for the performance of fatigue tests using (as a forcing function) a periodic constant amplitude force.

1.2 This practice applies primarily to one-piece prostheses and modular components, with head in place such that prostheses should not have an anterior/posterior bow, and should have a nearly straight section on the distal 50 mm of the stem. This practice may require modifications to accommodate other femoral stem designs.

1.3 The values stated in SI units are to be regarded as the standard.

1.4 For additional information see Refs. **(1-5)** .

2. Referenced Documents

2.1 *ASTM Standards:*

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

E 466 Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials[2]

E 467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System[2]

E 468 Practice for Presentation of Constant Amplitude Fatigue Test Results for Metallic Materials[2]

3. Terminology

3.1 *Definitions and Symbols* (see Fig. 1(*a*) and 1(*b*)):

3.1.1 *cantilever plane*—a plane perpendicular to the line of load application at the level on the stem where the stem becomes unsupported.

3.1.2 *distal stem axis*—the centerline in the anterior/posterior projection of the most distal 50 mm of the stem.

3.1.3 *estimated maximum bending moment*—the maximum load times the unloaded moment arm.

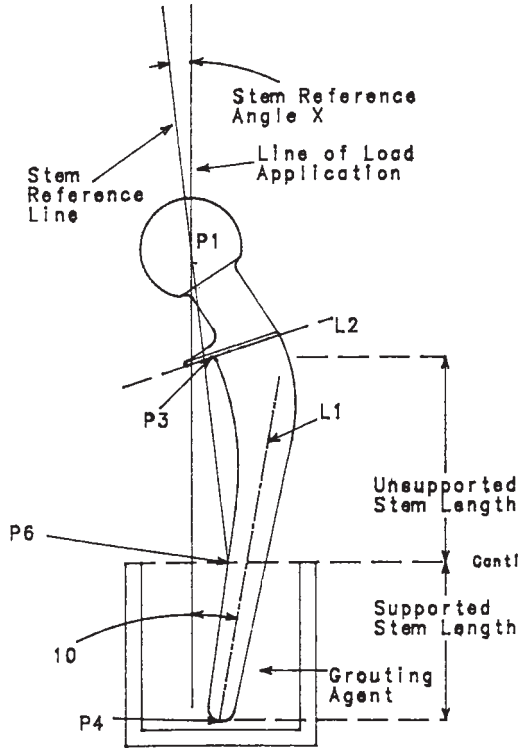

FIG. 1 Collared Device

3.1.4 *geometric centroid (cantilever plane)*— the point in a cross-sectional area of the cantilever plane whose coordinates are the mean values of the coordinates of all the points in the area.

3.1.5 *line of load application*—the loading axis of the test machine.

3.1.6 *Reference Line L1, distal stem axis*—the medial-lateral (M-L) centerline of the most distal 50 mm of stem in the A-P projection.

3.1.7 *Reference Line L2*:

3.1.7.1 *collared device*— the plane of the distal side of the collar in the A-P projection.

3.1.7.2 *collarless device*—the resection plane recommended for the device in the A-P projection.

3.1.8 *Reference Point P1*—the spherical center of the prosthesis head.

3.1.9 *Reference Point P3*:

[1] This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.22 on Arthroplasty.

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

3.1.9.1 *collared device*— the intersection of the principal axis of the collar (L2) with the medial surface of the stem in the A-P projection.

3.1.9.2 *collarless device*—the intersection of the resection plane (L2) with the medial surface of the stem in the A-P projection.

3.1.10 *Reference Point P4*—the distal tip of the stem.

3.1.11 *Reference Point P6*[3]— the intersection of the cantilever plane with the medial surface of the stem in the A-P projection.

3.1.12 *R value*—the *R* value is the ratio of the minimum force to the maximum force.

$$R = \frac{\text{minimum force}}{\text{maximum force}}$$

3.1.13 *Stem Reference Angle X*—the angle between the stem reference line and the line of load application.

3.1.14 *stem reference line*—a line passing through Reference Point P6 and the center of the prosthesis head (P1).

3.1.15 *supported stem length*—the vertical distance between the distal tip of the stem (P4) and the cantilever plane.

3.1.16 *unloaded moment arm*—the perpendicular distance between the line of load application and the geometric centroid of the stem cross section at the cantilever plane.

3.1.17 *unsupported stem length*—the vertical distance between Point P3 and the cantilever plane.

3.2 See Figs. 1 and 2.

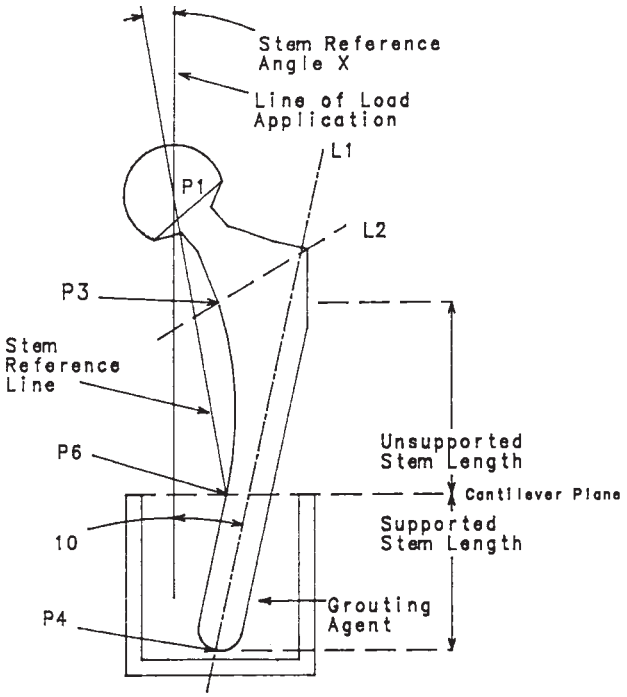

FIG. 2 Collarless Device

4. Significance and Use

4.1 This practice can be used to describe the effects of materials, manufacturing, and design variables on the fatigue resistance of metallic stemmed femoral components subjected to cyclic loading for relatively large numbers of cycles. The recommended test assumes a "worst case" situation where proximal support for the stem has been lost. It is also recognized that for some materials the environment may have an effect on the response to cyclic loading. The test environment used and the rationale for the choice of that environment should be described in the report.

4.2 It is recognized that actual *in vivo* loading conditions are not constant amplitude. However, there is not sufficient information available to crate standard load spectrums for metallic stemmed femoral components. Accordingly, a simple periodic constant amplitude force is recommended.

4.3 In order for fatigue data on femoral stems to be useful for comparison, it must be reproducible among different laboratories. Consequently, it is essential that uniform procedures be established.

5. Specimen Selection

5.1 The specimen selection should have the same geometry as the final finished product, and the stem should be in the final finished condition.

6. Apparatus

6.1 The specimen shall be constrained by a suitable grouting agent within a rigid cavity. A common grouting agent used is poly methyl methacrylate (PMMA—bone cement) that is polymerized in place. The minimum thickness of the grouting agent should be 1 cm. Although bone cement is the recommended grouting agent, other material may be used provided it does not chemically or mechanically interact with the test specimen.

6.2 The test fixtures shall be constructed so that the line of load application is in the implant anterior/posterior symmetry plane of the supported portion of the stem.

6.3 The test fixtures shall be constructed so that the line of load application passes through the ball center.

6.4 A ball- or roller-bearing low-friction mechanism shall be included in the loading apparatus to minimize loads not perpendicular to the cantilever plane. An example of such a mechanism is included in Appendix X1.

7. Equipment Characteristics

7.1 The action of the machine should be analyzed to ensure that the desired form and periodic force amplitude is maintained for the duration of the test. (See Practice E 467.)

7.2 The test machine should have a load monitoring system such as the transducer mounted in line with the specimen. The test loads should be monitored continuously in the early stages of the test and periodically thereafter to ensure the desired load cycle is maintained. The varying load as determined by suitable dynamic verification should be maintained at all times to within ±2 % of the maximum force being used.

8. Procedure

8.1 *Specimen Test Orientation*—The angle between the distal stem axis and the line of load application shall be 10 ± 1° %. An example of a method to accomplish mounting the stem at the desired angle is given in Appendix X2.

[3] The reference points and lines are consistent with the Proposed Standard Specification for Cementable Total Hip Prostheses with Femoral Stems. The reference points "P2" and "P5" in that proposed specification are not relevant to this practice. Consequently, they are not used in this practice.

8.2 *Specimen Mounting*:

8.2.1 Maintain the stem Reference Angle X within a range of ±1° over a test group.

8.2.2 Maintain the unsupported stem length at ±2 mm.

8.2.3 No relative motion between the prosthesis and the grouting agent is permitted during hardening of the grouting agent.

8.2.4 The surface of the grouting agent at the cantilever plane shall be approximately level and perpendicular to the line of load application.

8.2.5 An example of a technique for setting a specimen in the grouting agent in the correct orientation is given in Appendix X2.

8.3 *Test Frequency*— Run all tests at a test frequency of 30 Hz or less.

8.4 *R Value*—Run all tests with an R value of 10.0.[4]

8.5 Measure the unsupported stem length, stem reference angle, and moment arm for each test specimen prior to testing. A possible means would be to use a shadowgraph of the anterior posterior projection as shown in Fig. 1.

8.6 Estimate the amount of horizontal deflection of the head in response to the periodic forcing function one time after the beginning of each test. Possible methods included dial gages, optical micrometers, or linear scales viewed with a strobe light to slow the apparent motion of the deflection.

[4] In strict terms, since the force applied to the head is compressive, the maximum force is the smallest negative amplitude. Consequently the *R* value is 10 when the negative signs cancel each other. In terms of applied bending moment at the cantilever plane, the *R* value would be 0.1

9. Test Termination

9.1 Continue the test until the specimen fails or until a predetermined number of cycles has been applied to the specimen. Failure should be defined as a complete separation, or exceeding of a deflection limit on a test machine. In reporting results, state the criteria selected for defining failure and the number of cycles shown as the predetermined runout of the test. Discard the data for a specific sample if the grouting agent fractured prior to test completion.

10. Report

10.1 Report the fatigue test specimens, procedures, and results in accordance with Recommended Practice E 468.

10.2 In addition, report the following parameters: Stem Reference Angle X, supported stem length, maximum force, R value, specimen material, cycles to failure, location of fractures in relation to the cantilever plane, average dimensions of the stem cross section in the cantilever plane, grouting agent, test environment, and test frequency.

11. Precision and Bias

11.1 The precision and bias of this practice is being established.[5]

12. Keywords

12.1 arthroplasty; femoral components; hip arthroplasty; metallic stemmed femoral components; orthopaedic medical devices

[5] Test results that can be used to establish precision and bias are solicited.

APPENDIXES

(Nonmandatory Information)

X1. EXAMPLE OF A LOW-FRICTION MECHANISM

X1.1 See Fig. X1.1.

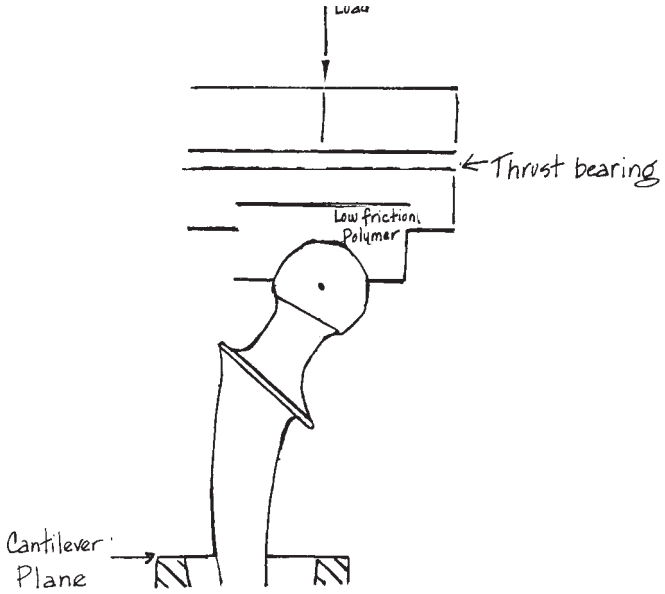

FIG. X1.1 Example of a Low Friction Mechanism

X2. EXAMPLE PROSTHESIS MOUNTING PROCEDURE

X2.1 A drawing or shadowgraph of the prosthesis should be available before mounting to establish the angular relationship between the distal stem axis and the stem reference angle.

X2.2 A gripping device as illustrated in Fig. X2.1 or a ringstand and test tube holder can be used to grip the head of the subject prosthesis.

X2.3 The prosthesis is held by the head permitting the distal tip to rest on a flat surface. The angle jig is positioned with the distal stem in the notch. The stem is adjusted so that it is centered in the notch of the angle jig. This will orient the distal stem at approximately 10 deg to the line of load application. The head is now firmly gripped to maintain the angular orientation of the stem.

X2.4 The angle jig can be removed and the prosthesis mounted at the appropriate depth in an appropriate specimen holder.

X2.5 Grouting material can be placed around the test prosthesis into the specimen holder and allowed to harden.

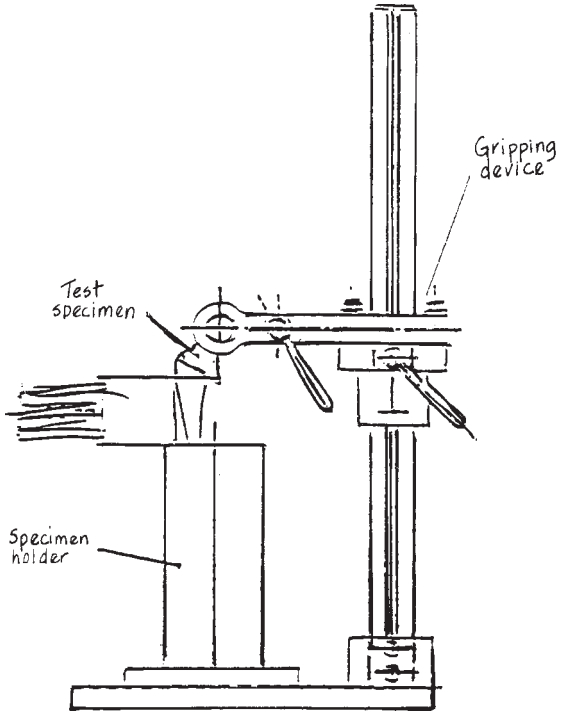

FIG. X2.1 Apparatus for Gripping the Test Specimen While Embedding it in the Correct Orientation

X2.6 After hardening of the grouting agent the grip on the head of the prosthesis is released and a shadowgraph may be prepared of the profile of the test specimen/specimen holder assembly.

X2.7 A second adjustable stop may be added below the grip and adjusted to rest against the medial surface of an appropriately oriented prosthesis to facilitate repeatable mounting of the test group.

X3. RATIONALE

X3.1 Fracture of femoral stems in THA has been a problem in clinical application. The stem design, PMMA support, quality of bone, and other features contribute to stem fracture. One recognizable mode of failure is with the distal portion of the stem firmly anchored, while medial proximal support is lost. As the body loads are applied through the head of the prosthesis, significant stem stresses can result at the area where the cement is still firmly anchored. Because it is believed that this proximal cement breakdown model is the primary reason behind fracture of the femoral stems, this simplified model was chosen for the fatigue testing of actual stems. There are some problems with the proposed simplified model. The worst case assumes that proximal cement breakdown has already occurred. It does not address any features of a THA system that might help prevent cement breakdown or any features that aid in placing the femoral component in an optimal position with good cement support. While the latter approach is desirable, the test described can give information on the relative fatigue strengths.

X3.2 In 8.1 there is no specification of the number of cycles for test runout. The fundamental idea behind this type of test is that the number of cycles to runout represents a limiting point beyond which the material will not fracture no matter how many more cyclic loads are applied. This is referred to as a fatigue limit. However, in real life most materials do not possess a true fatigue limit. Consequently, a compromise must be made between the amount of testing, (the number of test cycles) and the relationship of the test to actual device performance and device life. Since most of these tests are plotted and evaluated on a semi-log or log-log plot, a typical runout point is often ten million cycles. Doubling or tripling the number of test cycles to twenty or thirty million contributes only a small amount to the trend analysis on the log scale, but it doubles or triples the length of the test. In Europe five million cycles has been used as a runout value for some stem tests.

X3.3 This test is a cantilever beam bend test. In a cantilever beam bend test the load point will tend to deflect in the direction of the applied load, the amount of deflection depending on the elasticity of the test sample With this test the head of the prosthesis is the cantilever load point. Since the direction of the load also applies a compressive force down the stem, only the vector portion of the force, perpendicular to the prosthesis long axis, will contribute to the beam deflection. That contribution of beam bending will deflect the head to the side. This motion effectively increases the bending moment arm. This motion must be permitted. If the head is not allowed

to deflect in a near frictionless manner the portion of the test fixture that prevents the deflection is actually applying an unknown force against the head to keep it from deflecting. If the device is flexible enough, the magnitude of periodic motion of the head of the prosthesis (in the plane perpendicular to the line of load application) in response to the periodic forcing function; can significantly increase the applied maximum bending moment. It may be wise to estimate this deflection and include it in bending moment calculations.

X3.4 Any fatigue strength as predicted by tests following the method described herein must be considered on a relative basis, that is, these tests may yield valuable information about the relative merits of different devices for particular applications, but should not be used as a quantitative indicator of expected *in vivo* device lifetime.

X3.5 There is limited information in the literature as to whether the materials used in THA femoral components experience a significant degradation in high-cycle fatigue initiation properties due to the presence of a physiological environment. If there is concern that the material used in the device may degrade significantly in a physiological environment; such material characteristics would be more realistically determined fatigue testing a material test specimen in a simulated physiological environment at rates of one cycle per second or less. For these reasons, a particular environment is not specified in this practice. However, a simulated environment is not prohibited. However, if a simulated environment is used, the test frequency should be selected so as to not mask the expected effects of the environment.

REFERENCES

(**1**) *Manual on Statistical Planning and Analysis of Fatigue Experiments, ASTM STP 588*, Little and Jebe, eds.

(**2**) Semlitsch, M., and Panic, B., "Ten Years of Experience with Test Criteria for Fracture-Proof Anchorage of Stems of Artificial Hip Joints," *Engineering in Medicine*, Vol 12, No. 4, 1983, pp. 185–198.

(**3**) *Handbook of Fatigue Testing, ASTM STP 566*, Swanson, S. R., ed.

(**4**) *Statistical Analysis of Fatigue Data, ASTM STP 744*, Little and Evkal, eds.

(**5**) *Technolgische und biomechanische Aspekte der Hüft-und Kniealloar thoplastik*; Statisch-biomechanische spannungs—analysen und dynamische Prüfungen von Hüftprothesen, Ungethum pp. 90–110, Huns Huber, Bern.