Designation: F 1612 – 95 (Reapproved 2000)

Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion[1]

This standard is issued under the fixed designation F 1612; 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 the fatigue testing of metallic stemmed femoral components used in hip arthroplasty. The described method is intended to be used for evaluation in comparisons 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 femoral stems with modular heads, with the head in place. Such prostheses should not have an anterior-posterior A-P bow or a medial-lateral M-L bow, and they 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 *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]

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

E 467 Practice for Verification of Constant Amplitude Dynamic Loads in an Axial Load Fatigue Testing Machine[2]

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

E 1150 Definitions of Terms Relating to Fatigue[2]

2.2 *ISO Document:*[3]

ISO 7206-3 (1988) Stem Test

3. Terminology (see Fig. 1 Fig. 2)

3.1 *Definitions of Terms Specific to This Standard:*

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

3.1.2 *distal stem axis*—the centerline in the A-P projection and the M-L projection of the most distal 50 mm of the stem.

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

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 of the points in the area.

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

3.1.6 *R value*—the ratio of the minimum force to the maximum force,

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

3.1.7 *Reference Line L1:*

3.1.7.1 *distal stem axis*—the M-L centerline of the most distal 50 mm of stem in the A-P projection.

3.1.8 *Reference Line L2:*

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

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

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

3.1.10 *Reference Point P3:*

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

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

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

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

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

[3] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

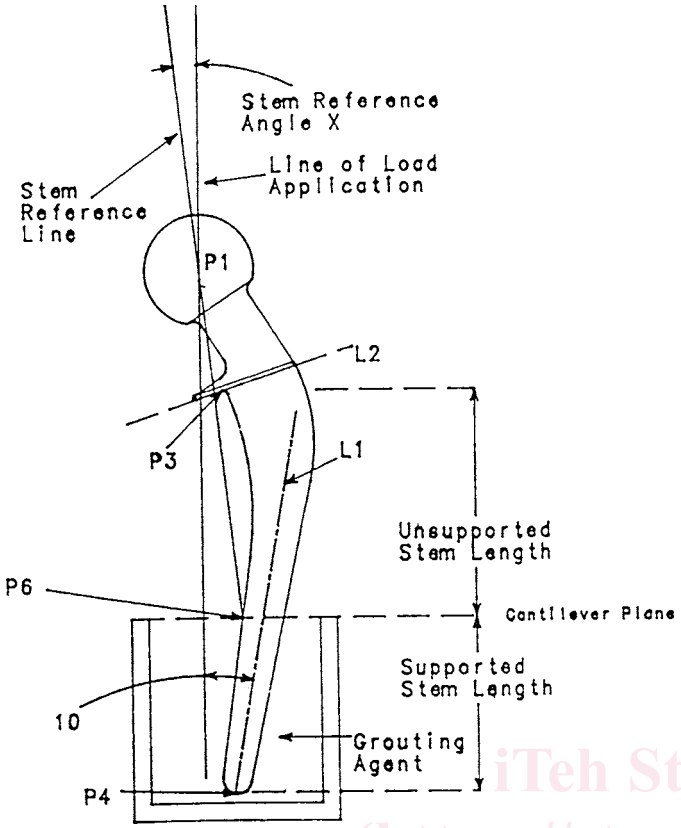

FIG. 1 1(a) Collared Device, M-L Projection

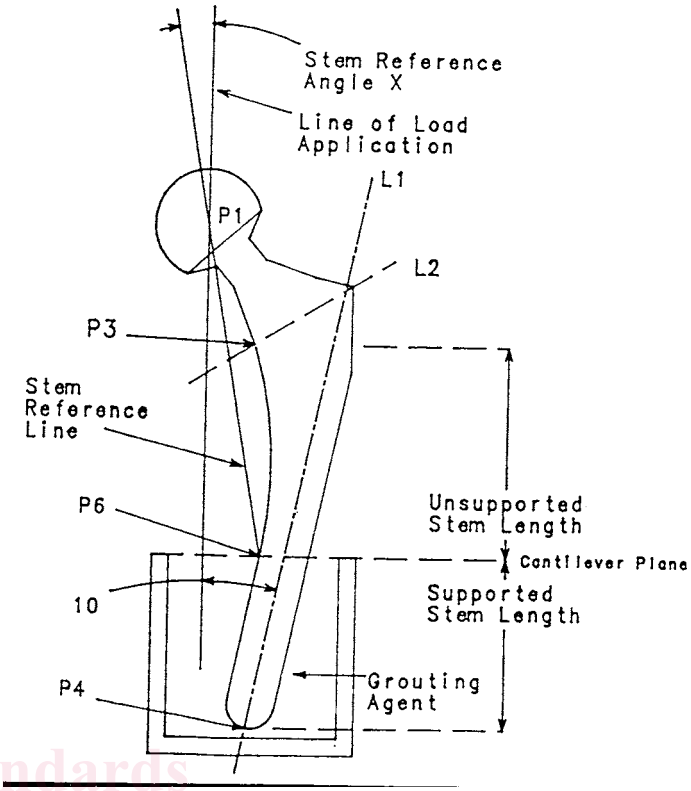

FIG. 2 1(b) Collarless Device, M-L Projection

3.1.12 *Reference Point P6*[4]— the intersection of the cantilever plane with the medial surface of the stem in the A-P projection.

3.1.13 *stem reference angles*—Since the distal stem axis is obscurred by the grouting agent after preparation of the test sample, the stem reference angles are to be used to measure the repeatability of the stem orientation. They may also be used to estimate the actual orientation of the distal stem to the line of load application if the stem geometry is well known.

3.1.13.1 *X (M-L)*—the angle between the stem reference line and line of load application in the M-L projection.

3.1.13.2 *X (A-P)*—the angle between the stem reference line and line of load application in the M-L and A-P projections.

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 cantilever plane.

3.1.16 *unloaded moment arm*—the vector sum of the perpendicular distance between the line of load application and geometric centroid of the stem cross section at the cantilever plane in the A-P and M-L projections.

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

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

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 in which proximal support for the stem has been lost. It is also recognized that, for some materials, the environment has an effect on the response to cyclic loading (see section 12.7). The test environment used and rationale for the choice of that environment should be described in the test report.

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

5. Purpose

5.1 In order for fatigue data on femoral stems to be useful for comparison, it must be reproducible among different laboratories. It is consequently essential that uniform procedures for testing and reporting test data be established.

6. Apparatus

6.1 The specimen shall be constrained by a suitable grouting agent within a rigid cavity. A common grouting agent used is polymethyl methacrylate (PMMA, bone cement). 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 that it does not alter the test specimen chemically or mechanically.