



Designation: F 1440 – 92 (Reapproved 1997)

Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion¹

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

2. Referenced Documents

2.1 ASTM Standards:

- E 4 Practices for Load Verification of Testing Machines²
- E 466 Recommended Practice for Constant Amplitude Axial Fatigue Tests for Metallic Materials²
- E 467 Practice for Verification of Constant Amplitude Dynamic Loads in an Axial Load Fatigue Testing Machine²
- E 468 Recommended Practice for the Presentation of Constant Amplitude Fatigue Test Results for Metallic Materials²

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.

3.1.4 *geometric centroid (cantilever plane)*— the point in a cross-sectional area of the cantilever plane whose coordinates

¹ This practice is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.22 on Arthroplasty.

Current edition approved Sept. 15, 1992. Published November 1992.

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

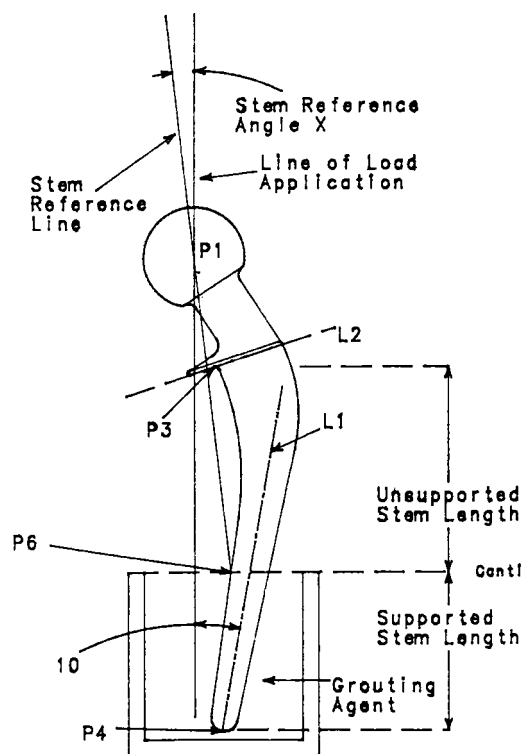


FIG. 1 Collared Device

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:*

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.

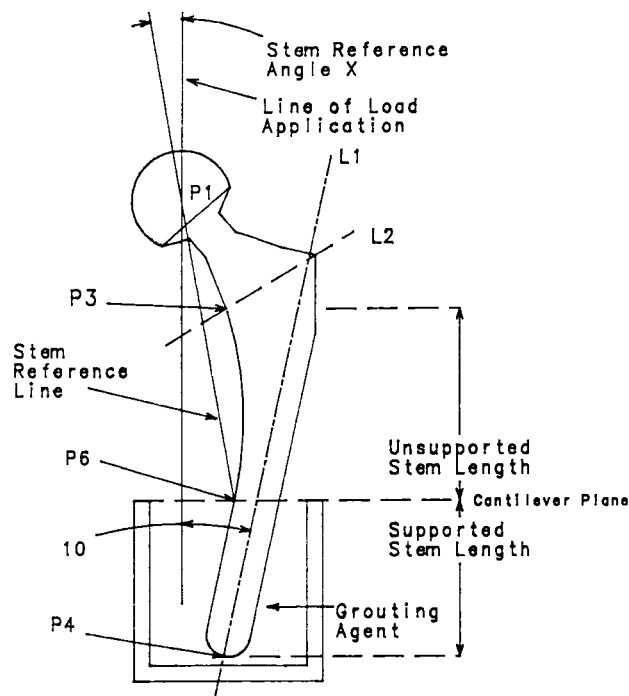


FIG. 2 Collarless Device

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

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.

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 create 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 $\pm 2\%$ 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 deg %. An example of a method to accomplish mounting the stem at the desired angle is given in Appendix X2.

8.2 *Specimen Mounting*: