Designation: F2580 – 13

Standard Practice for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis[1]

This standard is issued under the fixed designation F2580; 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 procedure for the fatigue testing of metallic femoral hip prostheses used in hip joint replacements. This practice covers the procedures for the performance of fatigue tests on metallic femoral hip stems using a cyclic, constant-amplitude force. It applies to hip prostheses that utilize proximal metaphyseal fixation and are of a modular construct, and it is intended to evaluate the fatigue performance of the modular connections in the metaphyseal filling (that is, proximal body) region of the stem.

1.2 This practice is intended to provide useful, consistent, and reproducible information about the fatigue performance of metallic hip prostheses while held in a proximally fixated manner, with the distal end not held by a potting medium.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this 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:*[2]

E467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System

E468 Practice for Presentation of Constant Amplitude Fatigue Test Results for Metallic Materials

E1150 Definitions of Terms Relating to Fatigue (Withdrawn 1996)[3]

2.2 *ISO Standards:*[4]

ISO 7206–4 Determination of Endurance Properties of Stemmed Femoral Components with Application of Torsion

3. Terminology

3.1 *Definitions:*

3.1.1 *R value, n*—The R value is the ratio of the minimum load to the maximum load.

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

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *extraction*—removal of the femoral hip implant from the femur during surgery.

3.2.2 *extractor hole*—a hole in the proximal body of the stem in which an apparatus is placed to remove the implant from the femur.

3.2.3 *femoral head*—convex spherical bearing member for articulation with the natural acetabulum or prosthetic acetabulum.

3.2.4 *femoral head offset*—the perpendicular distance from the centerline of the implant stem to the center of the femoral head.

3.2.5 *frontal plane*—the plane that lies in the medial-lateral direction of the implant. Adduction occurs in this plane.

3.2.6 *implant centerline*—the axis that runs vertically from the proximal body of the implant, down the center of the stem to the distal end.

3.2.7 *pivot axis*—the center of rotation of the pivot fixture (and prosthesis potted within it) within the test fixture setup; its location is determined by the intersection of the neck and stem centerlines of the prothesis (Figs. 1 and 2).

[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] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

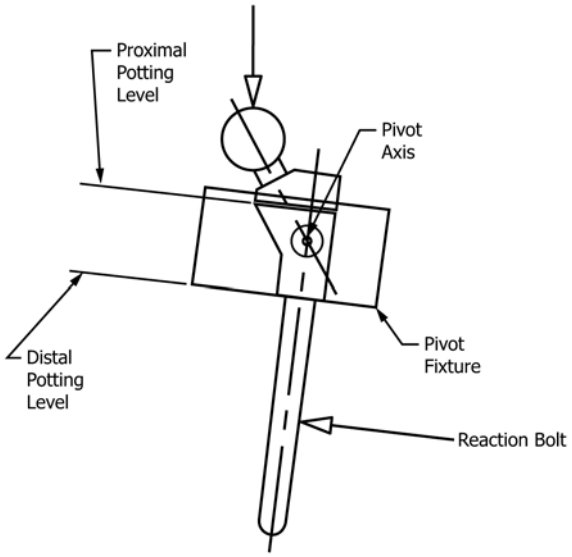


FIG. 1 Free Body Diagram of Test Setup

3.2.8 *pivot fixture*—the fixture in which the specimen is potted, and is attached to the main test fixture; characterized by two pins on the side that serve as the pivot axis.

3.2.9 *rotational plane*—the plane that lies perpendicular to the stem axis of the implant.

3.2.10 *sagittal plane*—the plane that lies perpendicular to the Frontal plane; flexion occurs in this plane.

4. Significance and Use

4.1 This practice can be used to describe the effects of materials, manufacturing, and design variables on the fatigue performance of metallic femoral hip prostheses subject to cyclic loading for large numbers of cycles.

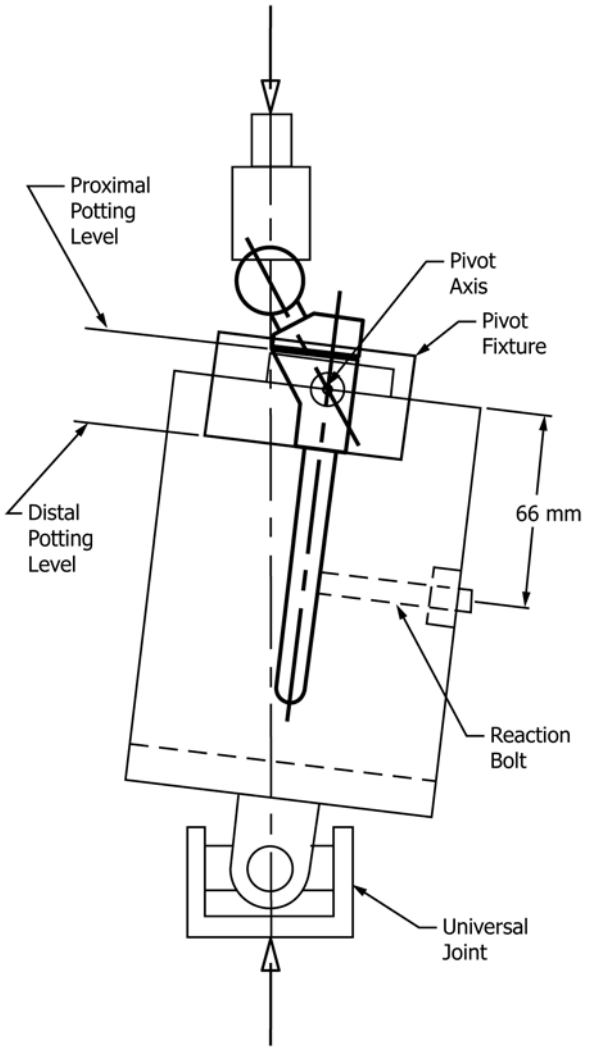


FIG. 2 Schematic Representation of the Test Set-up

4.2 The loading of femoral hip designs *in vivo* will, in general, differ from the loading defined in this practice. The results obtained here cannot be used to directly predict *in vivo* performance. However, this practice is designed to allow for comparisons between the fatigue performance of different metallic femoral hip designs, when tested under similar conditions.

4.3 In order for fatigue data on femoral hip prostheses to be comparable, reproducible, and capable of being correlated among laboratories, it is essential that uniform procedures be established.

5. Specimen Selection

5.1 The test component selected shall have the same geometry as the final product, and shall be in finished condition. The test component shall be of the worst-case size and configuration (that is, the component that produces the highest stresses) of the implant family to be tested.

5.2 The femoral head component selected for load application shall be of the same design and material as a current product in use, but may be previously tested.

5.3 The femoral head selected shall offer the greatest load offset from the hip centerline, to represent a worst-case bending scenario during testing.

6. Apparatus

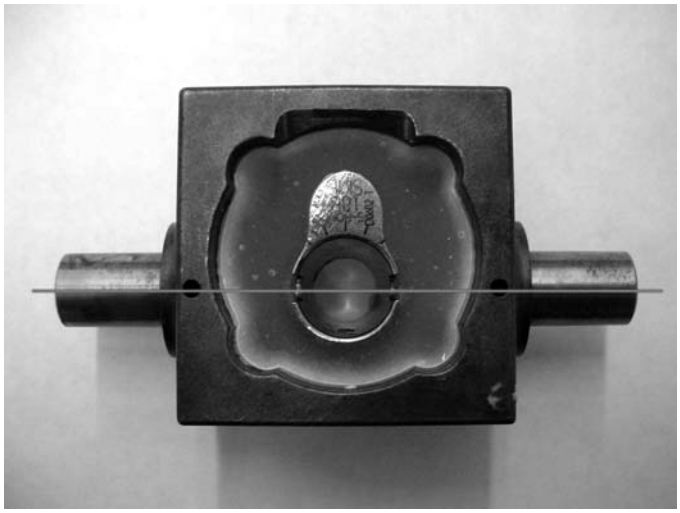
6.1 The hip implant may be tested in different orientations to better reproduce specific testing conditions that are being evaluated. For example: An anatomical orientation of 9° flexion, and 10° adduction (per ISO 7206-4), or vertically in both planes. The criteria used to determine the orientation should be reported.

6.2 Care shall be taken to ensure that the fixation of the implant does not produce abnormal stress concentrations that could change the failure mode of the part.

6.3 A fixed-bearing load applicator shall be used to keep the specimen aligned in the chosen orientation during testing, as well as a fixture that allows the stem to bend during testing, such as a u-joint.

6.4 The fixture used to hold the implant during testing should have a reaction bolt that will oppose the loading on the femoral head, keeping the implant in equilibrium. The position of the reaction bolt should be adjustable to accommodate stems of different lengths and design features.

6.5 The fixtures and aligning materials used should be of a design that positions the implant, when potted, so that: the point defined by the intersection of the neck and stem centerlines is coincident with the pivot axis (Fig. 1), the stem is fixed vertically in both medial/lateral and anterior/posterior directions, the stem is aligned facing forward in the rotational plane (that is, the frontal plane is normal to the pivot axis of the fixture), (Fig. 3) and that any mating surfaces between modular components of the specimen do not come in contact with the potting medium.



NOTE 1—Once assembled, the pivot axis will be coincident with the point on the implant defined by the intersection of the neck and stem centerlines.

FIG. 3 Proximal Sleeve Component Potted in Pivot Fixture

7. Equipment Characteristics

7.1 Perform the tests on a fatigue test machine with adequate load capacity.

7.2 Analyze the action of the machine to ensure that the desired form and periodic force amplitude is maintained for the duration of the test (see Practice E467 or use a validated strain-gauged part).

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

8. Procedure

8.1 This procedure details a potting method centered about potting the proximal body portion of the implant first, and assembling the remainder of the implant after potting. Other methods of potting the specimen exist, including methods for implants that are not of a modular design, and may be used in place of this, providing that the general terms and limitations are still achieved. The potting procedure used should be included in the test report.

8.2 *Specimen Preparation:*

8.2.1 Apply a moderate coat of lubricant (that is, any household cooking spray) to the interior of the pivot fixture and any other fixture surfaces that will contact the potting medium to prevent adhesion during potting.

8.2.2 Align the proximal body component of the implant in the pivot fixture, using the aligning materials to ensure it is in the correct orientation. Be sure the component and fixtures are fitted tightly so the specimen does not move during potting and curing. The distal potting level shall be at the distal surface of the proximal body component (see Figs. 1 and 2).

8.2.3 An appropriate potting medium should be chosen which displays the correct load carrying capabilities and resistance to cracking or crumbling during fatigue. Examples of different potting media include bone cement, dental acrylic, or a low melting point alloy. The type and manufacturer of the potting material chosen should be reported.

8.2.4 Pour the potting material into the pivot fixture, around the specimen. If necessary, use another material such as tape or clay to block any gaps to prevent the material from seeping through to any area outside the pivot fixture. Care should be taken to ensure that potting medium does not come in contact with any mating surfaces on the proximal component.

8.2.5 The proximal potting level shall be at the proximal surface of the proximal body component (see Figs. 1 and 2). No potting material should enter any space between modular components of the specimen.

8.2.6 Allow the material to cure completely before continuing.

8.3 *Specimen Assembly and Impaction:*

8.3.1 Remove all secondary fixtures used to align the implant in the pivot fixture.

8.3.2 Clean the internal and distal surfaces of the proximal component with acetone to remove any potting or other material that came into contact with the surface. Avoid allowing the acetone to contact the good potting material.

8.3.3 Assemble the remainder of the implant, ensuring that the stem remains aligned properly in all planes of interest.

8.3.4 Assemble the modular components of the stem body as specified by the surgical technique for the device.

8.3.5 Place the femoral head on the neck taper of the hip implant and impact the head on the taper with three blows with a rubber mallet.

8.3.6 Determine the femoral head offset from the centerline of the stem. This can be done by means of a height gauge or optical comparator.

8.4 *Test Set-up:*

8.4.1 Attach the pivot fixture with the specimen to the test frame fixture in the correct orientation.

8.4.2 Attach the polyethylene load applicator to the actuator.

8.4.3 Bring the load applicator into contact with the femoral head of the specimen so that a low load (approximately 10 lbf) is applied.

8.4.4 Vertically position the reaction bolt assembly so that it is located 66 mm from the pivot axis (Fig. 2). If the stem design includes a coronal slot, the reaction bolt should be located above the highest level of the coronal slot.

NOTE 1—The vertical position of the reaction bolt may be modified to accommodate designs and test purposes different from what is explained in this practice.

8.4.5 Adjust the main fixture and the pivot fixture so that the specimen is aligned at the proper angles in the frontal plane (adduction) and in the sagittal plane (flexion) (See 6.1). The test setup is represented in Fig. 2.

8.4.6 Proper measures should be taken to ensure that the fixturing is secure and the specimen or equipment does not get damaged should unloading occur during testing

8.4.7 *Test Frequency*—Run all tests at a frequency of 10 Hz or less. constant frequency with a maximum allowable frequency of 10 Hz. Take care to ensure that the test machine can maintain the applied load at the chosen frequency and that resonant conditions are not reached.

8.4.8 *Input Loading Profile*—Run all tests using a sinusoidal waveform input load with an R value of 10.0

NOTE 2—In strict terms, since the force applied to the femoral head is compressive, the maximum force is the smallest negative amplitude. Consequently, the R value is ten when the negative signs cancel each other. In terms of applied bending moment at the potting plane, the R value would be 0.1. See Terminology E1150 for the definition of the R value.

9. Test Termination

9.1 Continue the test until the femoral prosthesis fails or until a predetermined number of cycles have been applied to the implant. The suggested number of cycles is ten million. Failure may be defined as: a fracture of the femoral implant; formation of a crack detectable by eye, fluorescent dye penetrant, or other non-destructive means; or exceeding a predetermined deflection limit.

10. Report

10.1 Report the fatigue test specimens, procedures, and results in accordance with Practice E468.

10.2 In addition, report the following parameters:

10.2.1 Femoral implant (size, configuration, material, and so forth),

10.2.2 Femoral head size and offset,

10.2.3 Femoral head offset measured from stem center,

10.2.4 Method of assembly of the modular components,

10.2.5 Stem orientation and the criteria used to determine it (per 6.1),

10.2.6 Distance to reaction bolt from distal potting plane,

10.2.7 Potting procedure,

10.2.8 Potting medium,

10.2.9 Largest compressive load,

10.2.10 R value,

10.2.11 Cycles to failure,

10.2.12 Mode and location of failures,

10.2.13 Test environment, and

10.2.14 Test frequency.

11. Precision and Bias

11.1 A precision and bias statement does not exist for this practice.

12. Keywords

12.1 arthroplasty; femoral hip prostheses; orthopedic medical devices; proximal fixation; total hip arthroplasty

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 It is 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 that choice shall be described in the test report.

X1.2 It is also recognized that the actual *in vivo* loading conditions are not constant amplitude. However, there may be insufficient information available to create standard load spectrums for metallic femoral hip implants. Accordingly, a simple periodic constant amplitude force is recommended.

X1.3 Worst-case loading of the hip implant may vary depending on material, design, and clinical indications. The researcher shall evaluate the possible clinical and design-related failure modes and attempt to determine a worst-case situation. Also, as the method of heat treatment can affect the strength of the hip implant material, it shall be considered. For example, the high temperature sintering treatment used to apply a porous coating to a hip implant may affect the fatigue strength of the implant.

X1.4 It is recommended that testing be terminated at ten million cycles if failure of the hip implant has not occurred. The implant design addressed in this testing is designed to replace the hip joint and intended to carry load over the life of the implant. Ten million cycles represents the number of loading cycles a hip implant might experience over ten years of clinical use (estimated at one million loading cycles per year).

X1.5 In developing this practice, it was recognized that alternative methods for testing hip implants exist. One such test method would include distal fixation of a hip implant, rather than proximal fixation. This practice attempts to simplify the loading conditions while addressing clinical failure modes of a modular hip implant that was designed for proximal fixation in the bone. Based on various goals, investigators may seek to deviate from the practice defined here.

X1.6 Documents that have been used as references for this practice are available.[5,6]

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[5] Bobyn, J. D., Dujovne, A. R., Krygier, J. J., "Fatigue Behavior of a Titanium Femoral Hip Prosthesis with Proximal Sleeve-Stem Modularity," *Journal of Applied Biomaterials*, Vol 5, 1994, pp. 195–201.

[6] Heim, C. S., Postak, P.D., Greenwald, A. S. "Femoral Stem Fatigue Characteristics of Modular Hip Designs," *ASTM STP 1301 – Modularity of Orthopedic Implants*, DE Marlow, JE Parr, MB Mayor, (Editors), 1997, pp. 226–243.