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Designation: ~~F2580 – 13~~ F2580 – 18

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.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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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~~E1150~~E1823 ~~Definitions of Terms~~ Terminology Relating to Fatigue and Fracture Testing ~~(Withdrawn 1996)~~

2.2 *ISO Standards:*[3]

ISO 7206–4 ~~Determination of Endurance Properties of Stemmed Femoral Components with Application of Torsion~~Implants for surgery -- Partial and total hip joint prostheses -- Part 4: Determination of endurance properties and performance of stemmed femoral components

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*—~~*extraction, n*—removal of the femoral hip implant from the femur during surgery.

[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.

Current edition approved ~~Feb. 1, 2013~~July 1, 2018. Published ~~February 2013~~September 2018. Originally approved in 2007. Last previous edition approved in ~~2009~~2013 as ~~F2580 – 09.~~F2580 – 13. DOI: ~~10.1520/F2580-13.~~10.1520/F2580-18.

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

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3.2.2 *extractor ~~hole—~~hole, n—*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—~~head, n—*convex spherical bearing member for articulation with the natural acetabulum or prosthetic acetabulum.

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

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

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

3.2.7 *pivot ~~axis—~~axis, n—*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).

3.2.8 *pivot ~~fixture—~~fixture, n—*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—~~plane, n—*the plane that lies perpendicular to the stem axis of the implant.

3.2.10 *sagittal ~~plane—~~plane, n—*the plane that lies perpendicular to the ~~Frontal~~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.

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,~~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.

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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.

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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.

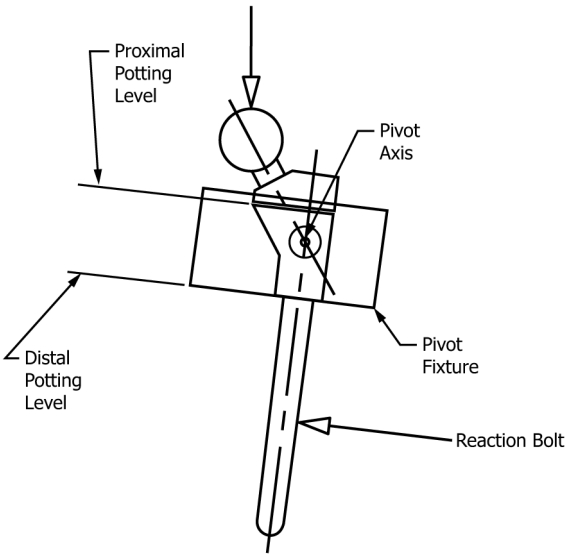

FIG. 1 Free Body Diagram of Test Setup

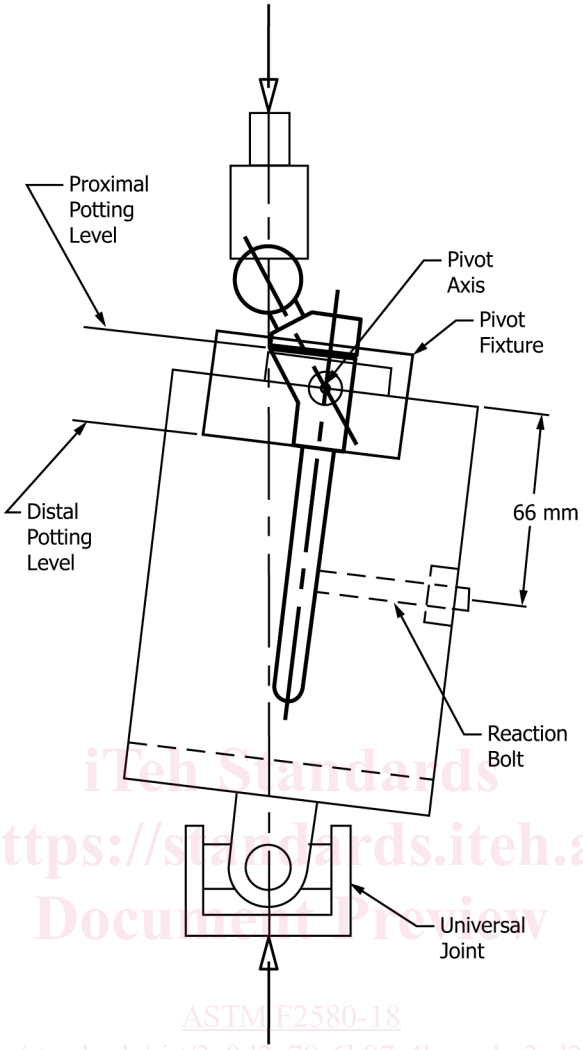

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FIG. 2 Schematic Representation of ~~the~~ Test ~~Set-up~~Setup

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),~~fixture (Fig. 3~~)~~)), and that any mating surfaces between modular components of the specimen do not come in contact with the potting medium.

7. Equipment Characteristics

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