Designation: 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, health, and environmental 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.*

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

E1823 Terminology Relating to Fatigue and Fracture Testing

2.2 *ISO Standards:*[3]

ISO 7206–4 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.

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

3.2 *Definitions of Terms Specific to This Standard:*

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

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

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

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

3.2.6 *implant centerline, n*—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, 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).

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

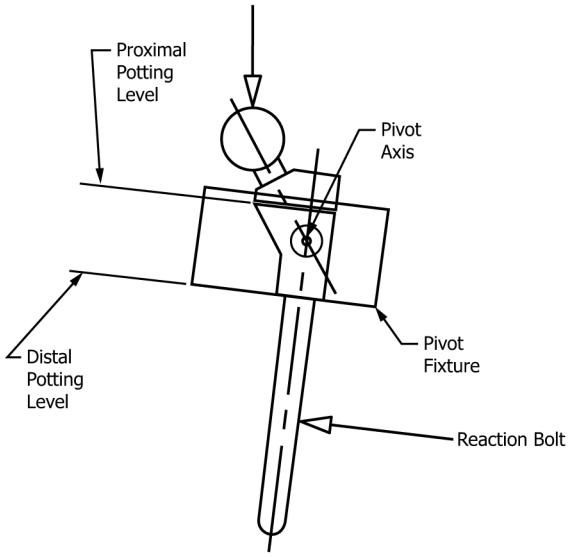

FIG. 1 Free Body Diagram of Test Setup

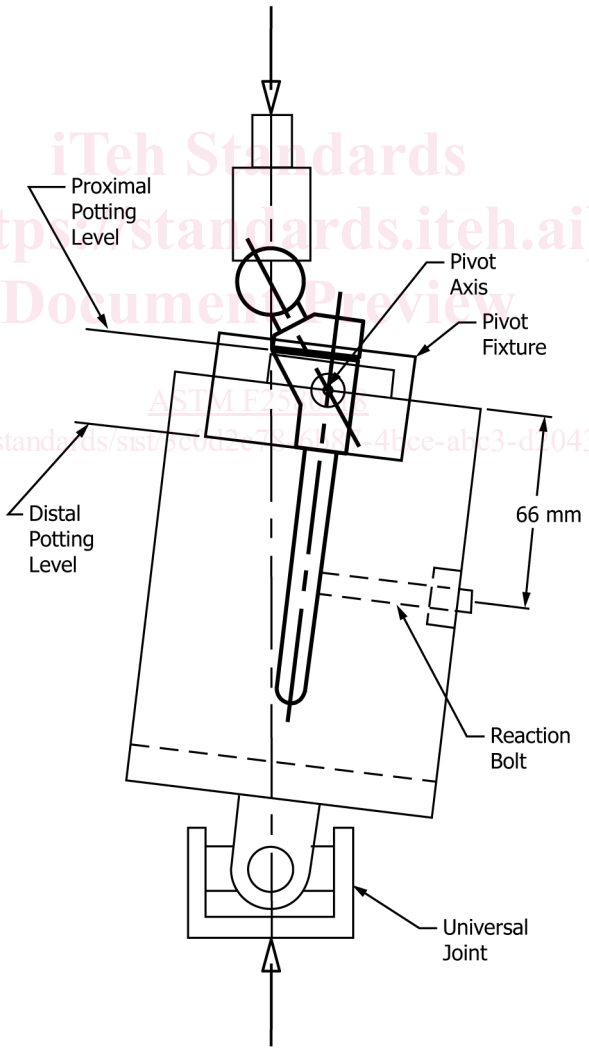

FIG. 2 Schematic Representation of Test Setup