Designation: F3210 – 22ε1

Standard Test Method for Fatigue Testing of Total Knee Femoral Components Under Closing Conditions[1]

This standard is issued under the fixed designation F3210; 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.

ε[1] NOTE—The designation was updated editorially in March 2022.

1. Scope

1.1 This standard applies to metallic total knee femoral components used in total knee arthroplasty (TKA). Femoral components made of nonmetallic materials (for example, ceramic, polymer) could possibly be evaluated using this test method. However, such materials may include risks of new failure mechanisms which are not considered in this test method.

1.2 The procedure described in this standard is performed on total knee femoral components for supporting determination of fatigue behavior under closing-style loading conditions. Closing-style loading refers to forces that act to reduce the femoral intercondylar depth, resulting in a tensile stress on the articular surface of the femoral condyle. (See 3.2.2.)

1.3 Different designs can be characterized as, but not limited to, posterior cruciate ligament retaining (CR), posterior stabilizing (PS), and revision.

1.4 This standard does not address evaluation of femoral components under opening-style loading conditions which have also generated clinical failures. Under opening-style loading conditions, forces are applied to the inner contour of the femoral component in a way that the forces act to increase the intercondylar depth, or open the femoral component.

1.5 *Units*—The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *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.*

1.7 *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]

E4 Practices for Force Calibration and Verification of Testing Machines

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

E739 Practice for Statistical Analysis of Linear or Linearized Stress-Life (*S-N*) and Strain-Life (ε-*N*) Fatigue Data

E1823 Terminology Relating to Fatigue and Fracture Testing

F1800 Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements

F2083 Specification for Knee Replacement Prosthesis

F3140 Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Unicondylar Knee Joint Replacements

F3161 Test Method for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Femoral Components under Closing Conditions

2.2 *ISO Standards:*[3]

ISO 5833 Implants for Surgery—Acrylic Resin Cements

ISO 7207-1 Implants for Surgery—Components for Partial and Total Knee Joint Prostheses—Part 1: Classification, Definitions and Designation of Dimensions

3. Terminology

3.1 *Definitions:*

[1] This test method 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.

3.1.1 *femoral intercondylar depth*—distance between the anterior and posterior internal surfaces of the femoral component, as defined in ISO 7207-1 and shown in Fig. 1(a).

3.1.2 *total knee femoral component*—a component of a total knee joint prosthesis intended to be secured to the femur to replace its articulating surfaces.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *bisection plane*—for a femoral component that does not have posterior curvature in the transverse plane (that is, flat in the transverse view), the condyle bisection plane is a plane parallel to the sagittal plane that bisects the medial or lateral posterior condyle at 90° of tibiofemoral flexion (shown in Fig. 1(b), medial condyle).

3.2.2 *femoral closing*—the result of a force that acts to reduce the femoral intercondylar depth, resulting in a tensile stress on the articular surface of the femoral condyle.

3.2.3 *potting medium*—a casting or embedding medium for supporting the specimen and providing fixation to the test frame.

3.2.4 *runout*—predetermined number of cycles at which the testing on a particular specimen will be stopped, and no further testing on that specimen will be performed.

3.2.5 *transverse condylar crown*—for a femoral component that has a posterior curvature in the transverse plane, the peak of this curvature is the transverse condylar crown (shown in Fig. 1(b), lateral condyle).

4. Summary of Test Method

4.1 This method provides guidance on how to test a total knee femoral component in closing fatigue. Total knee femoral components will be tested to simulate single condyle loading at 90° of tibiofemoral flexion. The highest load for which a group of samples completes the predefined runout without failure is the maximum runout load. (See X1.1 for recommendations on runout and X1.2 and X1.3 on methods to determine fatigue strength.)

5. Significance and Use

5.1 Clinical fractures of total knee femoral components have been observed and reported in the literature (**1-12**).[4] (See X1.4.)

5.2 This test method provides a procedure to perform fatigue testing on total knee femoral components under closing conditions caused by an unsupported condyle that result in a tensile stress on the articular surface and a compressive stress on the interior, beveled surfaces.

5.3 This test method is intended to evaluate the fatigue performance of knee femoral components under a simulated articulation loading condition. The load acts to move the posterior femoral condyle toward the anterior flange.

[4] The boldface numbers in parentheses refer to a list of references at the end of this standard.

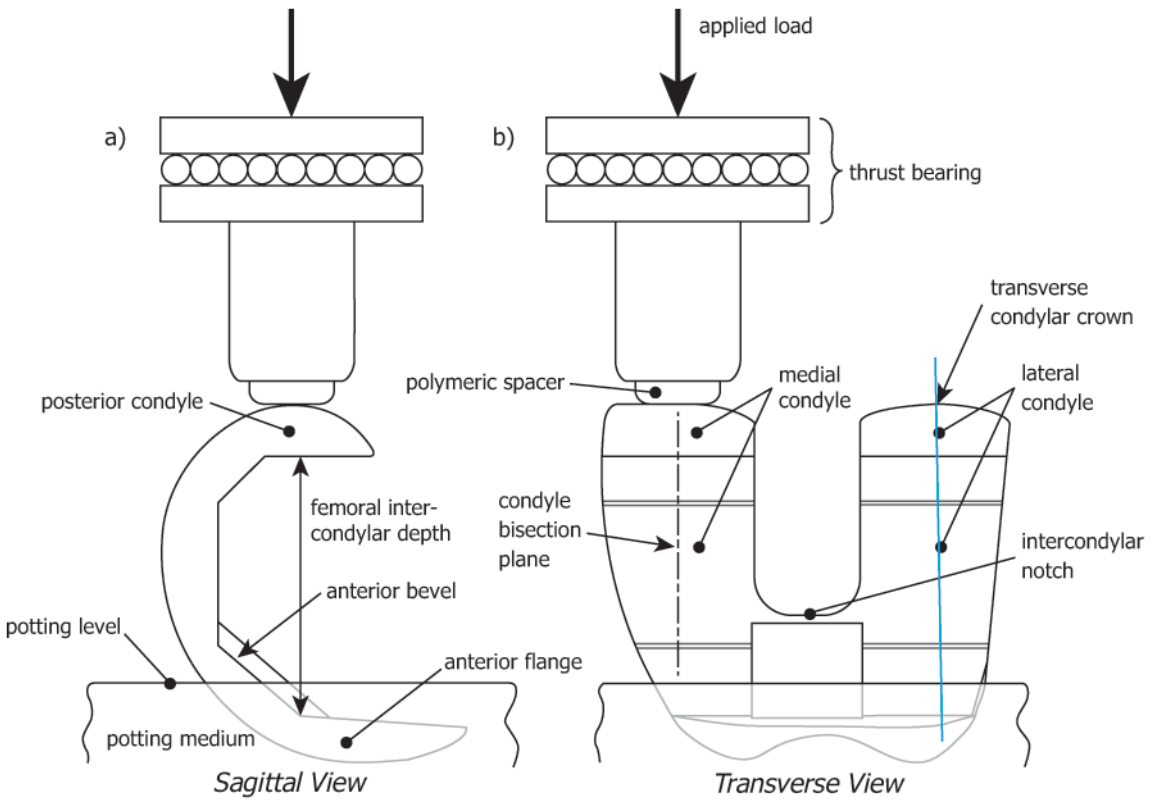

FIG. 1 Terminology and Test Configuration