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.

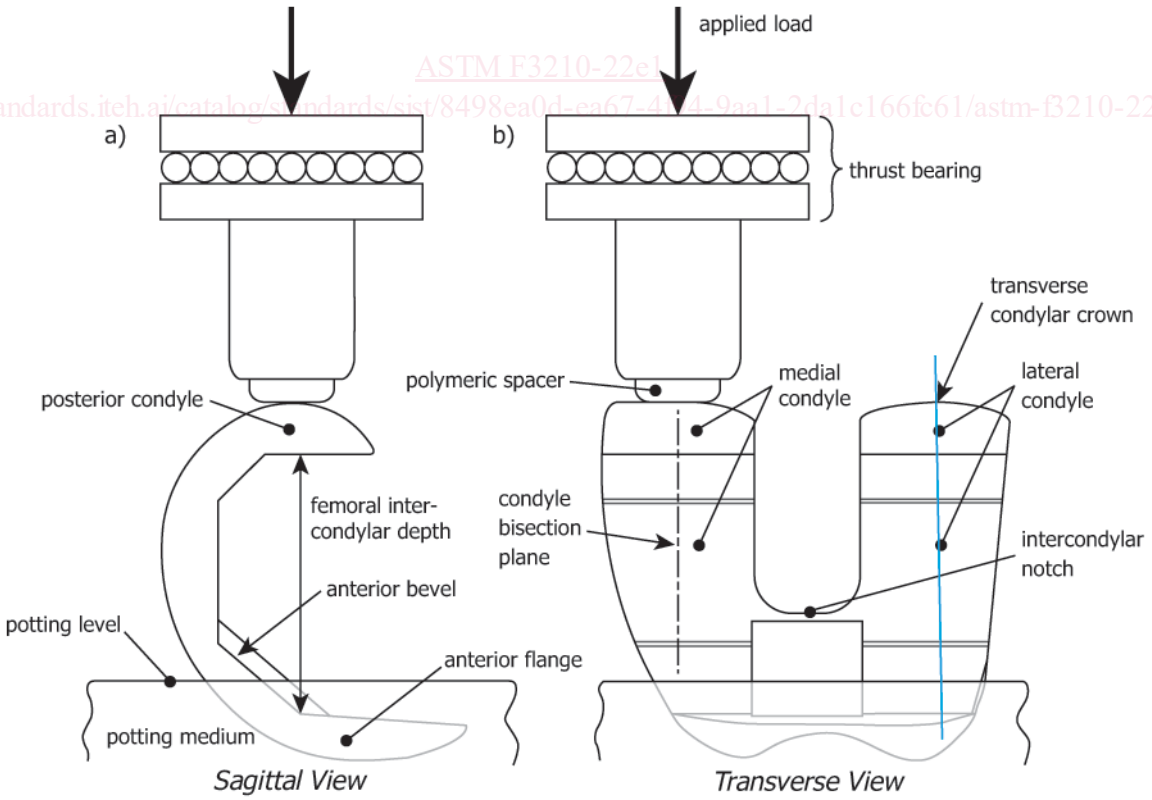

FIG. 1 Terminology and Test Configuration

5.4 This test method simulates a clinically severe condition in which all bony support is lost and one condyle is supporting the complete load at the knee joint at 90° of tibiofemoral flexion.

5.5 Testing in accordance with this test method typically produces regions of high tensile stress in the intercondylar notch and on the articular surface where the anterior flange transitions to condyle.

5.6 The loading of total knee femoral components using this test method may differ from actual *in vivo* loading conditions. The results obtained here cannot be used to directly predict *in vivo* performance. However, this test method is designed to enable comparison between the fatigue performance of different total knee femoral component designs when tested under similar closing conditions.

6. Apparatus

6.1 Perform the tests using a properly calibrated fatigue test machine with adequate load capacity (see Practice E4 for guidance).

6.2 Analyze the dynamics of the machine to ensure that the desired periodic force amplitude is maintained for the duration of the test (see Practices E467 and E468 for guidance).

6.3 The fatigue test machine shall have a load and deflection monitoring system such as the transducer mounted in line with the specimen. Monitor the test loads and deflections continuously in the early stages of the test and periodically thereafter to ensure that the desired load cycle is maintained. The control system shall maintain the varying load at all times to within ±2 % of the magnitude of the largest compressive force being used.

6.3.1 The potting medium for the specimen(s) shall:

6.3.1.1 Not break under the load applied during testing;

6.3.1.2 Not exhibit excessive deformation or creep; and

6.3.1.3 Be reproducible in strength and other characteristics. (See X1.5 for recommended potting media.)

6.4 The load applicator shall be free to move in the transverse direction of load application.

6.5 Damage to the femoral component can occur; therefore, the use of a polymeric spacer and/or a lubricant between the load applicator and the femoral component should be considered.

6.5.1 The spacer should possess sufficient stiffness and creep resistance. Recommended spacer materials are ultra high molecular weight polyethylene (UHMWPE) or acetal copolymer.

6.5.2 In order to maintain the load application centered on the condyle, the side of the spacer/load applicator should feature a slight concavity with a large radius relative to the curvature of the femoral condyle. This provides self-centering of the applicator on the condyle while still approximating point contact. If a flat spacer/load applicator is used, the user must ensure that the load applicator does not migrate off of the femoral component during testing. If adhesive is used to secure the load applicator to the femoral component, evidence must be provided that the adhesive does not shield the femoral component from stress.

6.5.3 The minimum spacer thickness is recommended to be at least 6 mm to minimize the chance of spacer fracture under load.

6.5.4 The recommended spacer diameter is at least 13 mm.

7. Hazards

7.1 Hazards may include, but are not limited to, the following:

7.1.1 *Physical Hazards*—Mechanical testing may expose the user to several hazards including crush hazards, pinch points, and sharp objects. Users should be aware of hazards and utilize appropriate safety precautions.

7.1.2 *Chemical Hazards*—The use of potting media, such as poly(methyl methacrylate) (PMMA) bone cement and epoxy, are potentially hazardous and may cause irritation to the skin, eyes, and nasal passages. The mixing of the potting medium and the potting of the femoral component should be performed in a fume hood or similarly well-ventilated area.

8. Sampling

8.1 The test specimens shall conform to the final design specifications. Specific processes in the manufacturing flow chart may be omitted if they have been proven to not affect the fatigue characteristics of the materials or devices. Design characteristics include, but are not limited to, the following:

8.1.1 Material and post-manufacture treatment;

8.1.2 Dimensions and tolerances;

8.1.3 Surface characteristics including surface roughness, surface features, and coatings; and

8.1.4 Sterilization method.

9. Procedure

9.1 Test the worst-case condyle and component size, and this shall be justified. Depending on the design, either the medial or the lateral condyle may be the worst-case, and one method that can be used for this determination is Test Method F3161.

9.2 *Test Specimen Preparation and Potting*—Pot or fix the femoral component in such a manner that the load applied by the fatigue test machine simulates a force acting at 90° ± 2° of tibiofemoral flexion and 0° ± 2° of internal/external rotation (Fig. 1). The depth of the femoral component into the potting medium shall be sufficient such that the femoral component is rigidly fixed and does not loosen during testing, while leaving the regions of highest stress exposed. The potting level should be at least 5 mm below the intercondylar notch to expose this area, since this is typically a region of concentrated stress. Additional external fixation (such as a plate and a clamp) that does not interfere with the test may be used over the potting medium to increase the fixation strength.

9.3 *Alignment*—The condyle to be tested shall be aligned to the fatigue machine load axis. The load applicator shall be free to move in the transverse direction of load application. One method of aligning during setup is provided in X1.6.

9.3.1 *Sagittal View Alignment*—In the sagittal view, position the condyle under the load axis of the fatigue test machine to make contact with the posterior condyle at its peak curvature with a tolerance of ±1 mm.

9.3.2 *Transverse View Alignment:*

9.3.2.1 If the posterior articulation surface is flat in the transverse view, position the load application axis ±1 mm from the condyle bisection plane, as demonstrated in Fig. 1(b) on the medial condyle.

9.3.2.2 If the posterior articulating surface is curved in the transverse view, position the load application axis ±1 mm from the transverse condylar crown, as demonstrated in Fig. 1(b) on the lateral condyle.

9.4 *Test:*

9.4.1 The test shall be conducted under force control using a minimum force corresponding to 10 % of the maximum force in terms of absolute values. Run all tests at a frequency of 20 Hz or less. Take care to ensure that the test machine can maintain the applied load at the chosen frequency and that resonant conditions are not reached.

9.4.2 Measure the vertical deflection of the specimen using a dial gauge, displacement gauge, or other displacement measurement device. Note the location at which the deflection is measured under applied load.

9.4.3 The testing should be performed in ambient air, unless the environment is anticipated to have an effect on the fatigue testing results. It is recognized that for some materials, the environment may have an effect on the response during cyclic loading. The test environment used and the rationale for that choice shall be described in the test report.

9.5 *Test Termination*—Continue until one of the following occurs:

9.5.1 The femoral component fails (fractures).

9.5.2 Cracks are observed when the specimen is inspected under normal or corrected vision, or other nondestructive means.

9.5.3 A predetermined deflection limit is exceeded.

9.5.4 A predetermined number of cycles has been applied to the implant.

9.5.4.1 The recommended runout for this test method is ten million (10^7) cycles (X1.1).

9.5.5 The test machine fails to maintain the specified loading.

9.5.6 If a loading spacer is used, and if the spacer fragments or deforms so that it no longer serves its intended purpose. (In this case, note the occurrence and fit a new spacer before continuing the test.)

10. Report

10.1 Maintain the proper terminology when describing fatigue and fracture-related events (see Terminology E1823 for guidance).

10.2 The test report should include the following:

10.2.1 Test setup parameters:

10.2.1.1 Fixation method and potting medium.

10.2.1.2 The test environment.

10.2.1.3 The criteria for which condyle (medial or lateral) was chosen for load application (if available).

10.2.1.4 The applied load (maximum and minimum) and loading location relative to the femoral component, and its justification.

10.2.1.5 Test frequency and load waveform. Provide a rationale for the test frequency if a test frequency higher than 20 Hz was used.

10.2.1.6 A description of the load applicator.

10.2.1.7 Report if a spacer was used and its dimensions and material. Report if one or more replacement spacers was used.

10.2.2 The number of specimens tested.

10.2.3 All details relevant to the implants tested including type, size, material, and a rationale describing the selection of the worst-case components.

10.2.4 The number of fatigue cycles achieved.

10.2.5 The reason for test termination.

10.2.5.1 If failure was observed, provide photographs of the components before and after fracture to document the location and mode of failure.

10.2.6 If necessary, report the deflection limit, method of measurement, and the point at which the deflection was measured.

10.2.7 A statement indicating conformance or nonconformance with this test method.

11. Precision and Bias

11.1 It is not possible to have a precision statement because there is not a standard implant available to all users of the test method to develop such a statement. Additionally, it is not possible to specify the precision of the procedure in this test method because of the wide variance in design of the components to be tested.

11.2 No statement can be made as to the bias of this test method since no acceptable reference values are available.

12. Keywords

12.1 fatigue; FEA; finite element analysis; TKA; TKR; total knee arthroplasty; total knee femoral component; total knee replacement