Designation: F3140 – 23

Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Unicondylar Knee Joint Replacements[1]

This standard is issued under the fixed designation F3140; 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 test method covers a procedure for the fatigue testing of metallic tibial trays used in partial knee joint replacements.

1.2 This test method covers the procedures for the performance of fatigue tests on metallic tibial components using a cyclic, constant-amplitude force. It applies to tibial trays which cover either the medial or the lateral plateau of the tibia.

1.3 This test method may require modifications to accommodate other tibial tray designs.

1.4 This test method is intended to provide useful, consistent, and reproducible information about the fatigue performance of metallic tibial trays with unsupported midsection of the condyle.

1.5 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]

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 Guide 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

3. Terminology

3.1 *Definitions:*

3.1.1 *R value*—the *R* value, also known as the force ratio, is the ratio of the minimum load to the maximum load. See Terminology E1823.

$$R = \frac{\text{minimum load}}{\text{maximum load}} \quad (1)$$

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *anteroposterior (A/P) centerline*—a line that passes through the center of the tibial tray, parallel to the sagittal plane, perpendicular to the line of load application, and which is ½ the maximum tibial tray width in the M/L direction.

3.2.2 *distance, d_{ap}*—the perpendicular distance between the mediolateral centerline of the tibia component and the point of load application.

3.2.3 *distance, d_{ml}*—the perpendicular distance from the anteroposterior centerline of the tibia component to the center of the load application.

3.2.4 *fixture centerline*—a line that passes through the center of the fixture, aligned with the anteroposterior centerline.

3.2.5 *mediolateral (M/L) centerline*—a line that passes through the center of the tibial tray, parallel to the coronal or frontal plane, perpendicular to the line of load application, and which is ½ the maximum tibial tray length in the A/P direction.

4. Significance and Use

4.1 This test method can be used to describe the effects of materials, manufacturing, and design variables on the fatigue performance of metallic tibial trays subject to cyclic loading for relatively large numbers of cycles.

[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.

4.2 The loading of tibial tray 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 tibial tray designs, when tested under similar conditions.

4.3 In order for fatigue data on tibial trays 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 processed and finished condition.

6. Apparatus

6.1 The tibial tray shall be mounted as a three-point bend test. Care shall be taken to ensure that the three-point bend fixture does not produce abnormal stress concentrations that could change the failure mode of the part, especially at the two reaction locations. The reaction locations should include cylindrical rollers of 6 mm diameter to avoid constrained forces that will increase the run-out load. Deviation from cylindrical rollers or the suggested diameter shall be justified in test methods. One possible setup where walls are present on the anterior and posterior locations as well as medial lateral central locations is shown in Fig. 1. These walls are necessary to prevent a possible rotation or spit-out of the implant during the relatively high frequency fatigue test. Friction between the implant and the walls should be minimized.

6.1.1 The implant shall be placed on the rollers such that the distance between the centers of rollers shall not be less than 80 % of the A/P distance as shown in Fig. 1. The roller contact lengths should overlap with the A/P centerline to minimize moments causing rotation about the y-axis on Fig. 1.

6.1.2 The implant should be sufficiently supported to allow for bending forces to be applied while minimizing the moment imparted about the A/P or M/L axis that would result in test instability. In some cases, this location may mask the worst-case M/L load location. An analysis should be conducted to find the physiological worst-case location and fixture may need to be designed to accommodate this location.

6.2 The tibial tray shall be positioned such that the antero-posterior centerline and the fixture centerline are aligned with an accuracy of ±1 mm in the x-direction and ±2° in the x-y plane (see Fig. 1).

6.3 When the tibial tray design includes a central keel or other prominence, enough space shall be left under the tray to prevent the keel from impacting during the deflection.

6.4 Apply the force by means of a spherical indenter of either a diameter of 32 mm or use the femoral component at the tibiofemoral flexion angle that generates the smallest contact area between the femur and the tibial insert observed during flexion between 0° and 60°, whichever is smaller, to be used as worst-case loading condition. A spacer possessing sufficient stiffness and creep resistance (for example, ultra-high molecular weight polyethylene, acetal co-polymer) and a recommended circular footprint of 13 mm in diameter (see Fig. 2) shall be placed between the tibial tray and the load applicator to act as a spacer. In the case of semi-constrained or monoblock designs, it may be more appropriate to use the worst-case

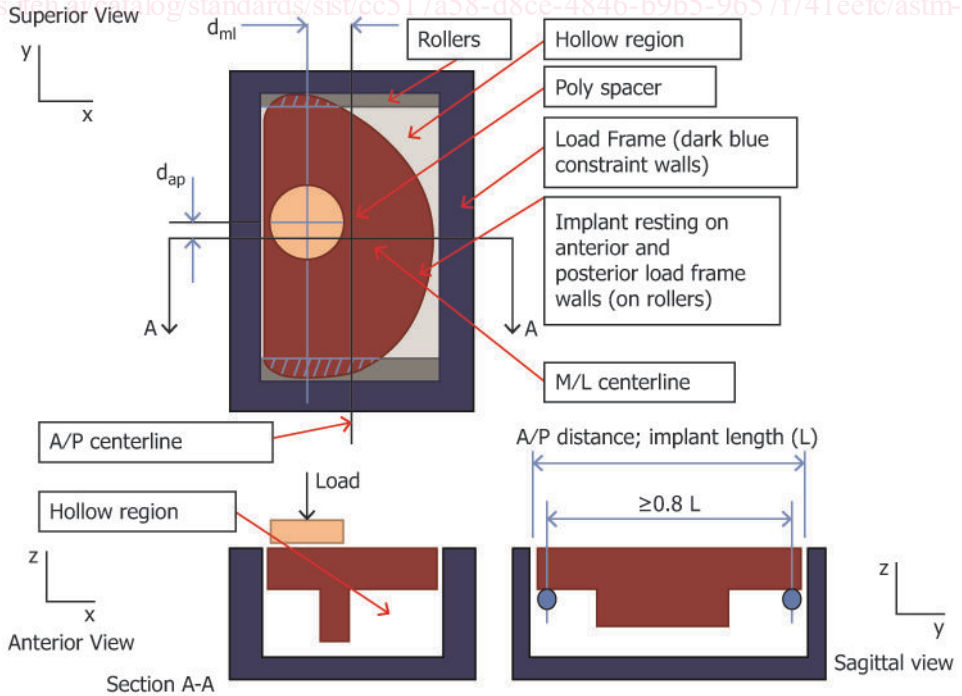

FIG. 1 Schematic of Suggested Test Setup

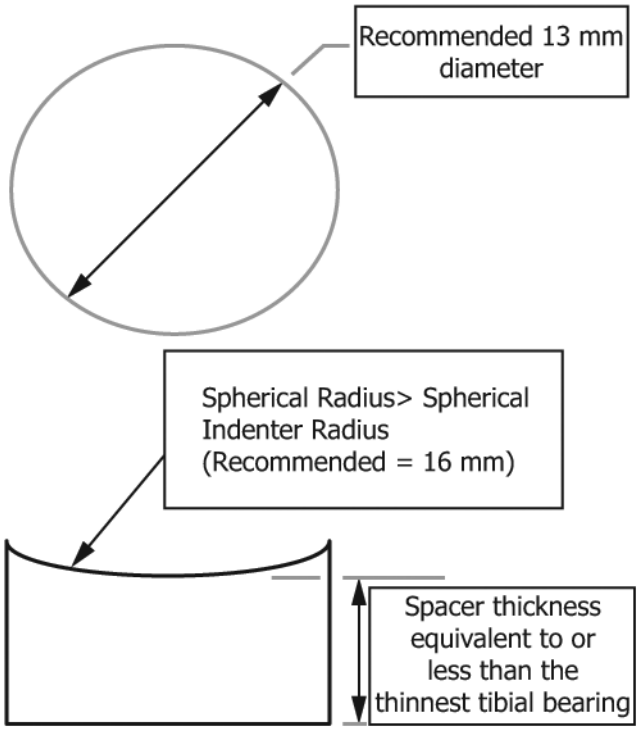

FIG. 2 Suggested Spacer Drawing with Concave Top Surface Cross Section Shown on Bottom Image
(Actual dimensions of the spacer may vary as smaller tibial tray designs may require a smaller diameter disk)

bearing. The choice of bearing used shall be justified in the final report. This spacer shall contain an indentation conforming to the load applicator. The load applicator shall be a spherical indenter or the intended femoral component fixed at a flexion angle consistent with the curvature representative of the walking gait contact geometry. The spacer recess shall be greater than or equal to the diameter of the load applicator.

6.4.1 The spacer shall be placed on the sulcus point of the tibial condyle. The purpose of the spacer is to distribute the load to the tibial tray condyle and to eliminate possible fretting fatigue initiated by contact between the metal indenter and the tibial tray.

6.4.2 The thickness of the spacer, measured at the thinnest point between the flat and indented surfaces, shall be no greater than the equivalent dimension of the thinnest tibial bearing.

6.5 The fixturing shall be constructed so that the load is applied perpendicular to the undeflected superior surface of the tibial tray.

6.6 Use one of the following two methods for determining the position of the loading point:

6.6.1 For tibial articulating surface designs that have a curved surface, the loading point shall be the intersection with the tray of a line perpendicular to the tray which intersects the deepest part of the curved recess of the articulating surface of the tibial component.

6.6.2 For other tibial designs, the femoral component, the tibial articulating surface, and the tibial tray shall be assembled at 0° flexion and the position of the center of pressure determined. The loading point shall be the intersection of the line perpendicular to the tray which intersects the center of the pressure contact area.

NOTE 1—Optionally, define the worst-case scenario considering the potential translation in the transverse plane and/or the potential axial rotation (**1**)[3] of the femoral component relative to the tibial baseplate, and apply 6.6.1 or 6.6.2. The rationale for the choice of femoral component placement relative to the tibial baseplate should be reported. Femoral loading location that has the potential to generate worst-case stress concentrations on the fixation features should be considered to address the true worst-case loading location.

NOTE 2—If the geometry of the tibial baseplate superior surface prevents using and d_{ap} and d_{ml} for the load application (for example, the presence of protrusion at the location of the theoretical load application), the rationale for the choice of the appropriate load location should be reported (X1.6 is an example of the variation that could occur due to tibial baseplate misalignment). Investigators may elect to use the thinnest tibial insert in lieu of the spacer for such a situation.

6.6.3 The d_{ap} and the d_{ml} shall be determined from either of the above techniques and will be used for all testing of that design in that size.

7. Equipment Characteristics

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

7.2 The dynamic loading waveform is sinusoidal at the primary frequency. 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-gaged part).

7.3 The 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 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. An initial number of cycles of loading may need to be applied to reach the desired load parameters before the initiation of the test.

7.3.1 Applied forces outside the ±2 % deviation limit at the beginning of the test will not invalidate the test. However, these cycles shall not be counted toward the completion count. Once counting begins, all cycles must be counted and the applied forces must remain within the deviation limit.

8. Procedure

8.1 Determine the size of the tibial tray component used by the investigator. Dimensions shall be reported.

8.1.1 A worst-case analysis shall be conducted and the resulting implant size(s) tested. A finite element analysis may be used in this determination.

8.1.1.1 Any deviation from the worst-case analysis shall be justified.

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

8.2 Position the test specimen such that the load axis is perpendicular to the undeflected superior surface of the tray since the tray surface will not remain perpendicular to the load axis during loading.

8.2.1 For implants that do not have flat superior faces, justify the orientation of the load axis.

8.3 Mount the tibial component on the fixture (see Fig. 1). Use the centerline of the tray to align the fixture.

8.4 Once aligned, clamp the fixture down to the test machine.

8.4.1 Use appropriate constraints to the fixture to maintain A/P and M/L axis shown in Fig. 1.

8.5 Apply the force by means of a spherical indenter either of radius 16 mm or the smallest contact area between the femur and the tibial insert observed during flexion between 0° and 60°, whichever is smaller, as worst-case loading conditions.

8.6 The magnitude of the load applied and number of samples tested are to be established by the user, with justification. See X1.8.

8.7 *Test Frequency*—Run all tests at a frequency of 20 Hz or less. Take care to ensure that the test machine can maintain the applied force at the chosen frequency and that resonant conditions are not reached.

8.8 *R value*—Run all tests with force ratio of 0.1.

NOTE 3—In strict terms, since the force applied to the tray 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 cantilever plane, the *R* value would be 0.1. See Terminology E1823 for the definition of the *R* value (in other words, force ratio).

8.9 Record the actuator position throughout the test and report the maximum deflection.

8.10 Report the test environment used.

9. Test Termination

9.1 The test shall run until the tibial tray fails or until the predetermined number of test cycles is reached. The suggested number of cycles is ten million. See X1.8.

9.1.1 Failure may be defined as a fracture of the tibial tray; 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: tibial tray material, spacer diameter and thickness, indenter diameter or smallest femoral component contact area at 0° to 60° flexion, overall anteroposterior and mediolateral dimensions of the tray, location of anteroposterior and mediolateral centerlines (for asymmetric tibial trays), tibial condyle maximum deflection during test, d_{ml}, d_{ap}, fixation method, largest compressive force, *R* value, cycles to failure, mode and location of failures, test environment, and test frequency. The method for determining the loading location on the tibial tray (that is, d_{ml} and d_{ap}) shall be documented.

10.3 Pictures of the tray and test setup pre- and post-testing should be included in the report. If the tibial tray fractured during the test, pictures should include superior and inferior views to document the location of crack and failure mode.

10.4 If any test results are excluded for any reason, the report must include adequate documentation justifying their exclusion.

11. Precision and Bias

11.1 *Precision*—It is not possible to have a precision statement because there is not a standard implant available to all users of this 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 *Bias*—No statement can be made as to the bias of this test method since no acceptable reference values are available.

12. Keywords

12.1 arthroplasty; orthopaedic medical devices; tibial components; unicondylar knee arthroplasty

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 Fractures of tibial trays in unicondylar knee replacement (UKR) have occurred in clinical applications (**2, 3**). The tray design, quality of bone, flatness of the cut surface, and other features contribute to implant fracture. One recognizable mode of clinical failure occurs when the anterior and posterior edges of the implant are resting on cortical bone while the mid-section is unsupported. This can be due to the skiving of the cutting tool or the posterior bone fragments left behind due to the breaking off of the cut bone to prevent posterolateral corner ligament damage. As the body loads are applied through the tray of the prosthesis, significant stresses can result at the area where the tray is unsupported. Because it is believed that this lack of support is the primary reason behind fracture of the tibial trays, this practice was chosen as a simplified model to