Designation: F1800 – 12

Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements[1]

This standard is issued under the fixed designation F1800; 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 tibial trays used in knee joint replacements. This practice 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 both the medial and lateral plateaus of the tibia. This practice may require modifications to accommodate other tibial tray designs.

1.2 This practice is intended to provide useful, consistent, and reproducible information about the fatigue performance of metallic tibial trays with one unsupported condyle.

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.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E4 Practices for Force 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

E1150 Definitions of Terms Relating to Fatigue (Withdrawn 1996)[3]

3. Terminology

3.1 *Definitions:*

3.1.1 *R value*—The R value is the ratio of the minimum load to the maximum load.

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

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *anteroposterior centerline*—a line that passes through the center of the tibial tray, parallel to the sagittal plane and perpendicular to the line of load application. For asymmetric tibial tray designs, the appropriate center of the tibial tray shall be determined by the investigator and the rationale reported.

3.2.2 *fixture centerline*—a line that passes through the center of the fixture, parallel to the anteroposterior centerline. This line represents the separation between the supported and unsupported portions of the test fixture.

3.2.3 *mediolateral centerline*—a line that passes through the center of the tibial tray, parallel to the coronal, or frontal, plane and perpendicular to the line of load application. For asymmetric tibial tray designs, the appropriate center of the tibial tray shall be determined by the investigator and the rationale reported.

3.2.4 *moment arm, d_{ap}*—the perpendicular distance between the mediolateral centerline of the tibia component and the line of load application.

3.2.5 *moment arm, d_{ml}*—the perpendicular distance between the anteroposterior centerline of the tibia component and the line of load application.

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 tibial trays subject to cyclic loading for relatively large numbers of cycles.

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.

[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] The last approved version of this historical standard is referenced on www.astm.org.

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 finished condition.

6. Apparatus

6.1 The tibial tray shall be mounted as a cantilever beam (see Fig. 1 and Fig. 2). Care shall be taken to ensure that the fixation of the tibial tray does not produce abnormal stress concentrations that could change the failure mode of the part. One possible setup involving fixation of the inferior surface or clamping of the superior surface is shown in Fig. 1 and Fig. 2. If necessary, bone cement or other high strength epoxy may be used on the supported aspect of the tibial tray to prevent loosening during the test.

6.2 The tibial tray shall be positioned such that the anteroposterior 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 and Fig. 2).

6.3 When the tibial tray design includes a central keel or other prominence, the proper method for support of the keel must be determined. Depending on the tibial tray design, it may be necessary to evaluate the design with or without support of the keel (see Fig. 2). The method of supporting (or not supporting) any such feature shall be reported.

6.4 A spacer of plastic possessing sufficient stiffness and creep resistance (for example, ultra high molecular weight polyethylene, acetal co-polymer) shall be placed between the tibial tray and the load applicator (see Fig. 3). The spacer shall contain a spherical indentation (or recess) for the spherical indenter. This recess shall be greater to or equal than the diameter of the spherical indenter and is included to minimize the chance of spacer fracture under load. The spacer shall have a minimum thickness of 6 mm, measured at the dome of the sphere. It is recommended that the diameter of the spacer is 13 mm.

NOTE 1—Actual dimensions of the spacer may vary as smaller tibial tray designs may require a smaller diameter disk.

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

6.5 The fixturing shall be constructed so that the load shall be 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.

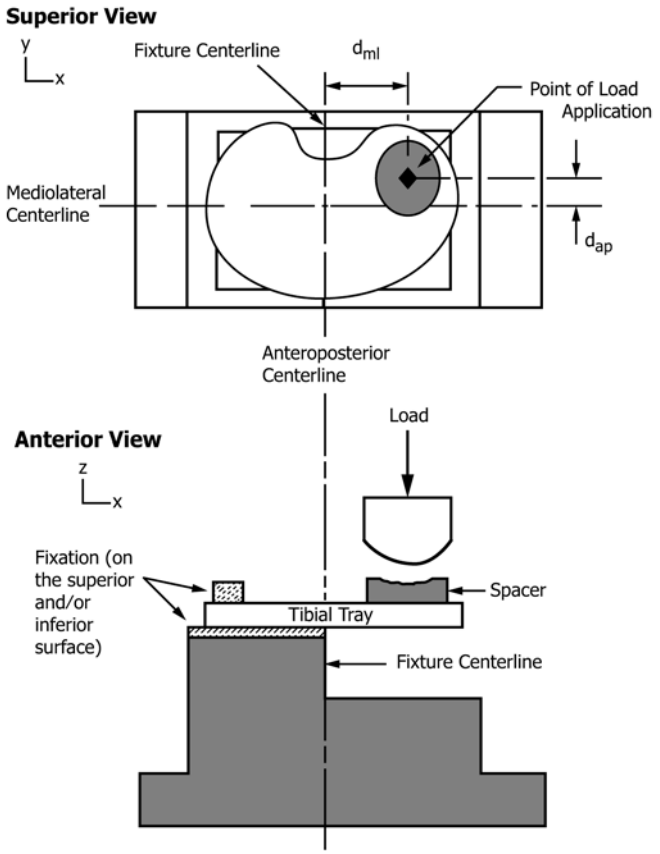

FIG. 1 Schematic of Test Setup Without a Central Keel

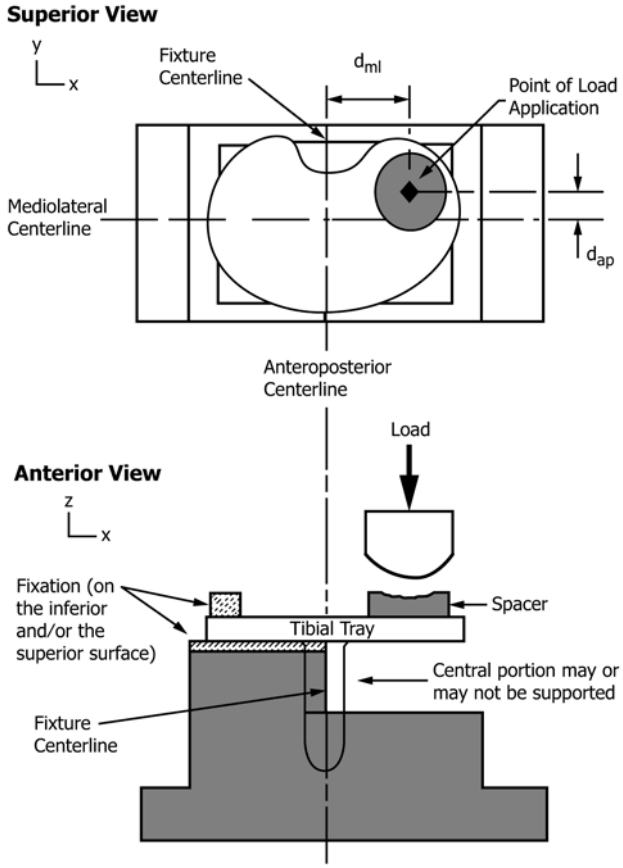

FIG. 2 Schematic or Test Setup With a Central Keel

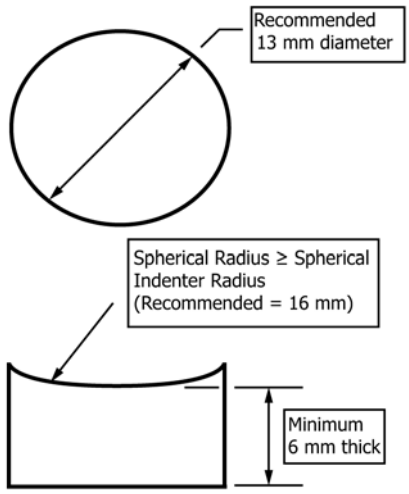

FIG. 3 Recommended Spacer Drawing

6.6.1 For tibial articulating surface designs that have a concave 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 concave 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 2—Optionally, define the worst-case scenario considering the potential translation in the transverse plane and/or the potential axial

rotation (**1**)[4] 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.

NOTE 3—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).

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.

6.7 The load shall be applied by means of a spherical indenter, a diameter of 32 mm is recommended.

7. Equipment Characteristics

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

7.2 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 monitoring system such as the transducer mounted in line with the specimen. Monitor the test loads 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.

8. Procedure

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

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.

8.3 Mount one side of a symmetric tibial component on the fixture (see Fig. 1 and Fig. 2). Use the centerline of the tray to distinguish between supported and non supported sides. If asymmetrical, fix the tibial component such that a worst case condition is tested. Report the criteria used to distinguish between supported and not supported sides.

8.4 Apply the load by means of a spherical indenter.

8.5 *Test frequency*—Run all tests at a frequency of 30 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.

8.6 *R value*—Run all tests with an *R* value of 10.0.

NOTE 4—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 E1150 for the definition of the *R* value.

8.7 Measure the vertical deflection of the tibial tray using a dial gage, displacement transducer, and so forth. Record the point at which the deflection is measured (that is, under the applied load, at the point of maximum deflection).

8.8 Report the test environment used.

9. Test Termination

9.1 Continue the test until the tibial tray fails or until a predetermined number of cycles has been applied to the implant. The suggested number of cycles is ten million. 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, overall anteroposterior and mediolateral dimensions of the tray, location of anteroposterior and mediolateral centerlines (for asymmetric tibial trays), tibial condyle loaded (for asymmetric tibial trays), d_{ml}, d_{ap}, fixation method, largest compressive load, *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.

11. Precision and Bias

11.1 A precision and bias statement does not exist for this practice.

12. Keywords

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

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

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 Fractures of tibial trays in TKR have occurred in clinical applications (**2-6**). The tray design, quality of bone, and other features contribute to implant fracture. One recognizable mode of clinical failure occurs when the lateral portion of the tray is firmly anchored while bone support of the medial condyle is absent. As the body loads are applied through the tray of the prosthesis, significant stresses can result at the area where the tray is still firmly supported. 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 use in fatigue testing of actual implants.

X1.2 It is recognized that for some materials the environment may have an effect on the response to cyclic loading. The test environment used and the rationale for that choice shall be described in the test report.

X1.3 It is also recognized that actual *in vivo* loading conditions are not constant amplitude. However, there is insufficient information available to create standard load spectrums for metallic tibial components. Accordingly, a simple periodic constant amplitude force is recommended.

X1.4 Worst case loading of the tibial tray may vary depending on material, design, and clinical indications. The researcher shall evaluate the possible clinical and design related failure modes and attempt to determine a worst case situation. As stated above, loss of medial bone support has been clinically and is thus incorporated in this practice. Additional factor that may be of importance include wear that has been reported in the posterior medial region of the tibia (**7**). Also, as the method of heat treatment can affect the strength of the tibial tray material, it shall be considered. For example, the high temperature sintering treatment used to apply a porous coating to a tibial tray may affect the fatigue strength of the tibial tray.

X1.5 The size of tibial tray to be tested shall be determined by the investigator. In general, the worst case size shall be chosen based on evaluation or experience, or both. In a design with a constant tray thickness, maximizing the d_{ml} will result in the largest moment arm and therefore the highest stresses in the tray; however, a tray of non-uniform thickness may not adhere to this rule. There may also be a reason why an investigator wishes to test a size that is not worst case. This practice may also be used for this purpose.

X1.6 The tolerance chosen for the alignment of the tibial tray is based on finite element analysis of a tibial tray design with and without a central keel. The analysis represents one design under specific boundary conditions and is shown as one example of the variation that can occur due to tibial tray misalignment. The results of this analysis were as follows:

Effect of Malignment (1 mm Shift)

Design	Change in Stress from Correct Alignment
no keel	4 % increase
keel	8 % increase

Effect of Malrotation (5° Rotation)

Design	Change in Stress form Correct Alignment
no keel	5.5 % increase
keel	10 % increase

The required tolerance limits (± 1 mm and $\pm 2°$) were chosen to minimize the change in stress while ensuring a reasonable test setup.

X1.7 It is recommended that testing be terminated at ten million cycles if failure of the tibial tray has not occurred. The tibial tray design addressed in this testing are designed to replace the knee joint and intended to carry load over the life of the implant. Ten million cycles represents the number of loading cycles a tibial tray might experience over ten years of clinical use (estimated at one million loading cycles per year). It is recognized that in this unsupported condition, the implant may not be required to withstand this number of loading cycles prior to revision.

X1.8 In developing this practice, it was recognized that alternative methods for testing tibial trays exist. One such test method would include placing a tibial insert in the metal tray and applying load through femoral component with a greater distribution on the medial condyle (at a ratio of 60/40 or 80/20). This practice attempts to simplify the loading conditions while addressing clinical failure modes of tibial tray designs. Based on various goals, investigators may seek to deviate from the test method defined here.

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