



Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements¹

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- E1150 Definitions of Terms Relating to Fatigue (Withdrawn 1996)³

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.

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.