



Designation: F3140 – 17

Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Unicondylar Knee Joint Replacements¹

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 mid-section 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:

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 ($\epsilon-N$) Fatigue Data

E1823 Terminology Relating to Fatigue and Fracture Testing

E1800 Specification for Adhesive for Bonding Foam Cored Sandwich Panels (160°F Elevated Humidity Service), Type I Panels

E1823 Terminology Relating to Fatigue and Fracture Testing

E2083 Classification for Building Construction Field Requirements, and Office Overhead & Profit

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 and perpendicular to the line of load application.

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

3.2.3 *mediolateral (M/L) 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.

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

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

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.

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*

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.

Current edition approved Sept. 1, 2017. Published October 2017. DOI: 10.1520/F3140-17.

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 6mm 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 $\pm 2^\circ$ in the x-y plane (see Fig. 1).

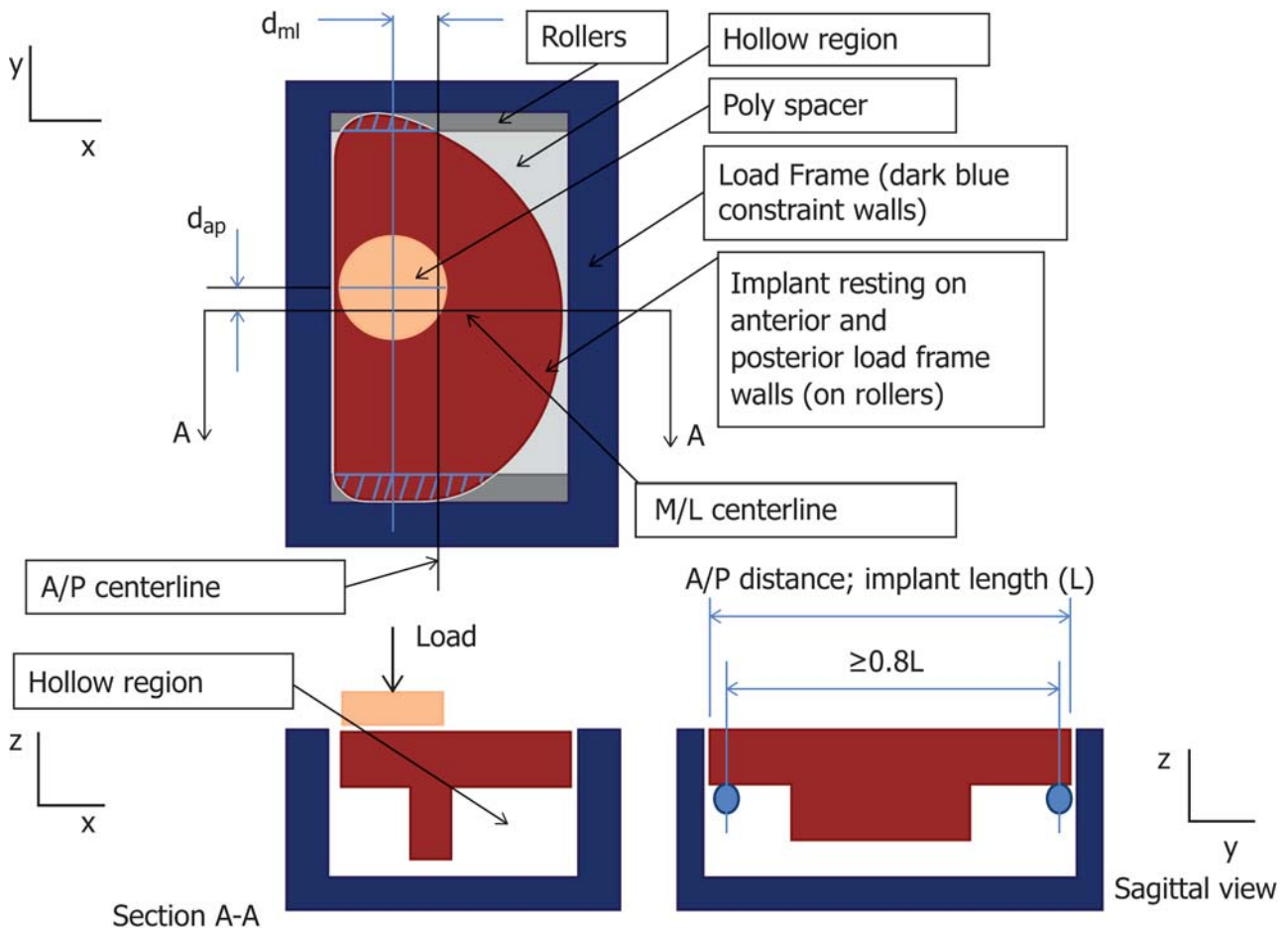


FIG. 1 Schematic of Suggested Test Setup