



Standard Test Method for Determination of Total Knee Replacement Constraint¹

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1. Scope

1.1 This test method covers the establishment of a database of total knee replacement (TKR) motion characteristics with the intent of developing guidelines for the assignment of constraint criteria to TKR designs. (See the Rationale in [Appendix X1](#).)

1.2 This test method covers the means by which a TKR constraint may be quantified according to motion delineated by the inherent articular design as determined under specific loading conditions in an *in vitro* environment.

1.3 Tests deemed applicable to the constraint determination are antero-posterior draw, medio-lateral shear, rotary laxity, valgus-varus rotation, and distraction, as applicable. Also covered is the identification of geometrical parameters of the contacting surfaces which would influence this motion and the means of reporting the test results. (See Practices [E4](#).)

1.4 This test method is not a wear test.

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 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](#)
[F2083 Specification for Knee Replacement Prosthesis](#)

3. Terminology

3.1 *Definitions*—Items in this category refer to the geometrical and kinematic aspects of TKR designs as they relate to

their human counterparts:

3.1.1 *anterior curvature, n*—a condylar design which is generally planar except for a concave—upward region anteriorly on the tibial component.

3.1.2 *anterior posterior (AP), n*—any geometrical length aligned with the AP orientation.

3.1.3 *AP displacement, n*—the relative linear translation between components in the AP direction.

3.1.4 *AP draw load, n*—the force applied to the movable component with its vector aligned in the AP direction causing or intending to cause an AP displacement.

3.1.5 *biconcave, n*—a condylar design with pronounced AP and ML condylar radii seen as a “dish” in the tibial component or a “toroid” in the femoral component.

3.1.6 *bearing surface, n*—those regions of the component which are intended to contact its counterpart for load transmission.

3.1.7 *condyles, n*—entity designed to emulate the joint anatomy and used as a bearing surface primarily for transmission of the joint reaction force with geometrical properties which tend to govern the general kinematics of the TKR.

3.1.8 *distraction, n*—the separation of the femoral component(s) from the tibial component(s) in the *z*-direction.

3.1.9 *femoral side constraint, n*—that constraint provided by the superior articulating interfaces, determined by fixing the inferior surface of the mobile bearing component during testing.

3.1.10 *flexion angle, n*—the angulation of the femoral component (about an axis parallel to the *y*-axis) from the fully extended knee position to a position in which a “local” vertical axis on the component now points posteriorly.

3.1.10.1 *Discussion*—For many implants, 0° of flexion can be defined as when the undersurface of the tibial component is parallel to the femoral component surface that *in vivo* contacts the most distal surface of the femur. This technique may not be possible for some implants that are designed to have a posterior tilt of the tibial component. In these cases, the user shall specify how the 0° of flexion position was defined.

3.1.11 *hinge, n*—a mechanical physical coupling between femoral and tibial components which provides a single axis about which flexion occurs.

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.