



Standard Test Method for Determination of Total Knee Replacement Constraint¹

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1. Scope

1.1 The purpose of this test method is to establish 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 while 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 E 4.)

1.4 This test method is not a wear test.

1.5 *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

- E 4 Practices for Force Verification of Testing Machines
- F 2083 Specification for Total Knee 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*—a condylar design which is generally planar except for a concave—upward region anteriorly on the tibial component.

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

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

3.1.4 *AP draw load*—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*—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*—those regions of the component which are intended to contact its counterpart for load transmission.

3.1.7 *condyles*—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*—the separation of the femoral component(s) from the tibial component(s) in the z-direction.

3.1.9 *flexion angle*—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.

3.1.9.1 *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.

3.1.10 *hinge*—a mechanical physical coupling between femoral and tibial components which provides a singular axis about which flexion occurs.

3.1.11 *hyperextension stop*—a geometrical feature which arrests further progress of flexion angles of negative value.

3.1.12 *internal-external rotation*—the relative angulation of the moveable component about an axis parallel to the z-axis.

3.1.13 *joint reaction force*—the applied load whose vector is directed parallel to the z-axis, generally considered parallel to tibial longitudinal axis.

3.1.14 *medio-lateral (ML)*—the orientation that is aligned with the y-axis in the defined coordinate system.

3.1.15 *ML condylar radius*—the geometrical curvature of the component’s condyle in the frontal plane.

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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.