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Designation: ~~F1223 – 14~~ F1223 – 20

Standard Test Method for
Determination of Total Knee Replacement Constraint[1]

This standard is issued under the fixed designation F1223; 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 the establishment of a database of total knee replacement (TKR) motion characteristics~~ may be used to compare the constraint characteristics of total knee replacements (TKRs) with the intent of ~~developing guidelines for the assignment of constraint criteria to TKR designs. (See the Rationale in~~comparing new designs to existing clinically successful designs or to determine the constraint differences ~~Appendix X1.)~~between two similar or dissimilar designs.

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~~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~~ safety, health, and ~~health~~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:*[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:

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[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.

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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*~~—*adj*—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,*~~*condyle, 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.

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

3.1.13 *inferior articulating interfaces, n*—any interface in which relative motion occurs between the underside of the mobile bearing component and the tibial tray.

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

3.1.15 *joint reaction force, n*—the applied load whose vector is directed parallel to and collinear with the *z*-axis, generally considered parallel to tibial longitudinal axis.
  3.1.15.1 *Discussion*—
The applied load may be optionally offset medially yet continuing to be parallel to the *z*-axis.

3.1.16 *medio-lateral* (ML),~~*n*~~—*adj*—referring to the orientation that is aligned with the *y*-axis in the defined coordinate system.

3.1.17 *ML condylar radius, n*—the geometrical curvature of the component's condyle in the frontal plane.

3.1.18 *ML dimension, n*—any geometrical length aligned with the ML orientation.

3.1.19 *ML displacement, n*—the relative linear translation between components in the ML direction.

3.1.20 *ML shear load, n*—the force applied to the moveable component with its vector aligned in the ML direction and causing or intending to cause an ML displacement.

3.1.21 *mobile bearing component, n*—the ultra-high molecular weight polyethylene (UHMWPE) component that, by design, articulates against both the femoral bearing and the tibial tray.

3.1.22 *mobile bearing knee system, n*—a knee prosthesis system, comprised of a tibial component, a mobile bearing component that can rotate or rotate and translate relative to the tibial component, and a femoral component.

3.1.23 *post-in-well feature, n*—a TKR design which tends to influence kinematics through the coupling of a prominent eminence with a recess or housing in a mating component.

3.1.24 *rotary laxity* (RL),*n*—degree of relative angular motion permitted for a moveable component about the *z*-axis as governed by inherent geometry and load conditions.

3.1.25 *rotary torque, n*—the moment applied to the moveable component with its vector aligned to an axis parallel to the *z*-axis and causing or intending to cause an internal or external rotation.

3.1.26 *superior articulating interfaces, n*—any interface in which relative motion occurs between the topside of the mobile bearing component and the femoral bearing component.

3.1.27 *tibial eminence, n*—a raised geometrical feature separating the tibial condyles.

3.1.28 *tibial side constraint, n*—that constraint provided by the inferior articulating interface.

3.1.29 *valgus-varus constraint, n*—degree of relative angular motion allowed between the femoral and tibial components of post-in-well ~~designs (or similar designs)~~similar) designs in the coronal plane.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *constraint, n*—the relative inability of a TKR to be further displaced in a specific direction under a given set of loading conditions as dictated by the TKR's geometrical design. This motion is limited, as defined in this test, to the available articular or bearing surfaces found on the tibial component. The actual relative motion values shall be provided as indicators of this type of constraint.

3.2.2 *coordinate system* (see Fig. 1),*n*—a set of ~~arbitrary cartesian coordinates~~ Cartesian axes affixed to the stationary ~~component and aligned such that the origin is located at the intersection of the~~ component.~~y and z axes.~~
    3.2.2.1 *Discussion*—
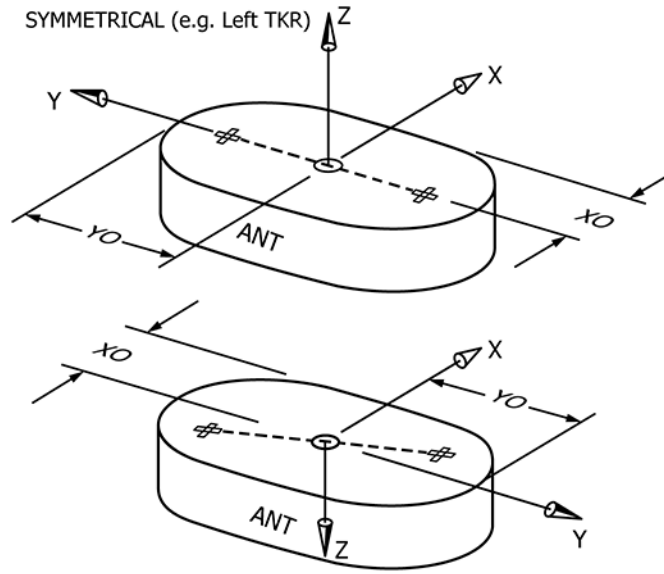Examples of symmetrical and asymmetrical designs are shown in Fig. 1.
    3.2.2.2 *Discussion*—
The *y*-axis is parallel to the ML direction, directed medially, and is coincident with the mated components' contact points when the knee is in the neutral position (see 7.2). The *z*-axis is located midway between the mated components' contact points (or in the case of a single contact point, located at that point) and aligned in the superior-inferior direction of the distal component. A third axis, *x*, mutually orthogonal to the two previous axes is directed posteriorly. For determination of contact points, see Annex A1 and Fig. 2. The contact point shall be located to a tolerance of ±1 mm. In the case of multiple contact points on a condyle, an average location of the contact points shall be used.

3.2.3 *degrees of freedom, n*—although the knee joint is noted to have 6 ~~df,~~ degrees of freedom (df), or directions in which relative motion is guided (three translations: AP, ML, vertical; three angulations: flexion, internal-external rotation, valgus-varus), the coupling effects due to geometrical features reduce this number to five which are the bases of this test method: AP draw, ML shear, internal-external rotation, valgus-varus rotation, and distraction.
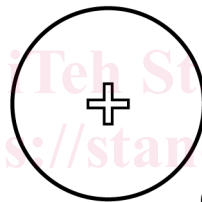
3.2.4 *neutral position* (see 7.2),*n*—that position in which the TKR is at rest with no relative linear or angular displacements between components.
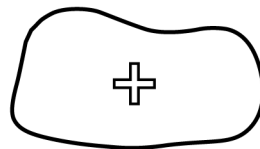   3.2.4.1 *Discussion*—

SYMMETRICAL (e.g. Left TKR)

FIG. 1 Examples of Defined Coordinate System Examples

CIRCULAR

RECTANGULAR

GENERAL

CONTACT POINT (✛) IS CENTROID OF CONTACT AREA

FIG. 2 Examples of Tibial Condyle Contact Point Location Examples

This is design-dependent and there may be a unique neutral position at each flexion angle. It may be indicated that the femoral component, when implanted, be positioned at some angle of hyperextension as seen when the patient's knee is fully extended; this, then becomes the neutral position for negative flexion angle tests. The neutral position may be determined either by applying a compressive force of 100 N and allowing the implant to settle or by measuring the vertical position of the movable component

with respect to the stationary and using the low point of the component as the neutral point. In those implants with a flat zone and no unique low point, the midpoint of the flat zone can be used as the neutral point. For those implants having a tibial component with a posterior tilt, the user may use other means to define the neutral point, but shall report on how it was found.

3.2.5 *set point, n*—that numeric quantity assigned to an input, such as a load.

3.2.6 *movable component, n*—that component identified either through design or test equipment attributes as providing the actual relative motion values.
 3.2.6.1 *Discussion—*
Depending upon the user's fixtures and the stationary component, it can be either the tibial or femoral component.

3.2.7 *stationary component, n*—that component identified either through design or test equipment attributes as being at rest during that test and to which actual relative motion values are referenced.

 3.3 *Symbols:* Parameters:

3.3.1 *TAP*—overall AP tibial surface ~~dimension.~~dimension (see Fig. 3).

3.3.2 *TML*—overall ML tibial surface ~~dimension.~~dimension (see Fig. 4 and Fig. 5).

3.3.3 *x, y, z*—axes of neutral position coordinate system as defined in Annex A1 and Fig. 1.

3.3.4 *DIST*—a "yes/no" response to distraction test at the reported angle at which distraction is most likely to occur.

4. Significance and Use

4.1 This test method, when applied to available products and proposed prototypes, is meant to provide a database of product functionality capabilities (in light of the suggested test regimens) that is hoped will aid the physician in making a more informed total knee replacement (TKR) selection.

4.2 A proper matching of TKR functional restorative capabilities and the recipient's (patient's) needs is more likely to be provided by a rational testing protocol of the implant in an effort to reveal certain device characteristics pertinent to the selection process.

4.3 The TKR product designs are varied and offer a wide range of constraint (stability). The constraint of the TKR in the *in vitro* condition depends on several geometrical and kinematic interactions among the implant's components which can be identified and quantified. The degree of TKR's kinematic interactions should correspond to the recipient's needs as determined by the physician during clinical examination.

4.4 For mobile bearing knee systems, the constraint of the entire implant construct shall be characterized. Constraint of mobile bearings is dictated by design features at both the inferior and superior articulating interfaces.
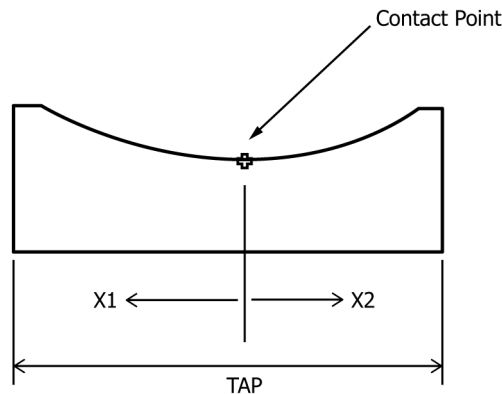
NOTE 1—Sagittal plane section view. Cut taken through the condylar contact points. Anterior is to the left.
FIG. 4~~3~~ AP Dimensions and Displacement Examples

5
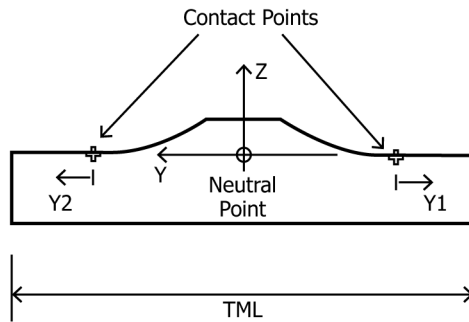
NOTE 1—Coronal plane section view. Cut taken though the condylar contact points. Medial is to the left.

FIG. 5 ML Dimensions and Displacements Example

4.5 The methodology, utility, and limitations of constraint/laxity testing are discussed.[3,4] The authors recognize that evaluating isolated implants (that is, without soft tissues) does not directly predict *in vivo* behavior, but will allow comparisons among designs. Constraint testing is also useful for characterizing implant performance at extreme ranges of motion which may be encountered *in vivo* at varying frequencies, depending on the patient's anatomy, pre-operative capability, and post-operative activities and lifestyle.

5. Apparatus

5.1 *General:*

5.1.1 The stationary component should be free to move only in directions parallel to the *z*-axis and not permitted to rotate about this axis in all but the distraction test. In the distraction test it is fully fixed.

NOTE 1—In order to test asymmetrical designs, which may be asymmetrical about the sagittal or frontal planes, it may be necessary to allow additional degrees of freedom in addition to those discussed in 5.1, 5.2, 5.3, and 5.4. For example, the anterior ridge of the tibial bearing insert may be thicker than the posterior ridge. Also the medial and lateral surfaces may not be identical. As a result of this implant asymmetry, condylar liftoff may occur. For example, during a rotary test, one may need to allow valgus/varus angulation to ensure that both condyles remain in contact. If one does allow additional degree(s) of freedom, these changes to the test method shall be included in the report. For the internal/external rotation test, asymmetrical designs may also require a different center of rotation than as defined in Section 3 and Annex A1. If a different center of rotation is used, it shall be stated in the report section.

5.1.2 The movable component shall be the displaced member when under loads specific to that test and shall be instrumented accordingly to obtain data pertinent to that test.

5.1.3 Load or torque actuators producing input vectors which tend to displace the movable component relative to the stationary component according to the guidelines of the specific tests shall be provided with a means of gradually applying the load or torque to the set point of that test.

5.1.4 Displacement sensing devices shall be arranged so as to measure relative motion between components in accordance with the prescribed coordinate system.

5.1.5 Output graphs depicting the relationship of load and displacement are required (see Fig. 3 6).

5.1.6 The moveable component shall be mounted on a fixture with near zero friction or the effect of that friction shall be subtracted from the applied force.

5.1.7 *Tibial Tray Alignment*—The tibial tray shall be mounted to reflect the recommended amount of posterior slope, if any.

5.1.8 The femoral component alignment shall be mounted according to the manufacturer's specifications, such that during flexion both femoral condyles are in contact with the tibial condyles.

[3] Walker PS, Haider H, "Characterizing the Motion of Total Knee Replacements in Laboratory Tests," *Clin. Ortho. Rel. Res*., 410, 2003, pp. 54–68.
[4] Haider H, Walker PS, Measurements of Constraint of Total Knee Replacement, *Journal of Biomechanics*, Vol. 38, No. 2, 2005, pp. 341–348.
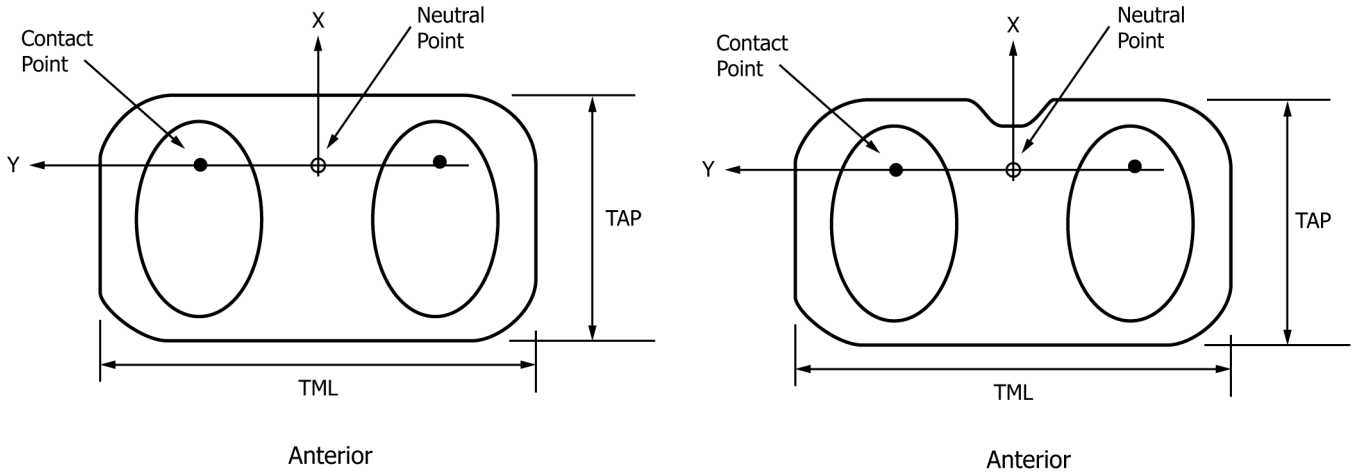
Note 1—Transverse plane section view. Center of rotation for rotary laxity test is about the neutral point.

FIG. 6 5 A,B Example of Neutral Point Determination Example
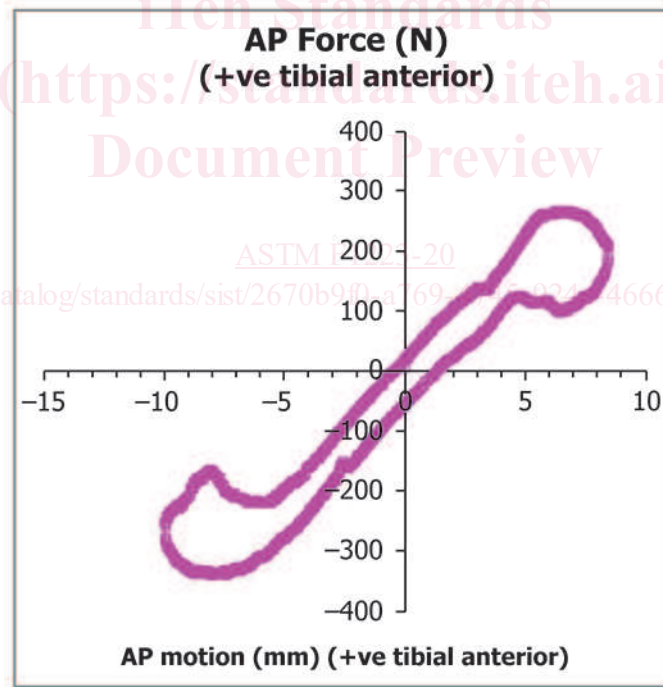

FIG. 3 6 Output Graph Examplegraph example showing AP displacement as a result of AP loading

Note 1—This figure corresponds to 3 cycles of loading. The graph's *y*-axis is AP force and the graph's *x*-axis is AP displacement. This figure demonstrates the hysteresis effect that occurs due to loading in each direction.

5.2 *Antero-Posterior Draw Test*—The movable component shall be rigidly set in a fixture free to move in linear directions parallel to the *x*-axis only.

5.3 *Medio-Lateral Shear Test*—The movable component shall be rigidly set in a fixture free to move in linear directions parallel to the *y*-axis only.