



Standard Test Method for External Fixator Connectors¹

This standard is issued under the fixed designation F 1745; 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 procedures for determining the stiffness and strength of external fixator connecting elements (clamps) under axial loads and bending moments. Depending on the design of the connector and its use in the overall construct, the connector needs to transmit one or more components of loading (tension, compression, torsion, or bending, or all of these) between the elements it grips (anchorage elements or bridge elements), without itself undergoing either permanent deformation or excessive elastic deformation.

1.2 *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:

E 4 Practices for Force Verification of Testing Machines²

F 1541 Terminology and Classification of External Skeletal Fixators³

F xxxx Test Method for External Fixator Performance and Testing³

3. Terminology

3.1 Definitions:

3.1.1 *connectors*—external fixator elements used to join bridge elements either to other bridge elements, or to anchorage elements.

3.1.2 *input loading axis*—the line of application in the case of a force input, or the axis about which a moment is applied in the case of a moment input.

3.1.3 *input loading platen*—a member, not normally part of the connector during clinical usage, through which the input force (or moment) is delivered from the testing machine actuator to the connector.

3.1.4 *support platen*—a member, also not normally part of the connector during clinical usage, through which the connector is rigidly affixed to the testing machine base.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *connectors*—of the two elements comprising any joint or junction, the connector is that element to which the end-user applies an active gripping force or torque in order to engage the attachment.

3.2.1.1 *Discussion*—Connectors should be described in terms of the types of elements that they connect, and where appropriate, in terms of their adjustment or unlocked degrees of freedom.

3.2.2 *pin(-rod) clamps, pin cluster(-rod) clamps, ring-rod clamps, and rod-rod clamps*—examples of connectors.

4. Summary of Test Method

4.1 Connecting elements (clamps) are obtained, and if applicable, assembled using the techniques and equipment recommended by the manufacturer. Platens substituting for the body or anchorage elements, or both, are attached to the connector in such a manner that no slippage can occur relative to the connector. Axial loads or bending moments are applied to the connector, and a graphical plot of load (or moment) versus displacement is used to determine the intrinsic stiffness (and strength, if tested to failure) of the connector.

5. Significance and Use

5.1 These laboratory benchtop tests are used to determine values for the intrinsic stiffness (or strength, or both) of connectors, under force or moment loadings. During testing, the connectors are loaded and supported in such a manner that all measured deformation occurs within the connector itself, rather than at the interface between the connector and the fixator element(s) gripped.

5.2 The results obtained in this test method are not intended to predict the clinical efficacy or safety of the tested elements. This test method is intended only to measure the uniformity of the elements tested, or to compare the mechanical performance of different connectors.

5.3 This test method may not be appropriate for all types of external skeletal fixator applications. The user is cautioned to consider the appropriateness of the method in view of the materials and designs being tested and their potential application.

6. Apparatus

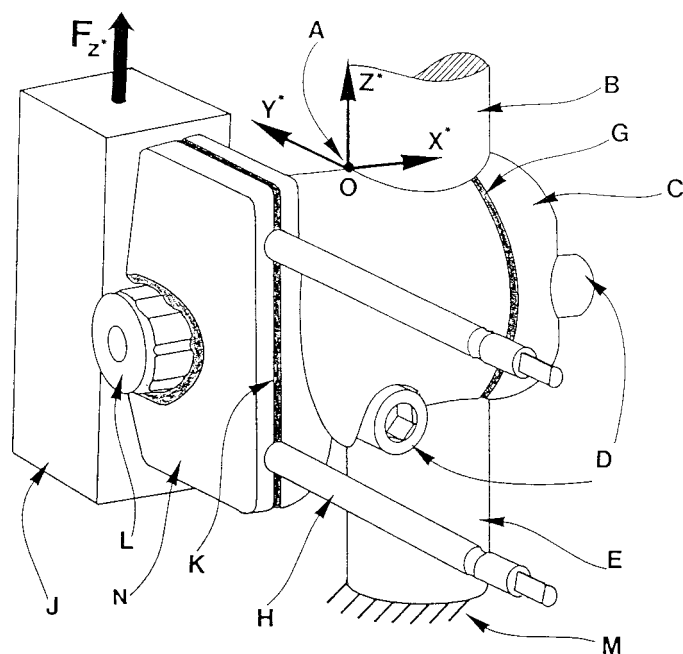
6.1 *Force (or Moment, or Both) Application Fixture*—The loading configuration is shown schematically in Fig. 1. The

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² *Annual Book of ASTM Standards*, Vol 03.01.

³ *Annual Book of ASTM Standards*, Vol 13.01.



- A. Local coordinate system, defined with respect to landmark point O
- B. Rod (as normally gripped by connector)
- C. Connector body
- D. Connector tightening mechanism(s)
- E. Rod grip platen (support platen)
- G. Rod grip interface
- H. Pins (as normally gripped by connector)
- J. Pin grip/clamp platen (loading input platen, rigidly bonded to pin grip)
- K. Pin clamping interface
- L. Pin grip/clamp tightening mechanism
- M. Testing machine base (fixed)
- N. Pin grip/clamp

NOTE 1—In this illustration, the input loading is a force F_{z^*} in the z^* direction, delivered through a loading platen rigidly affixed to the pin grip/clamp.

FIG. 1 Schematic for Testing an External Fixator Connector (Example for a Pin-Rod Joint)

input loading axis must pass through one of the platens (the loading platen) rigidly affixed to the connector. The other platen (the support platen) is rigidly affixed to the base of the testing apparatus.

6.2 Load Frame—Machines used for testing shall conform to the requirements of Practice E 4. The loads used for the test shall be within the loading range of the test machine as defined in Practice E 4.

6.3 Data Acquisition Device—A suitable recorder to plot a graph of load versus load frame displacement on perpendicular axes. This optionally may include the use of computer-based digital sampling and output of the load and displacement signals.

7. Test Specimens

7.1 All tested connectors should normally be representative of new clinical quality products.

7.2 If the connector(s) to be tested have been previously used, appropriately describe the nature of such prior usage.

7.3 Prepare the test specimens in the manner in which they would normally be used clinically. For example, if a particular connector would normally be sterilized in a particular manner

prior to clinical use, it should be similarly sterilized prior to mechanical testing.

7.4 If the connector to be tested is a prototype or under development, or both, either include the geometric and material information needed to fully characterize the component in the report, or reference detailed descriptive information.

8. Procedure

8.1 Configuring the Connecting Element for Testing:

8.1.1 With the connecting element assembled in the configuration normally used, affix input and support platens. This should be done in a manner that ensures that all measured deformations are intrinsic to the connecting element itself, and are not influenced by possible interfacial slippage between the connecting element and the fixator elements (for example, rods or anchorage pins) that it clamps.

8.1.1.1 The input and support platens should be made of steel or other metal, and have negligible compliance relative to that of the connecting element itself.

8.1.1.2 The input and support platens should have recesses to geometrically accommodate those fixator elements (for example, anchorage pins or rods) normally clamped by the connecting element being tested.

8.1.1.3 Rigidly affix the input and support platens to the connecting element (for example, by welding, epoxy, cyanoacrylate cement, or other appropriate means).

8.1.2 The input and support platens serve as attachments for gripping by the testing apparatus. This test method is applicable only to those components of loading (force or moment, or both) that can be applied through such platens.

8.1.3 Define local right-handed coordinate system (X^* , Y^* , Z^*) with respect to a specific origin landmark point on (or in) the connecting element. Identify the platen locations (position and orientation) relative to these local coordinate axes.

8.2 Mounting the Test Connector:

8.2.1 Grip and appropriately align the platen through which the input force (or moment) is to be applied in the testing machine. Rigidly affix the support platen to the testing machine base.

8.2.2 The grips and the testing machine itself should be sufficiently stiff that their deformation under load is negligible relative to that of the connecting element being tested. Measure and report the tare compliance of the testing machine and grips (that is, without the connector mounted). Typically, the tare compliance of the testing machine plus grips should be less than 1 % of the compliance of the connector being tested. Clearly describe the gripping mechanism.

8.3 Deliver forces through an input platen that is rigidly bonded to the connector. Normally, the axis of loading will be referenced to that of a member (such as a rod or a pin) that would be clamped by the connector. Record the line of action of the input force relative to the local coordinate system. Provide appropriate fixturing detail as to how that force is applied through the input platen.

8.4 Deliver moments either by an eccentrically applied force, or alternatively, by a torsional actuator. In the former instance, record the offset from the local coordinate system origin. In either instance, record the orientation of the moment.