



Standard Test Method for External Fixator Subassemblies¹

This standard is issued under the fixed designation F 1748; 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 subassemblies, under force loadings (axial, medial-lateral shear, anterior-posterior shear), or under moment loadings (torsion, medial-lateral bending, anterior-posterior bending), or both.

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 1745 Test Method for External Fixator Connectors³
- F 1747 Test Method for External Fixator Joints³
- F xxxx Test Method for External Fixator Pin Anchorage Elements³

3. Terminology

3.1 Definition:

3.1.1 *subassembly*—that portion of an external fixator assembly specifically excluding the bony anchorage elements.

4. Summary of Test Method

4.1 Subassemblies to be tested are assembled from individual bridge and connector elements. All geometric, material, and assembly parameters necessary to unambiguously characterize the subassembly configuration are recorded. The subassembly is then mounted within the testing machine, rigidly gripped at two sites: the input platen, at which load is input and deformation measured (or vice-versa), and the support or restraint platen, that is rigidly coupled to the testing machine base. Loads (or displacements) are applied at the input platen, and the corresponding displacements (or loads) continuously

recorded, allowing calculation of the subassembly's effective stiffness (or strength, or both, if loaded to failure) in one or more specific testing modes (for example, axial load, medial-lateral bending, etc.).

5. Significance and Use

5.1 These laboratory tests are used to determine values for the effective stiffness (or strength, or both) of an external fixation subassembly, under force or moment loadings.

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

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:

6.1.1 The loading configuration is shown schematically in Fig. 1. 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, is designated as the input loading axis.

6.1.2 The subassembly undergoing testing is rigidly attached to two platens. One platen, termed the input platen, delivers the input load (or displacement) due to programmed motion of the actuator or crosshead of the testing machine. The other platen, termed the support or restraint platen, is rigidly affixed to the testing machine base, that in turn acts as a fixed support.

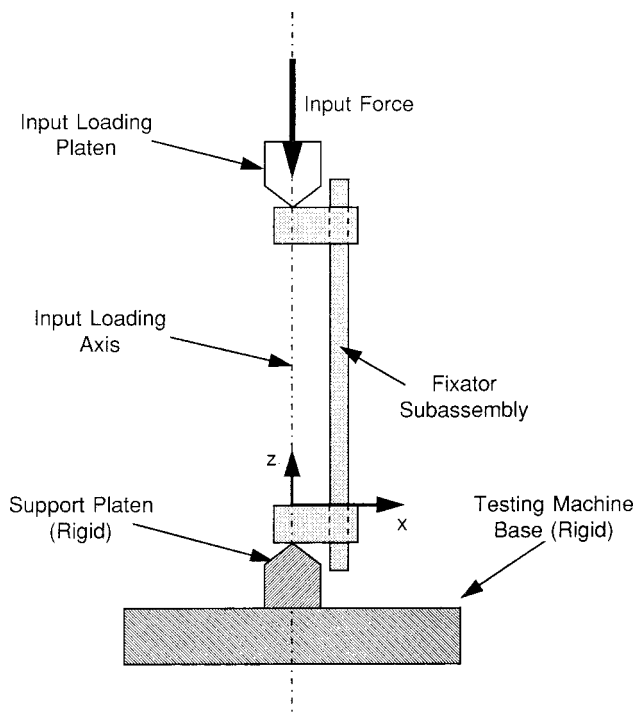
6.1.3 Both the loading axis and the platen positions, orientations, and unrestrained degrees of freedom should be prescribed or located with respect to a right hand coordinate system defined with respect to the undeformed position of the subassembly being tested, or both. Normally, the axes of this subassembly-based coordinate system should be chosen so as to align with what would be the principal anatomic directions if the subassembly were used in its typical skeletal fixation application. For example, this would correspond to the anterior, superior, and lateral directions for a subassembly to be mounted on the right tibia. In the case of a subassembly to be mounted on the left forearm, appropriate reference would be to

¹ This test method is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.21 on Osteosynthesis.

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² Annual Book of ASTM Standards, Vol 03.01.

³ Annual Book of ASTM Standards, Vol 10.01.



NOTE 1—Input force is delivered by the actuator (not shown) of the testing machine. Subassembly displacement is measured at the input loading platen.

FIG. 1 Schematic Test Configuration for Longitudinal (Z-Direction) Loading of an External Fixator Subassembly

the proximal, radial, and ventral directions.

6.2 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 A suitable device should be used to record load versus input platen displacement. Such recordings may be either continuous (for example, magnetic tape, stripchart recorder, *x-y* flatbed plotter, storage oscilloscope) or discrete (that is, analog-to-digital samples written to computer disk), but must suffice to allow subsequent reconstruction of the load/deformation curve to determine stiffness and strength.

7. Test Specimens

7.1 All tested subassemblies should normally be assembled from elements representative of new clinical quality products.

7.2 If one or more of the elements in the frame to be tested has been previously used, appropriately describe the nature of such prior usage.

7.3 If any elements of the subassemblies to be tested are prototypes or are under development, or both, either include the geometric and material information needed to fully characterize all such elements in the report, or reference the detailed descriptive information.

8. Procedure

8.1 Assembling the Sub-assembly to be Tested:

8.1.1 First, individually assemble those bridge or connecting elements, or both, that are comprised of sub-components according to manufacturer recommendations.

8.1.2 Then construct the subassembly. Measure and record assembly forces or torques used to engage the clamps of the connecting elements. In cases using a non-calibrated specialized assembly tool supplied by the manufacturer (for example, a ratchet wrench), note the use of such a tool.

8.2 *Mounting the Subassembly to be Tested*—Then rigidly affix the subassembly to the input and restraint platens. Normally, the sites of such gripping/attachment is at the connectors where the subassembly is coupled to anchorage elements for attachment to bone.

8.3 Stiffness or Strength Testing:

8.3.1 Run stiffness or strength tests under either load or displacement control.

8.3.2 The tests may be either single- or multi-cycle, and may either be restricted to the elastic regime, or taken to the point of failure.

8.3.3 Apply the input load (or displacement) quasistatically. Report the rate(s) used. It is recognized that no specific rate is applicable to all situations. However, in this context, interpret a quasi-static input rate as being sufficient to attain, in approximately 30 s, a load (or moment) magnitude in the range of typical physiologic usage, or sufficient to cause frame failure as defined below.

8.3.3.1 If no reasonable estimates of typical physiologic usage load or of failure load are available, it is recommended that the user conduct a preliminary trial to failure, on a similarly constructed subassembly.

8.3.4 For multi-cycle testing (fatigue or low cycle fatigue), the input loading frequency shall not exceed 5 Hz. Include maximum and minimum values of the loading cycle, as well as the input waveform, in the test report.

8.3.5 A subassembly will be defined as having failed if it undergoes irrecoverable deformation, either from destructive failure of one or more of its elements (for example, plastic bending of a rod), or from slip at one or more of the interfaces between individual components.

8.3.6 The threshold magnitude of irrecoverable deformation constituting failure is context specific, and often will depend on factors outside the scope of the immediate test (for example, clinically acceptable interfragmentary displacements at a fracture site). Report the specific threshold or irrecoverable deformation constituting failure, and state the rationale for that specific value.

8.3.7 Deliver input forces (or linear displacements) either along the input loading axis (axial load), or perpendicular to the input loading axis (shear load). Record the line of action of the input force with respect to the subassembly-based right-hand orthogonal coordinate system.

8.3.8 Input moments may be delivered either by an eccentrically applied force couple, or by a torsional actuator. These moments should be either about the input loading axis, or about an axis perpendicular to the input loading axis. If the moment is delivered by an eccentric force couple, report the points and lines of application if the individual forces.

8.4 Data Recording:

8.4.1 Continuously record the input load (N) or torque (N-mm) and the corresponding linear (mm) or angular (degrees) displacement of the input platen, or the versor (This