Designation: F 1541 – 01

Standard Specification and Test Methods for External Skeletal Fixation Devices[1]

This standard is issued under the fixed designation F 1541; 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 specification provides a characterization of the design and mechanical function of external skeletal fixation devices (ESFDs), test methods for characterization of ESFD mechanical properties, and identifies needs for further development of test methods and performance criteria. The ultimate goal is to develop a specification, which defines performance criteria and methods for measurement of performance-related mechanical characteristics of ESFDs and their fixation to bone. It is not the intention of this specification to define levels of performance or case-specific clinical performance of the devices, as insufficient knowledge is available to predict the consequences of the use of any of these devices in individual patients for specific activities of daily living. Furthermore, it is not the intention of this specification to describe or specify specific designs for ESFDs.

1.2 This specification describes ESFDs for surgical fixation of the skeletal system. It provides basic ESFD geometrical definitions, dimensions, classification, and terminology; material specifications; performance definitions; test methods; and characteristics determined to be important to the in-vivo performance of the device.

1.3 This specification includes a terminology and classification annex and five standard test method annexes as follows:

1.3.1 *Classification of External Fixators*—Annex A1.

1.3.2 *Test Method for External Skeletal Fixator Connectors*—Annex A2.

1.3.3 *Test Method for Determining In-Plane Compressive Properties of Circular Ring or Ring Segment Bridge Elements*—Annex A3.

1.3.4 *Test Method for External Skeletal Fixator Joints*—Annex A4.

1.3.5 *Test Method for External Skeletal Fixator Pin Anchorage Elements*—Annex A5.

1.3.6 *Test Method for External Skeletal Fixator Subassemblies*—Annex A6.

1.3.7 *Test Method for External Skeletal Fixator/Constructs Subassemblies*—Annex A7.

1.4 A rationale is given in Appendix X1.

1.5 The values stated in SI units are to be regarded as the standard.

1.6 The following safety hazards caveat pertains only to the test method portions (Annex A2-Annex A6):

1.7 *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:*

A 938 Test Method for Torsion Testing of Wire[2]

D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials[3]

E 4 Practices for Force Verification of Testing Machines[4]

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications[5]

F 90 Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (R30605)[5]

F 136 Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications

F 138 Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)[5]

F 366 Specification for Fixation Pins and Wires[5]

F 543 Specification for Metallic Medical Bone Screws[5]

F 544 Reference Chart for Pictorial Cortical Bone Screw Classification[6]

F 1058 Specification for Wrought Cobalt-Chromium-Nickel Molybdenum-Iron Alloy for Surgical Implant Applications (UNS R30003 and UNS R30008)[5]

F 1264 Specification and Test Methods for Intramedullary Fixation Devices[5]

F 1472 Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy for Surgical Implant Applications (UNS R56400)[5]

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[2] *Annual Book of ASTM Standards*, Vol 01.03.

[3] *Annual Book of ASTM Standards*, Vol 08.01.

[4] *Annual Book of ASTM Standards*, Vol 03.01.

[5] *Annual Book of ASTM Standards*, Vol 13.01.

[6] Discontinued; see 1998 *Annual Book of ASTM Standards*, Vol 13.01.

F 1713 Specification for Wrought Titanium-13 Niobium-13 Zirconium Alloy for Surgical Implant Applications[5]

3. Terminology

3.1 *Definitions*—The definitions of terms relating to external fixators are described in Annex A1.

4. Classification

4.1 External skeletal fixators are modular devices assembled from component elements.

4.2 Test methods can address individual elements, for example, anchorage elements, bridge elements; subassemblies of elements, for example, connectors, joints, ring elements; or the entire fixator.

4.3 Tests of an entire assembled fixator may include the fixator alone, or alternatively, the fixator as anchored to a representation of the bone(s) upon which it typically would be mounted in clinical usage.

5. Materials

5.1 All ESFDs made of materials, which have an ASTM standard, shall meet those requirements given in ASTM Standards listed in 2.1

6. Performance Considerations and Test Methods

6.1 *Individual Components*—The anchorage pins through which an ESFD is attached to a skeletal member or members typically experience high flexural, or torsional loads, or both. Often, the majority of the overall compliance of an ESFD is in its anchorage elements. A test method for evaluating the mechanical performance of an ESFD anchorage element in either of these loading modes is described in Annex A5.

6.2 *Subassemblies of Elements*:

6.2.1 The sites of junction between ESFD anchorage elements, for example, pins, and bridge elements, for example, rods, normally require specialized clamping or gripping members, known as connecting elements. Often, connecting elements are subjected to high loads, especially moments, so adequacy of their intrinsic mechanical stiffness, or strength, or both, is critical to overall fixator performance. A test method for evaluating the mechanical performance of ESFD connector elements is described in Annex A2.

6.2.2 ESFDs involving ring-type bridge elements are used widely both for fracture treatment and for distraction osteogenesis. The anchorage elements in such fixators usually are wires or thin pins, which pass transverse to the bone long axis and which are tensioned deliberately to control the longitudinal stiffness of the fixator. Tensioning these wires or pins causes appreciable compressive load in the plane of the ring element. A test method for evaluating the mechanical performance of ESFD ring elements in this loading mode is described in Annex A3.

6.2.3 The high loads often developed at ESFD junction sites are of concern both because of potentially excessive elastic deformation and because of potential irrecoverable deformation. In addition to the connecting element itself (Annex A2), overall performance of the junction also depends on the interface between the connecting element and the anchorage, or bridge elements, or both, which it grips. A test method for evaluating the overall strength, or stiffness, or both, at an external fixator joint, as defined in Annex A1 as the connecting element itself plus its interface with the anchorage, or bridge, or both, elements, which it grips, is described in Annex A4.

6.2.4 The modular nature of many ESFD systems affords the surgeon particularly great latitude as to configuration of the frame subassembly, as defined in Annex A1 as the bridge elements plus the connecting elements used to join bridge elements, but specifically excluding the anchorage elements. Since configuration of the frame subassembly is a major determinant of overall ESFD mechanical behavior, it is important to have procedures for unambiguously characterizing frame subassemblies, both geometrically and mechanically. Test methodology suitable for that purpose is described in Annex A6.

6.3 *Entire Assembled Fixator*—No test methods are yet approved for entire assembled fixators.

7. Keywords

7.1 anchorage element; bending; bridge element; connector; external skeletal fixation device; fracture fixation; joints; modularity; orthopedic medical device; osteosynthesis; ring element; subassembly (frame); terminology; torsion

ANNEXES

(Mandatory Information)

A1. CLASSIFICATION OF EXTERNAL SKELETAL FIXATORS

A1.1 Scope

A1.1.1 This classification covers the definitions of basic terms and considerations for external skeletal fixation devices (ESFDs) and the mechanical analyses thereof.

A1.1.2 It is not the intent of this classification to define levels of acceptable performance or to make recommendations concerning the appropriate or preferred clinical usage of these devices.

A1.1.3 *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.*

A1.2 Referenced Documents

A1.2.1 *ASTM Standards:*

F 366 Specification for Fixation Pins and Wires[5]
F 543 Specification for Cortical Bone Screws[5]
F 544 Reference Chart for Pictorial Cortical Bone Screw Classification[6]

A1.3 Background

A1.3.1 ESFDs are in widespread use in orthopedic surgery, primarily for applications involving fracture fixation or limb lengthening, or both. The mechanical demands placed on these devices often are severe. Clinical success usually depends on suitable mechanical integration of the ESFD with the host bone or limb.

A1.3.2 It is important, therefore, to have broadly accepted terminology and testing standards by which these devices can be described and their mechanical behaviors measured.

A1.3.3 Useful terminology and testing standards must take into account that the modular nature of most ESFDs deliberately affords a great deal of clinical latitude in configuring the assembled fixator.

A1.4 Significance and Use

A1.4.1 The purpose of this classification is to establish a consistent terminology system by means of which these ESFD configurations can be classified. It is anticipated that a companion testing standard using this classification system will subsequently be developed.

A1.5 Basis of Classification

A1.5.1 An assembled ESFD and the bone(s) or bone analog(s) to which it is affixed constitute a *fixator-bone construct*.

A1.5.1.1 The assembled ESFD itself, apart from the host bone, is termed the *fixator assembly*.

A1.5.1.2 The individual parts (or modules of individual parts) from which the end user assembles the fixator are termed its *elements*.

A1.5.2 An ESFD normally is configured to span a mechanical discontinuity in the host bone that otherwise would be unable to transmit one or more components of the applied functional load successfully. This bony discontinuity is termed the *mechanical defect*.

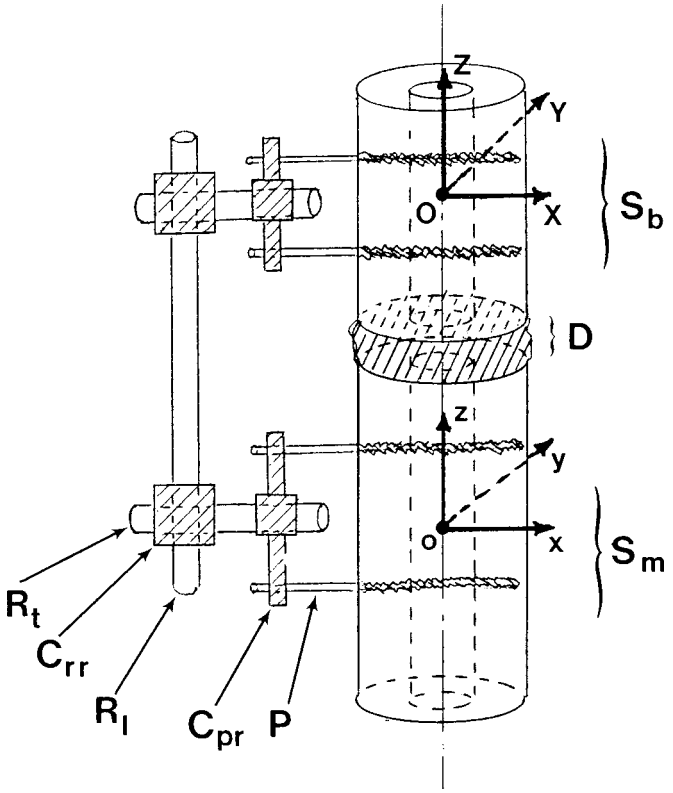
A1.5.3 Examples of mechanical defects are fracture surfaces, interfragmentary callus, segmental bone gaps, articular surfaces, neoplasms, and osteotomies.

A1.5.4 *Coordinate System(s)*—The relative positions of the bones or bone segments bordering the mechanical defect should be described in terms of an orthogonal axis *coordinate system* (Fig. A1.1).

A1.5.4.1 Where possible, coordinate axis directions should be aligned perpendicular to standard anatomical planes, for example, transverse (horizontal or axial), coronal (frontal), and sagittal (median).

A1.5.4.2 Where possible, translation directions should be consistent with standard clinical conventions, for example, ventral (anterior), dorsal (posterior), cranial (cephalad or superior), caudal (inferior), lateral, or medial.

A1.5.4.3 Rotation measurement conventions must follow the right-hand rule and, where possible, should be consistent with standard clinical terminology, for example, right or left lateral bending, flexion, extension, and torsion.



S_b	= base segment
S_m	= mobile segment
D	= mechanical defect
O	= origin of base reference frame
X, Y, and Z	= base reference frame axes
o	= origin of mobile reference frame
x, y, and z	= mobile reference frame axes
R_t	= transverse rod
R_L	= longitudinal rod
P	= pin
C_{rr}	= rod-rod connector
C_{pr}	= pin-rod connector

FIG. A1.1 External Fixator Definition Schematic

A1.5.5 A base coordinate system (X, Y, Z) should be affixed to one of the bones or major bone segments bordering the mechanical defect. This bone or bone segment is termed the *base segment*, S_b, and serves as a datum with respect to which pertinent motion(s) of bone segments or fixator elements, or both, can be referenced. Depending on context, S_b may be defined as being on either the proximal or the distal side of a mechanical defect.

A1.5.6 The other bone(s) or bone segment(s) bordering the mechanical defect, whose potential motion(s) with respect to S_b is of interest, is termed the *mobile segment(s)*, S_m. If necessary, a local right-handed orthogonal coordinate system (x, y, z) may be embedded within the S_m(s).

A1.5.7 *Degrees of Freedom:*

Describing the position, or change in position, of S_m relative to S_b requires specifying one or more independent variables. These variables will be termed *positional degrees of freedom* (P-DOF).

A1.5.7.1 Depending on context, this may involve as many as six variables (three translation and three orientation).

A1.5.7.2 Also depending on context, P-DOFs may be used

to describe motions of interest in various magnitude ranges. For example, P-DOFs may be used to describe one or more components of visually imperceptible motion, for example, elastic flexure of a thick rod) or one or more components of grossly evident motion, such as, interfragmentary motion at an unstable fracture site.

A1.5.8 Application or adjustment of an ESFD normally includes an attempt to achieve or maintain a specific position of S_m relative to S_b. The adjustability afforded by the ESFD design for this purpose, most commonly, fracture fragment reduction, will be characterized in terms of *adjustment degrees of freedom* (A-DOF).

A1.5.9 Some ESFDs are designed optionally to transmit selected components of loading or displacement across the defect, usually by disengaging a locking mechanism. The component of motion of S_m permitted by such unlocking, often given the clinical name "dynamization," will be termed *unlocked* degrees of freedom (U-DOF).

A1.5.9.1 Depending on the specifics of design, the motion permitted in an unlocked degree of freedom may be opposed substantially and deliberately by a specific mechanism such as a spring or a cushion. Such an unlocked degree of freedom is termed a *resisted* unlocked degree of freedom.

A1.5.9.2 Unlocked degrees of freedom in which motion is induced actively by external energy input from devices associated with the fixator are termed *actuated* degrees of freedom.

A1.5.9.3 An unlocked degree of freedom in which motion is unopposed by a specific design mechanism is termed an *unresisted* unlocked degree of freedom. Incidental friction in a dynamizing element shall not be construed as representing deliberately resisted motion; however, conditions involving untoward resistance to motion, for example, substantial binding friction, in a supposedly unresisted degree of freedom should be identified.

A1.5.10 For adjustment or unlocked DOFs, the extrema of angular or translational displacement between which motion is permitted before encountering a fixed or adjustable constraint are termed that DOF's *range of motion* (ROM).

A1.5.11 A *fixator assembly* consists of a structurally purposeful arrangement of three basic types of *elements*: bone anchorage elements, usually transcutaneous, bridge elements, usually extracutaneous, and connection elements.

A1.5.12 *Anchorage elements* are those that attach directly to the bone. Examples are smooth pins, threaded pins, screws, wires, or cortex clamps.

A1.5.13 *Bridge elements* are structural members designed to transmit loads over relatively long distances, and they are joined to one another or to anchorage elements, or both, by connectors. Bridge elements can either be simple or complex and should be described in terms of their characteristic shape and, where appropriate, their orientation with respect to the bone or the mechanical defect.

A1.5.13.1 Examples of *simple bridge elements* are longitudinal rods, transverse rods, rings, or ring segments. Simple bridge elements need not be single-piece. If multipiece, however, the individual parts are joined rigidly rather than adjustable by the end user.

A1.5.13.2 *Complex bridge elements* are mechanisms that consist of two or more subelements designed to function together to achieve a specific kinematic objective. Examples of complex bridge elements are articulated or telescoping mechanisms.

A1.5.14 *Connectors* join bridge elements either to other bridge elements or to anchorage elements. 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 to engage the attachment. 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. Examples of connectors are pin(-rod) clamps, pin cluster(-rod) clamps, ring-rod clamps, and rod-rod clamps.

A1.5.15 That portion of the fixator assembly specifically excluding the bony anchorage elements and their associated connectors is termed the *frame*. Connectors that join only bridge elements, or that join bridge elements to bone anchors but are not user removable from bridge elements, are considered to be part of the frame.

A1.5.16 A joint or junction for which the relative positions between any two elements or subelements can be controlled by the end user is termed an *articulation*. The components of relative motion permitted between the fixator elements at an articulation should be described in terms of that articulation's degrees of freedom, either A-DOF or U-DOF, depending on context. Additionally, articulations should be described in terms of the types of elements that they connect.

A1.5.17 Joints at which the relative positions of the elements connected are fixed and cannot be controlled by the end user are termed *nonadjustable*. Nonadjustable joints should be described in terms of the types of elements that they connect.

A1.6 Attributes

A1.6.1 Coupling between the assembled frame and the host bone is achieved by anchorage elements such as wires, pins (threaded or unthreaded), screws, or cortex clamps (sometimes called claws or prongs). In long bone applications, anchorage elements normally transmit load transversely from the host bone segments to the frame structure.

A1.6.1.1 *Wires* are thin, smooth, constant cross-section (usually circular) anchorage elements that transmit load from the host bone to the frame primarily by axial tension as a result of transverse ("bow string") distention by the host bone; therefore, wires must transfix the bone and must be clamped to the frame at two sites. The stiffness of bone-frame coupling achieved using a wire depends sensitively on the tension in the wire, which normally is controlled by the end user. *Stoppers* ("olives") sometimes are used to oppose incidental slippage along the length of a transfixing wire.

A1.6.1.2 *Pins* are slender anchorage elements, again, usually of circular cross section or envelope, for which bone-to-frame load transmission occurs primarily by longitudinal bending stresses. Pins can penetrate one or (usually) both cortices of a long bone, and they can be clamped to the frame at one end ("half-pins") or both ends ("through-and-through pins" or "full-pins"). Pins can either be smooth or threaded. Threaded pins can be designed for achieving purchase in cortical bone, cancellous bone, or in a combination of the two. Pins can either be of constant cross section, shouldered, or

tapered. They can be clamped to the frame either individually or in clusters. Depending on the flute or thread design, or both, pins can be classified as being one of the following:

(*1*) Self-drilling/self-tapping,

(*2*) Self-tapping/nonself-drilling, or

(*3*) Nonself-tapping/nonself-drilling.

A1.6.1.3 *Screws* are threaded anchorage elements, loaded primarily in axial tension or in transverse shear, or both. This term is sometimes (mis)used interchangeably as a descriptor for ESFD threaded pins, but it is reserved more properly for devices that have a head with a recess for wrenching (see Specification F 543 and Reference Chart F 544) and that are used to develop compression across a fracture site or across a bone/implant interface.

A1.6.1.4 *Cortex clamps* (claws/prongs) are anchors that grip the host bone externally at two or more sites, without penetrating through the full cortical thickness. Cortex clamps may or may not pierce the periosteum.

A1.6.2 Frame *bridge elements* are structural members configured in such a manner as to transmit functional load from the anchorage elements on one side of the mechanical defect to those on the other side of the defect. Bridge elements can be simple members such as smooth prismatic rods, threaded rods, bars, flat plates, curved plates, or arched plates. Alternatively, they can be complex assemblies of several members, designed to allow or induce specific motions such as fixed axis rotation, linear sliding, or active adjunct distraction. Most ESFD frames using simple bridge elements involve structural arrangements in which several simple bridge elements are linked to one another by connectors.

A1.6.3 *Fixator-Bone Construct Classifications*—Constructs may be classified in accordance with the anatomic skeletal structure to which the frame is applied. Common types are as follows:

A1.6.3.1 Long bone,

A1.6.3.2 Articular joint,

A1.6.3.3 Pelvis,

A1.6.3.4 Spinal, and

A1.6.3.5 Halo (skull).

A1.6.3.6 A *construct subunit* is one bony fragment plus its pins/wires and connectors and plus bridge elements not shared with other bony fragments.

A1.6.4 Long bone frames or frame subunits can be characterized in terms of limb access.

A1.6.4.1 Frames or frame subunits that encompass 90° or less of an extremity sector circumferentially are termed *unilateral*.

A1.6.4.2 Frames or frame subunits that encompass more than 90° of an extremity sector circumferentially are termed *multilateral*. Multilateral frames are often described in terms of their characteristic geometry: bilateral (two columns of longitudinal bridge elements), triangular (three longitudinal columns), quadrilateral (four columns), or circular (ring fixators).

A1.6.5 Long bone frames or frame subunits (unilateral or multilateral) can be classified according to pin configuration, as follows:

A1.6.5.1 As *one plane* if all of their pins lie approximately within a common plane,

A1.6.5.2 Or as *multiplane* if their pins lie in two or more distinct planes.

A1.6.6 Constructs may be classified in terms of the means by which the frame is coupled to the bone.

A1.6.6.1 A frame for which coupling to the bone is by a homogeneous group of primarily moment-transmitting anchors such as pins, screws, or cortex claws is termed a *pin-fixed* construct.

A1.6.6.2 If the coupling is by primarily tension-transmitting members instead, the construct is said to be *wire fixed*. The wire-fixed constructs involve ring-type bridge elements in almost all instances.

A1.6.6.3 If coupling involves a heterogeneous mixture of wires and pins (or screws or other anchorage elements, or both), the construct is said to incorporate *hybrid coupling*.

A1.6.7 Fixator constructs may be classified according to the degree of homology or similarity between the respective subunits.

A1.6.7.1 If the bone fragments on opposing sides of a mechanical defect are part of analogously assembled construct subunits, the overall fixator is said to be *symmetrically configured*. This does not imply strict geometric symmetry about the defect mid plane, but rather that each major element in each construct subunit possesses a similar counterpart in the other construct subunit.

A1.6.7.2 A construct whose subunits do not have such counterpart elements is said to have a *hybrid*, or *asymmetrically configured*, frame.

A1.6.8 Some pin-fixed constructs allow *independent control* of each pin's orientation and DOF of articulation with the frame. In other designs, *multipin clamps* are used to control the common orientation and DOF of frame articulation of a small group of pins termed a *pin cluster*. Pin cluster clamps most commonly enforce parallel alignment of the pins in the cluster. The specific A-DOF and U-DOF of pin/frame articulation in each instance, that is, either independent or clustered pins, depends on the design of the specific connecting element joining the pin(s) to the frame.

A1.6.9 *Ring fixators* have complex frames assembled from several transverse-plane ring or partial-ring bridge elements. The anchoring transfixation tensile wires are connected to the rings individually. Longitudinal rods normally are used to connect the transverse-plane rings.

A2. TEST METHOD FOR EXTERNAL SKELETAL FIXATOR CONNECTORS

A2.1 Scope

A2.1.1 This test method covers the procedures for determining the stiffness and strength of connecting elements (clamps) of external skeletal fixators 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 a combination thereof) between the elements it grips (anchorage elements or bridge elements), without itself undergoing either permanent deformation or excessive elastic deformation.

A2.1.2 *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.*

A2.2 Referenced Documents

A2.2.1 *ASTM Standards:*

E 4 Practices for Force Verification of Testing Machines[5]

A2.3. Terminology

A2.3.1 *Definitions of Terms Specific to This Standard:*

A2.3.1.1 *connectors, n*—external fixator elements used to join bridge elements either to other bridge elements, or to anchorage elements.

(1) 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 to engage the attachment.

(2) Connectors should be described in terms of the types of elements, which they connect, and where appropriate, in terms of their adjustment or unlocked degrees of freedom.

(3) Examples of connectors are pin(-rod) clamps, pin cluster(-rod) clamps, ring-rod clamps, and rod-rod clamps.

A2.3.1.2 *input-loading axis, n*—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.

A2.3.1.3 *input-loading platen, n*—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.

A2.3.1.4 *support platen, n*—a member, also not normally part of the connector during clinical usage, through which the connector is rigidly affixed to the testing machine base.

A2.4 Summary of Test Method

A2.4.1 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.

A2.5 Significance and Use

A2.5.1 These laboratory benchtop tests are used to determine values for the intrinsic stiffness, or strength, or both, of connectors, under force or moment loadings. Since different connectors have different materials and geometries, stresses within individual subcomponents or at subcomponent interfaces may differ substantially between designs. 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.

A2.5.2 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; however, the actual load that can be transmitted to the connector in clinical practice depends very much on the slippage resistance of the different subcomponent interfaces.

A2.5.3 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.

A2.6 Apparatus

A2.6.1 *Force or Moment or both Application Fixture:*

A2.6.1.1 The loading configuration is shown schematically in Fig. A2.1. The 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.

A2.6.2 *Load Frame*—Machines used for testing shall conform to the requirements of Practices E 4. The loads used for this test method shall be within the loading range of the test machine as defined in Practices E 4.

A2.6.3 *Data Acquisition Device*—A suitable recorder to plot a graph of load versus load frame displacement on prependicular axes. Optionally, this device may include the use of computer-based digital sampling and output of the load and displacement signals.

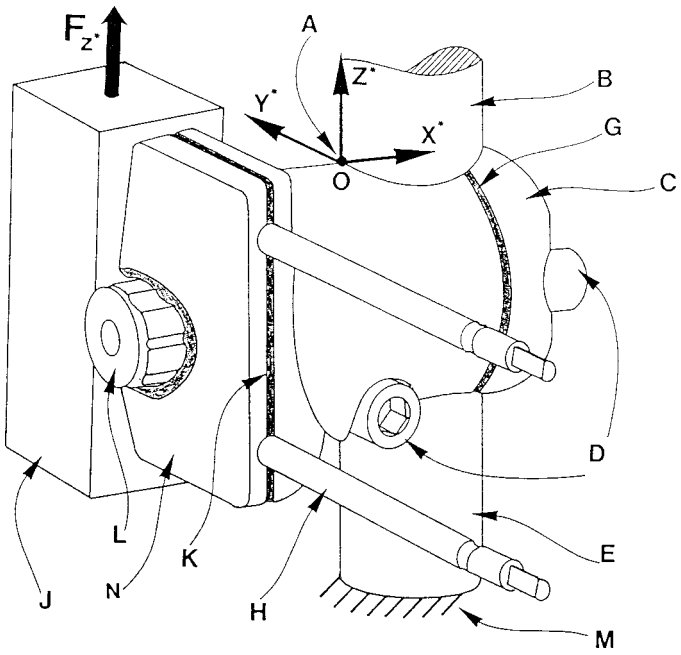
A2.7 Test Specimen

A2.7.1 All tested connectors should be representative of clinical quality products.

A2.7.2 If the connector(s) to be tested have been used previously, the nature of such prior usage should be described appropriately.

A2.7.3 The test specimens should be prepared 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 before clinical use, it should be similarly sterilized before mechanical testing.

A2.7.4 If the connector to be tested is a prototype, or under development, or both, the geometric and material information needed to characterize the component fully should either be



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 (in this illustration, the input loading is a force *Fz** in the *z** direction, delivered through a loading platen rigidly affixed to the pin grip/clamp. δ_z is the displacement of the loading platen in the *z* direction

FIG. A2.1 Schematic for Testing an External Fixator Connector (Example, Generic for a Pin-Rod Joint)

included in the report, or detailed descriptive information should be referenced.

A2.8 Procedure

A2.8.1 *Configuring the Connecting Element for Testing:*

A2.8.1.1 With the connecting element assembled in the configuration normally used, input and support platens are affixed in a manner that insures 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, which it clamps.

(1) The input and support platens should made of steel or other metal and should have negligible compliance relative to that of the connecting element itself.

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

(3) The input and support platens should be rigidly affixed to the connecting element, for example, by welding, epoxy, cyanoacrylate cement, or other appropriate means.

A2.8.1.2 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), which can be applied through such platens.

A2.8.1.3 A local right-handed coordinate system (*X**,*Y**,*Z**) should be defined with respect to a specific origin landmark point on (or in) the connecting element. The platen locations (position and orientation) should be identified relative to these local coordinate axes.

A2.8.2 *Mounting the Test Connector*:

A2.8.2.1 The platen through which the input force (or moment) is to be applied is gripped, appropriately aligned, in the testing machine. The support platen is rigidly affixed to the testing machine base.

A2.8.2.2 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. The tare compliance of the testing machine and grips, that is, without the connector mounted, should be measured and reported. Typically, the tare compliance of the testing machine plus grips should be less than 1 % of the compliance of the connector being tested. The gripping mechanism should be clearly described.

A2.8.3 Forces should be delivered through an input platen, which 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. The line of action of the input force should be recorded relative to the local coordinate system. Appropriate fixturing detail should be provided as to how that force is applied through the input platen.

A2.8.4 Moments may be delivered either by an eccentrically applied force, or alternatively, by a torsional actuator. In the former instance, the offset from the local coordinate system origin should be recorded. In either instance, the orientation of the moment axis should be recorded relative to the local coordinate system. Appropriate fixturing detail should be provided as to how that moment is applied through the input platen.

A2.8.5 For connectors made entirely of metal or other materials exhibiting elastic behavior, the load (or moment) may be applied quasistatically. An input rate sufficient to attain in 30-s force, or moment, magnitude in the range of typical clinical usage, or of connector failure, shall be deemed quasistatic. For connectors incorporating polymeric or other materials that exhibit viscoelastic behavior, load/stroke rates, which are in the range of those expected clinically, may instead be desirable. In either case, the rate(s) used and a rationale for its choice should be provided.

A2.8.6 Tests may be run under either load or displacement control. They may either be single- or multi-cycle, and can be either restricted to the elastic regime, or taken to failure of the connector. The specific conditions used should be described fully.

A2.8.7 If single-cycle testing is to be performed, the specimen must be subjected to several preconditioning load cycles to demonstrate that the reported load/deformation curve is

repeatable from cycle to cycle.

A2.8.7.1 Preconditioning should be continued until the apparent stiffness of the connector changes less than 5 % between subsequent cycles.

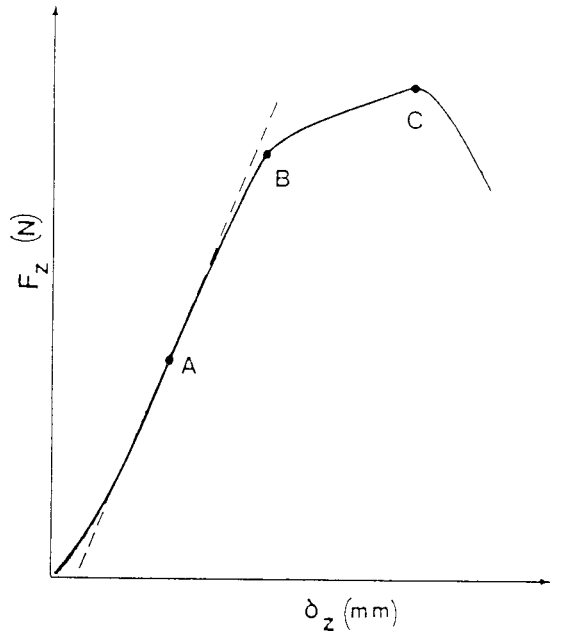
A2.8.7.2 Normally, about five preconditioning load cycles are suitable for this purpose, with peak applied load within the elastic range, approximately 50 % of the expected physiologic service load or 50 % of the expected connector failure load, whichever is lower.

A2.8.7.3 Load/deformation curves for the preconditioning cycles should be recorded. Preconditioning cycle stiffnesses should be reported.

A2.8.8 *Data Recording*—The load (N) or torque (N-m) and linear (mm) or angular (°) displacement measured by the testing machine should be continuously recorded. The linear displacement should be measured at the point of load application. In some instances it may be appropriate also to record components of deformation in directions other than that of the applied loading. If so, the sensors used, for example, dial gages or LVDTs, and the points and directions of their measured deformations should be recorded.

A2.9 Calculation or Interpretation of Results

A2.9.1 Stiffness (units according to the chosen load and deflection configuration, for example, N/mm for force, N-mm/degree for moment) shall be calculated from the slope of the linear-most portion of the load/deflection curve, as apparent visually (Fig. A2.2, Point A). If an objective slope determination technique, for example, curve fitting of a digitized tracing, is used, this should be described. The load and deflection configuration (location of measuring element and direction of the measured vector) must be defined clearly with respect to the loading axis of the testing equipment (Fig. A2.1).



NOTE—Stiffness is defined as the slope of the linear-most portion of the curve, here evaluated by a tangent drawn at Point A. Point B illustrates a slope discontinuity (possibly indicative of interfacial slip or subcomponent failure within the connector), and Point C illustrates the maximal load acceptance (ultimate strength).

FIG. A2.2 Load/Deformation Curve (Generic, Here Illustrated for the *z Direction)**

A2.9.2 Failure load (N or N-mm) of the connector is associated frequently with a discontinuity in the load/deformation curve. Depending on context, additional load uptake may or may not be possible after occurrence of this discontinuity. In the former circumstance (Fig. A2.2, Point B), the severity of the discontinuity should be measured in terms of change in slopes of the load/deformation curve for loads immediately below and above the discontinuity point. In the latter circumstance (Fig. A2.2, Point C), the failure load should be designated as the ultimate strength of the connector.

A2.9.3 In situations in which there is no clear discontinuity in the load displacement curve, other definitions of failure load may be used.

A2.9.3.1 For situations in which permanent deformation occurs, for example, as a result of interfacial slip or plastic deformation, or both, within the connector, an offset criterion may be used. In this instance, the failure load is defined as that load necessary to induce a specific amount of permanent deformation, either linear or angular, depending upon the degree of freedom being tested, upon release of the applied load.

A2.9.3.2 For situations in which excessive elastic deformation occurs within the connector, failure may be defined in terms of a specific fractional reduction of the connector's small-load stiffness. For example, failure might be defined in terms of the connector's tangent stiffness having fallen to 25 % of the tangent stiffness that was apparent at a load of 50 N.

A2.10 Report

A2.10.1 The test report shall include, but is not limited to, the following information:

A2.10.1.1 *Connecting Element Identification*, including manufacturer, part number, nomenclature, and quality control or lot number. If the part is a prototype, geometrical and material descriptions shall be included.

A2.10.1.2 Specimen preparation condition, for example, sterilization and description of prior usage history, if applicable.

A2.10.1.3 Connecting force or torque used to engage the connector's gripping mechanism.

A2.10.1.4 Configuration of the (bonded) platens and testing apparatus grips.

A2.10.1.5 Specific degrees of freedom tested, such as, tension or compression, torsion, or bending. In each case, the axis along which or about which loading is applied should be specified.

A2.10.1.6 Loading rate and number of cycles (fatigue tests).

A2.10.1.7 Stiffness, and, if loaded to failure, the failure criterion and strength, in the specific direction(s) tested.

A2.10.1.8 In cases in which the mode of failure is ascertainable, for example, visually apparent interfacial slippage of a specific subcomponent interface, the nature of such failure should be described.

A2.11 Precision and Bias

A2.11.1 Data establishing the precision and bias to be

expected from this test method have not yet been obtained.

12. Keywords

12.1 bending moments; connecting elements; connectors; external fixator; orthopedic device; stiffness; strength

A2.13 Rationale

A2.13.1 Connecting elements of various designs are used widely in external fixators. Both the elements connected and the pertinent directions of force, or moment, or both, transmission through them are design and site specific. This test method provides an outline by which the stiffness, or strength, or both, intrinsic to the connector itself, as opposed to the stiffness or strength by which it grips the elements it connects, can be measured. Since the joints of external fixators normally involve abrupt redirection of appreciable loads, substantial stresses often are developed within one or more of the subcomponents of the connector securing the joint.

A2.13.2 Even if there is no apparent interfacial slippage between the connector and the various bridge or anchorage elements it grips, the associated elastic deformations within the connector body itself may result in appreciable distension of the overall frame. Moreover, excessive forces, or more commonly, moments, applied to a connector may cause destructive failure of the connector body, even if gripped interfaces remain intact. This test method focuses on the intrinsic load/deformation behavior of the connector body, independent of whether or not there is interfacial slip between the connector and the bridge or anchorage elements, or both, which it grips. This goal is achieved by means of platens, which are bonded rigidly to the connector.

A3. TEST METHOD FOR DETERMINING IN-PLANE COMPRESSIVE PROPERTIES OF CIRCULAR RING OR RING SEGMENT BRIDGE ELEMENTS

A3.1 Scope

A3.1.1 This test method covers the test procedure for determining the in-plane compressive properties of circular or ring segment bridge elements of external skeletal fixators.

A3.1.2 *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.*

A3.2 Referenced Documents

A3.2.1 *ASTM Standards:*

E 4 Practices for Force Verification of Testing Machines[4]

A3.3. Terminology

A3.3.1 *Definitions of Terms Specific to This Standard:*

A3.3.1.1 *circular ring bridge element*, *n*—an external skeletal fixator component as described in Annex A1, which is circular, or may be assembled from several components to form a circular element, lies in a single plane, and has one center or curvature.

A3.3.1.2 *ring segment bridge element*, *n*—an external skeletal fixator component as described in Annex A1, which consists of a single ring segment, or is assembled from several components to form a ring segment, lies in a single plane, has one center of curvature, and whose arc spans 180° or more, but less than 360°.

A3.3.1.3 *test component*, *n*—a complete or assembled *circular ring bridge element* or *ring segment bridge element* prepared for testing according to A3.8.1 and A3.8.2.

A3.4 Summary of Test Method

A3.4.1 Complete circular ring elements (either a single component or an assembly of components to form a complete circular ring) or a ring segment (≥180° arc) are obtained for testing. In-plane compressive forces are applied quasistatically to the circular ring or ring segment, so that the load application points are 180° apart, measured along the arc of the ring. If appropriate, load is increased until part failure occurs. A graphical plot of load versus displacement is used to determine in-plane compressive strength and stiffness.

A3.5 Significance and Use

A3.5.1 This test method is used to measure the compressive strength and stiffness of circular ring or ring segment bridge elements of external skeletal fixators when loaded in the plane of the ring. The results obtained in this test are not intended to predict the clinical efficacy or safety of the tested products. This test method is intended only to measure the uniformity of the products tested or to compare the mechanical properties of different products.

A3.5.2 This test method may not be appropriate for all types of fixator applications. The user is cautioned to consider the appropriateness of the method in view of the materials being tested and their potential application.

A3.6 Apparatus

A3.6.1 *Pin and Clevis Fixture*—A U-shaped metal lug (“clevis”) with a hole drilled across both legs of the “U” to accommodate a clearance fit steel pin. The opposite end of the Clevis is attached to the grip of the load frame. The pin diameter should be of the approximate size of the holes in the test components, if applicable; or, if a hole must be drilled for testing, the pin shall be no greater than half the width of the test component at the point of load application.

A3.6.2 *Shims*—Metallic flat washers of varying specified thickness, which will fit over the pin and between the sides of the clevis and the test component.

A3.6.3 *Torquemeter*—An electronic, or mechanical device, or both, which is capable of measuring torque applied to a screw or bolt.

A3.6.4 *Load Frame*—Machines used for testing shall conform to the requirements of Practices E 4. The loads used for the test shall be within the loading range of the test machine as defined in Practices E 4.

A3.6.5 *Recording Device*—A suitable recorder to plot a

graph of load versus load frame displacement on perpendicular axes.

A3.7 Test Specimen

A3.7.1 All test components, including connection components, shall be representative of clinical quality products.

A3.7.2 If one or more of the elements to be tested has been used previously, the nature of such prior usage should be appropriately described.

A3.7.3 The test component, when assembled (if applicable), shall form a full or partial ring in a single plane, with a single center of curvature.

A3.7.4 The test specimens should be prepared in the manner in which they normally would be used clinically. For example, if components, particularly polymeric rings or ring segments, normally would be sterilized in a particular manner before use, they should be sterilized similarly before mechanical testing.

A3.8 Procedure

A3.8.1 *Constructing the Test Component*—Some ring external fixation systems may fit into both the circular ring and ring segment descriptions in A3.8.1.1 and A3.8.1.2, depending on how many components are assembled. The two types are discussed separately here to be congruent with the separate descriptions given in Annex A1. The user must consider the appropriateness of the two test component options in view of the materials being tested, their potential application, and the manufacturer's recommendations.

A3.8.1.1 *Circular Ring Bridge Element*—For circular ring bridge elements, which are not a complete circle, the individual arcs or segments must be joined together to form a single circular ring. The arcs or segments shall be jointed using the equipment, for example, nut and bolts, recommended by the manufacturer. For screw or bolted connections, the tightening torque recommended by the manufacturer shall be applied using a torque wrench. If a recommended torque value is not available, a sufficient torque shall be chosen by the user, and then used for all components.

A3.8.1.2 *Ring Segment Bridge Elements*—For ring segments whose arc spans less than 180°, individual arcs or segments must be joined together to form a ring segment that spans more than 180° but less than 360°. The arcs or segments shall be joined using the equipment, for example, nut and bolts, recommended by the manufacturer. For screw or bolted connections, the tightening torque recommended by the manufacturer shall be applied using a torque wrench. If a recommended torque value is not available, a sufficient torque shall be chosen by the user, and then used for all components.

A3.8.2 *Preparing the Test Component*—The test component must have two holes that are positioned 180° from each other, as measured along the arc of the ring, for introduction of the load. For rings with holes provided by the manufacturer, two holes must be chosen that are 180° apart. For rings without two properly positioned holes, holes may be drilled through the test component. The diameter of the hole shall be less than one half of the width of the test component at the drilling location. If the test component is constructed from ring segments, the critical joint, as determined by the user, shall be 90° from the two loading holes.

A3.8.3 *Mounting the Test Component*—The two clevis fixtures shall be secured to the upper and lower grips of the load frame. The test component shall be inserted into the clevis fixture so that the loading holes are aligned with the clevis holes. A clearance-fit pin will be inserted through the clevis and through the test component, securing the test component to the upper and lower fixtures. As necessary, shims will be inserted between the sides of the clevis and the test components to insure that the test component is centered in the clevis and to reduce the lateral movement of the test component on the pin. The diameter of the shims must be less than the width of the test component at the loading hole location. The total lateral movement of the test component in the clevis shall be less than 0.5 mm. An example test setup of a circular ring bridge element, constructed from two 180° ring segments bolted together, is shown in Fig. A3.1. An example test setup of a single ring segment bridge element is shown in Fig. A3.2.

A3.8.4 *Data Recording*—The load (N) and displacement (mm) measured by the testing machine shall be recorded on the recording device. The displacement is measured at the point of load application.

A3.8.5 *Load Application*—An increasing compressive load shall be applied to the test component. Either load or stroke control may be used. It is recognized that no specific rate is applicable to all situations. For rings or ring segments comprised entirely of metal or other elastic materials, quasistatic loading may be applied. In this context, a quasistatic input loading rate should be interpreted as being sufficient to attain in approximately 30 s a load magnitude in the range of typical clinical usage or a load sufficient to cause ring or ring segment failure, whichever is lower. For rings or ring segments containing polymeric or other materials exhibiting viscoelastic behavior, load/stroke rates, which are in the range of those expected clinically, may be desirable. In either case, the rate(s) of loading and the rationale for its choice should be specified.

A3.8.6 If tested to failure, the load application shall continue until a peak load is observed on the load displacement

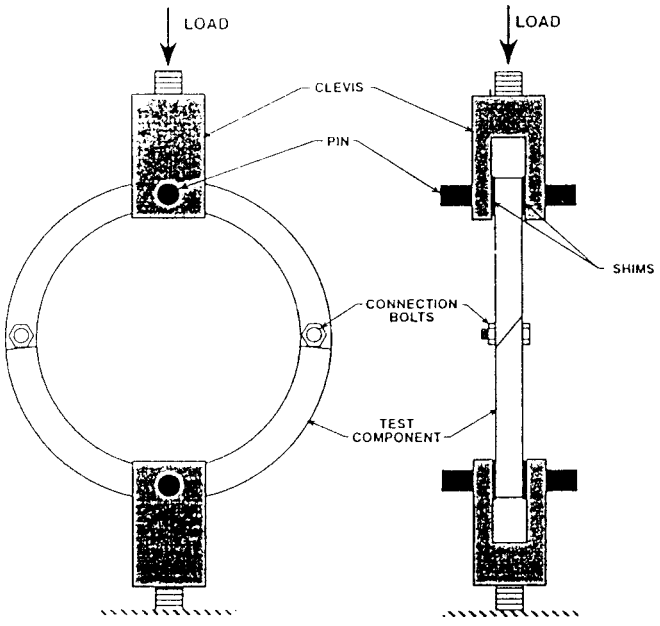


FIG. A3.1 Test Setup—Circular Ring Bridge Element

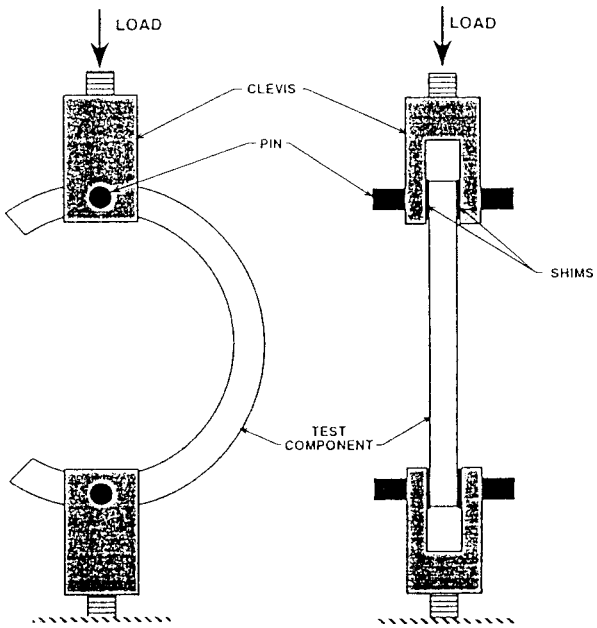


FIG. A3.2 Test Setup—Ring Segment Bridge Element

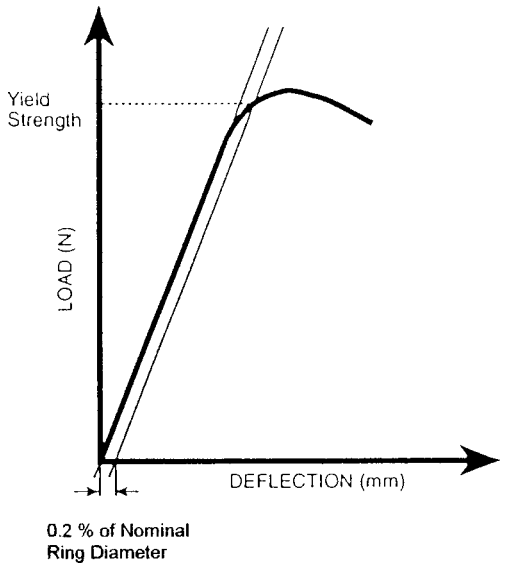


FIG. A3.3 Secant Offset Method

curve or until the load reaches a near constant value while significant irrecoverable deformation, typically 10 % of the nominal ring diameter, has occurred.

A3.8.7 *Test Component Examination*—After the test is complete, visual examination of the test component shall be made to determine the location and mode of failure of the test component.

A3.9 Calculation or Interpretation of Results

A3.9.1 *In-Plane Compressive Stiffness*—The in-plane compressive stiffness (N/mm) of the test component shall be determined from the maximum slope of the initial portion of the load-displacement curve.

A3.9.2 *In-Plane Compressive Yield Strength*—The in-plane compressive yield strength (N) of the component shall be determined from the load-displacement curve, using the secant-offset method shown in Fig. A3.3. A permanent deflection of 0.2 % of the nominal ring diameter is defined as yield.

A3.9.3 *In-Plane Maximum Compressive Strength*—The in-plane maximum compressive strength (N) of the test component shall be determined from the load-displacement curve, and is the maximum load (N) reached during the test, or the load level at which the component achieves a deflection of 10 % of the nominal ring diameter.

A3.10 Report

A3.10.1 The test report shall include the following information:

A3.10.1.1 *Ring Bridge Element Identification*, including manufacturer, part number(s), quality control or lot number(s), nominal size, element width and element thickness. For assembled components, a description of the connection method and components, and the final construct form and geometry is required.

A3.10.1.2 *Connection Torque*—Torque used on screws or bolts for connection, if applicable.

A3.10.1.3 Material composition and surface finish.

A3.10.1.4 *Load Pin Description*—Diameter of load pin used and explanation of whether holes were drilled in the test component for loading.

A3.10.1.5 In-plane compressive stiffness.

A3.10.1.6 In-plane compressive yield strength.

A3.10.1.7 *In-Plane Compressive Maximum Strength*—Identify whether the strength is determined from a maximum value or from when the load produced a deflection of 10 % of the nominal ring diameter.

A3.10.1.8 *Failure Mode and Location*—Identify the location of failure, for example, ring hole connection bolt, and the mode of failure, for example, yielding, localized buckling, interface slip, and so forth.

A3.11 Precision and Bias

A3.11.1 Data establishing the precision and bias to be expected from this test method have not yet been obtained.

12. Keywords

12.1 compression; external fixator; in-plane loading; ring element

A3.13 Rationale

A3.13.1 Circular ring and ring segment bridge elements commonly are found in commercial external skeletal fixators. They may consist of a single ring, two, or more ring segments connected to form a circular ring, or as individual ring segments. In clinical use, circular ring and ring segment bridge elements are subjected to a wide variety of loads, including in-plane compression. The in-plane compression loads are due primarily to tensioned wires connected from one side of the bridge element to the other.

A3.13.2 This test specification provides a relatively simple method to determine the in-plane compressive properties of single or joined-together circular ring or ring segment bridge elements. The results obtained in this test method are not intended to predict the clinical efficacy or safety of the tested

products. This test method is intended only to measure the uniformity of the products tested or to compare the mechanical properties of different products.

A4. TEST PROCEDURE FOR EXTERNAL SKELETAL FIXATOR JOINTS

A4.1 Scope

A4.1.1 Depending on its design and its use in the overall construct, the joint of an external skeletal fixator needs to transmit one or more components of loading (tension, compression, torsion, or bending, or a combination thereof) between the elements it grips (anchorage elements or bridge elements), without either the connector itself or its gripping interface(s) undergoing either permanent deformation or excessive elastic deformation.

A4.1.2 This test method covers the procedures for determining the stiffness and strength of external skeletal fixator joints under axial loads and bending moments.

A4.1.3 This document also covers procedures for determining the range of adjustability in degrees of freedom for which the joint's configuration can be adjusted by the user and procedures for determining the joint's range of motion in degrees of freedom for which motion is permitted if the fixator is unlocked.

A4.1.4 *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.*

A4.2 Referenced Documents

A4.2.1 *ASTM Standards:*

E 4 Practices for Force Verification of Testing Machines[4]

A4.3. Terminology

A4.3.1 *Definitions of Terms Specific to This Standard:*

A4.3.1.1 *connector*, *n*—of the two (or more) elements comprising any joint or junction, the connector is that element to which the end user applies an active gripping force or torque to engage the attachment.

A4.3.1.2 *hysteresis*, *n—for cyclic loading*, the unity minus the ratio of energy recovered (during load release) to energy input (during load uptake).

A4.3.1.3 *input loading axis*, *n*—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.

A4.3.1.4 *input loading element*, *n*—that fixator element, for example, pins, rod, gripped by the joint, through which the applied force or moment loading is transmitted to the joint.

A4.3.1.5 *joint*, *n*—an external skeletal fixator subassembly consisting of a connecting element and one or more bridge or anchorage elements gripped by that connector. Bridge, anchorage, and connection elements are as defined in Annex A1.

(*1*) *Joints* 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.

(*2*) Examples of joints are a pin/rod articulation, a pin-cluster/rod articulation, a ring/rod articulation, and a rod/rod articulation, in each case with the connector being considered as an integral part of the articulation.

(*3*) Joints whose configuration can be adjusted, or that can be unlocked selectively to permit specific types of motion, are said to possess adjustment degrees of freedom or unlocked degrees of freedom, respectively, in the corresponding linear or angular displacement directions.

A4.3.1.6 *output loading element*, *n*—that fixator element through which restraint to the applied load is provided, by means of attachment to the testing machine base.

A4.4 Summary of Test Method

A4.4.1 Unlike testing of the connecting element alone, testing a joint requires inclusion of the specific bridge or anchorage elements, or both, gripped by the connector, which in principle may slip with respect to the connector during load uptake.

A4.4.2 Connecting elements (clamps) are obtained, and if applicable, assembled using the techniques and equipment recommended by the manufacturer.

A4.4.3 Axial loads or bending moments are applied to the joint through one of the gripped elements, and a graphical plot of load (or moment) versus displacement is used to determine the effective stiffness (and strength, if tested to failure) of the joint.

A4.4.4 For range of adjustability/motion assessment, the joint is unlocked, and quasistatic linear or angular displacements are input until encountering a discontinuous increase in resisting force or moment, indicative of the limit of adjustability or motion of the joint in the particular degree of freedom considered.

A4.5 Significance and Use

A4.5.1 These laboratory tests are used to determine values for the effective stiffness, or strength, or both, of an external fixator joint, under force or moment loadings.

A4.5.1.1 The deformations accruing under loading consist of elastic deformation in the clamp body itself, plus any deformation, especially, slip, occurring at the interface between the clamp and the gripped element(s).

A4.5.1.2 Where appropriate, the joint's range of adjustability, or its range of motion when "dynamized," or both, also are measured.

A4.5.2 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 joints.

A4.5.3 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.

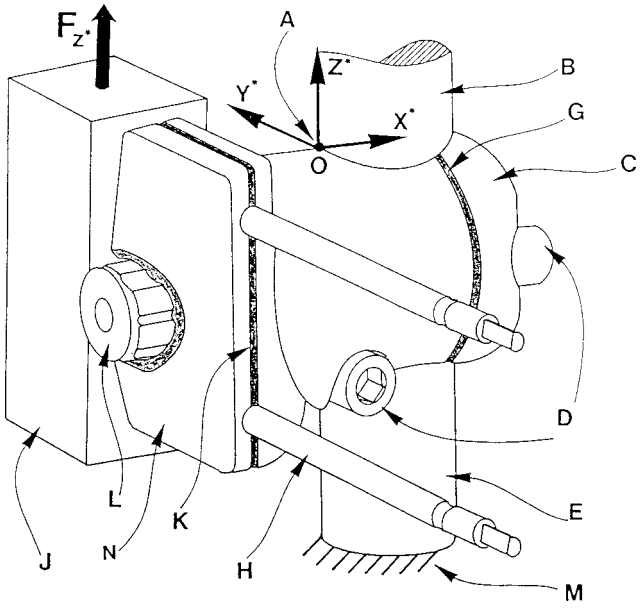
A4.6 Apparatus

A4.6.1 *Force, or Moment (or Both) Application Fixture*:

A4.6.1.1 The loading configuration is shown schematically in Fig. A4.1. The loading input axis must pass through the input loading element, that is, the bridge or anchorage element, gripped by the connector.

A4.6.1.2 Gripping of the input loading element by the testing apparatus should be at a site as close as possible to the body of the connector so as to minimize elastic flexure in the loading input element itself.

A4.6.1.3 Restraint is provided either by rigidly affixing the body of the connector to the testing machine base, in which case the only (potential slippage) interface included in the loading path is that between the loading input element and the connector body; or, by rigidly affixing another of the gripped elements, termed the loading output element, to the testing machine base, again, gripping as closely as possible to the connector. In this case, two potential slip interfaces are included in the loading path. An example of the input loading element and output loading element is shown in Fig. A4.1.



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 = output loading element (here, a rod gripped by the connector and rigidly affixed to the test machine base)
G = rod grip interface
H = pins (as normally gripped by connector)
J = loading platen, clamped to pins (the input loading element) as closely as possible to the site of connector gripping
K = pin clamping interface
L = pin grip/clamp tightening mechanism
M = testing machine base (fixed)
N = pin grip/clamp (in this illustration, the input loading is a force *Fz** in the *z** direction, delivered through an input platen clamped to the input loading element (the pins). δ_z is the corresponding displacement of the input platen in the *z* direction

FIG. A4.1 Schematic for Testing an External Fixator Joint (Example, Generic for a Pin-Rod Joint)

A4.6.2 *Load Frame*—Machines used for testing shall conform to the requirements of Practices E 4. The loads used for the test shall be within the loading range of the test machine as defined in Practices E 4.

A4.6.3 *Data Acquisition Device*—A suitable recorder to plot a graph of load versus load frame displacement on perpendicular axes.

A4.7 Test Specimen

A4.7.1 All tested elements should be representative of clinical quality products.

A4.7.2 If one or more of the elements to be tested has been used previously, the nature of such prior usage should be described appropriately.

A4.7.3 The test specimens should be prepared in the manner in which they normally would be used clinically. For example, if a particular joint normally would be sterilized in a particular manner before use, it should be sterilized similarly before mechanical testing.

A4.7.4 If the elements to be tested are prototypes, or are under development, or both, the geometric and material information needed to characterize fully all such elements should either be included in the report or detailed descriptive information should be referenced.

A4.8 Procedure

A4.8.1 *Assembling the Joint to Be Tested*:

A4.8.1.1 The input loading element, and, if appropriate, the output loading element, should be clamped by the connecting element according to the manufacturer's instructions. In situations in which this clamping force, or torque, is discretional, the magnitude of the applied tightening force, or torque, should be measured and recorded since this may affect interface slip.

A4.8.1.2 The input and output loading elements 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), which can be applied through such elements.

A4.8.1.3 A local right-handed coordinate system (*X**,*Y**,*Z**) should be defined with respect to a specific origin landmark point on, or in, the connecting element. The input and output loading element locations (position and orientation) should be identified relative to these local coordinate axes.

A4.8.2 *Mounting the Joint to Be Tested*:

A4.8.2.1 The input loading element is gripped, appropriately aligned, in the testing machine. Restraint is applied by rigidly gripping and attaching to the testing machine base either the connecting element body or the output loading element (see A4.6.1.3).

A4.8.2.2 The test specimen should be mounted in such a manner that there is no discontinuity of the load/deformation curve as a result of shifting or settling of the specimen in the testing machine grip(s) during load uptake.

A4.8.2.3 The grips should be sufficiently stiff that their deformation under load is negligible relative to that of the joint being tested. Normally, the tare compliance (testing machine + grips) should be less than 1 % of the compliance of the joint being tested. The gripping mechanism should be described clearly, and its tare stiffness measured and reported.

A4.8.3 *Stiffness or Strength Testing*:

A4.8.3.1 Forces should be delivered through a platen rigidly affixed to the input loading element. Normally, the axis of joint loading will be referenced to that of an element, such as a rod or a pin, that would be clamped at the joint. The line of action of the input force should be recorded relative to the local coordinate system.

A4.8.3.2 Moments may be delivered either by an eccentrically applied force couple or, alternatively, by a torsional actuator. In the former instance, the offset from the local coordinate system origin should be recorded. In either instance, the orientation of the moment axis should be recorded relative to the local coordinate system.

A4.8.3.3 Appropriate fixturing detail should be provided as to how the input force or moment is applied to the input loading element by the testing machine actuator.

A4.8.3.4 It is recognized that no specific loading rate is applicable to all situations. For joints comprised entirely of metal or other materials exhibiting elastic behavior, the load (or moment) may be applied quasistatically. An input rate sufficient to attain in 30 s a force, or moment, magnitude in the range of typical clinical usage, or of joint failure, shall be deemed quasistatic. For joints incorporating polymeric or other materials that exhibit viscoelastic behavior, load/stroke rates, which are in the range of those expected clinically, may instead be desirable. In either case, the rate(s) used and the rationale for its choice should be provided.

A4.8.3.5 Stiffness or strength tests may be run under either load or displacement control. They may either be single- or multi-cycle and may be either restricted to the elastic regime, or taken to the point in which one of the interfaces slips, or the connector body destructively fails. The specific conditions used should be described fully.

A4.8.3.6 If single-cycle testing is to be performed, the specimen must be subjected to several preconditioning load cycles to demonstrate that the reported load/deformation curve is repeatable from cycle to cycle. Preconditioning should be continued until the apparent stiffness of the joint changes less than 5 % between subsequent cycles. Normally, about five preconditioning load cycles are suitable for this purpose, with peak applied load within the elastic range, approximately 50 % of the expected physiologic service load or 50 % of the expected joint failure load, whichever is lower. Load/deformation curves for the preloading cycles should be recorded. Preconditioning cycle stiffnesses should be reported.

A4.8.3.7 If multicycle testing is to be performed, load deformation curves also must be recorded for at least the first five cycles during test startup. As stated in A4.8.3.6, apparent stiffness values should be reported for each of these cycles. The number of cycles needed to reach the point at which apparent stiffness changes less than 1 % should be noted.

A4.8.3.8 The severity of hysteresis in each of these preconditioning cycles, and in the testing cycle(s), also should be reported. These energy values for hysteresis correspond to the areas under the respective load/deformation curves. The areas under the load/deformation curves may be determined by graphical integration, by numerical integration, or by other appropriate technique.

A4.8.4 *Range of Adjustability or Range of Motion Tests*:

A4.8.4.1 These tests should be run under displacement control since there may be negligible resisting force, or moment, over the permitted range of travel.

A4.8.4.2 These tests should be run quasistatically. In this context, quasistatic linear or angular displacement input should be interpreted as a displacement rate sufficient to cause the joint to reach the extrema of its permitted adjustment or motion range in approximately 30 s.

A4.8.4.3 The test should terminate when there is an abrupt increase in the force (or moment) developed to resist the input linear (or angular) displacement.

A4.8.5 *Data Recording*:

A4.8.5.1 The load (N) or torque (N-m) and linear (mm) or angular (°) displacement measured by the testing machine should be continuously recorded by a data acquisition device. Alternatively, a digital recording and display device can be used, operating at a sampling rate sufficiently fast to capture accurately any discontinuities in the load/deformation curve accompanying subcomponent failure or interface slippage.

A4.8.5.2 The linear displacement should be measured at the point of load application.

A4.8.5.3 In some instances, it may be appropriate also to record components of deformation in directions other than that of the applied loading. If so, the sensors used, for example, dial gages or LVDTs, and the points and directions of their measured deformations should be recorded.

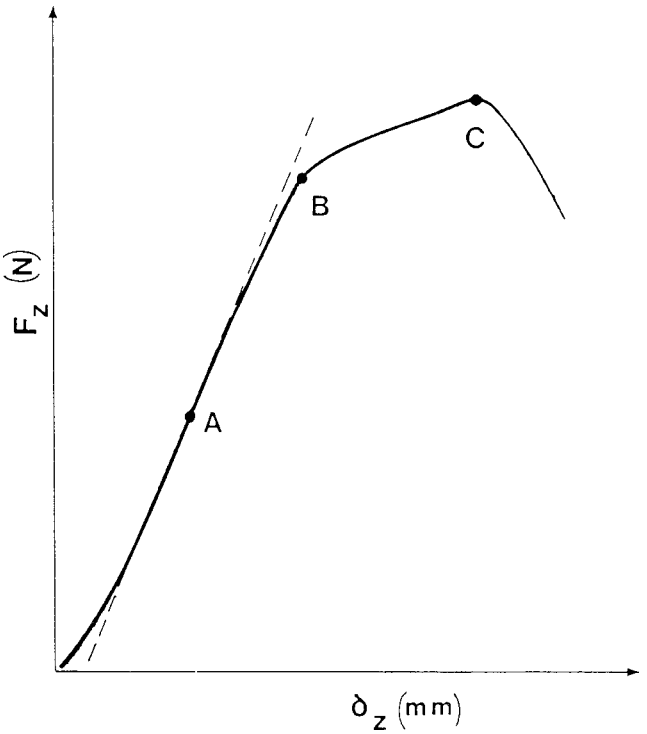
A4.9 Calculation or Interpretation of Results

A4.9.1 Stiffness (units according to the chosen load and deflection configuration, for example, N/mm for force, N-mm/degree for moment) shall be calculated from the slope of the linear-most portion of the load/deflection curve, as visually apparent (in Fig. A4.2). If an objective slope determination technique, for example, curve-fitting of a digitized tracing, is used, this should be described. The load and deflection configuration (location of measuring element and direction of the measured vector) must be defined clearly with respect to the loading axis of the test apparatus (Fig. A4.1).

A4.9.2 Failure load (N or N-mm) shall be defined as the point of maximum load (or moment) acceptance, as identified by a discontinuity in the load/deformation curve.

A4.9.2.1 In situations in which there is no clear discontinuity in the load displacement curve, other definitions of failure load may be used. For situations in which interfacial slip, or plastic, deformation, or both, occurs within the joint, an offset criterion may be used. In this instance, the failure load is defined as that load necessary to induce a specific amount of permanent deformation (either linear or angular, depending upon the degree of freedom being tested), upon release of the applied load. For situations in which excessive elastic deformation occurs within the joint, failure may be defined in terms of a specific fractional reduction of the joint's small-load stiffness. For example, failure might be defined in terms of the joint's tangent stiffness having fallen to 25 % of the tangent stiffness that was apparent at a load to 50 N.

A4.9.3 The range of adjustability or motion in a specific degree of freedom shall be defined as that linear or angular displacement value at which the joint develops an abrupt



NOTE—Stiffness is defined as the slope of the linear-most portion of the curve, here evaluated by a tangent drawn at Point A. Point B illustrates a slope discontinuity (possibly indicative of interfacial slip or subcomponent failure within the connector), and Point C illustrates the maximal load acceptance (ultimate strength).

FIG. A4.2 Load/Deformation Curve (Generic, Here Illustrated for the *z Direction)**

increase in the force or moment resisting the input displacement.

A4.10 Report

A4.10.1 The test report shall include, but is not limited to, the following information:

A4.10.1.1 *Connecting Element and Bridge/Anchorage Element Identification*, including manufacturer, part number, nomenclature, and quality control or lot number. If the part is a prototype, geometrical and material descriptions shall be included.

A4.10.1.2 Assembly force or torque used to engage the connector's gripping mechanism.

A4.10.1.3 Configuration of the input loading element, and, for A4.6.1.3, the output loading element, and testing apparatus grips. Describe the method/apparatus used to grip the input and output loading elements.

A4.10.1.4 Specific degrees of freedom tested in tension, compression, torsion, or bending. In each case, the axis along which or about which loading is applied should be specified.

A4.10.1.5 Loading rate and number of cycles (fatigue tests).

A4.10.1.6 Stiffness in the specific direction(s) tested. The stiffness of the initial load cycle, the "stable" stiffness determined after the preconditioning cycles, and the number of cycles needed to attain a "stable" stiffness should be reported.

A4.10.1.7 If loaded to failure, the failure criterion, strength, and the specific mode of failure, for example, slip at the interface between the clamp and the loading input element.

A4.10.1.8 Where appropriate, the range of adjustability or the unlocked range of motion in specific degrees of freedom. For unlocked degrees of freedom, the joint may be further characterized as having resisted motion (for example, spring-loaded), in which case either the tangent resisting stiffness or, if resistance is nonuniform, the load/deformation curve in the permitted motion range, may be reported; actuated motion, in which case the available actuating force may be reported; or, unresisted motion, in which case any factors identified as causing appreciable increase in the normally incidentally small friction, that is causing binding, should be reported.

A4.11 Precision and Bias

A4.11.1 Data establishing the precision and bias to be expected from this test method have not yet been obtained.

12. Keywords

12.1 bending; connecting elements; external fixator; joints; orthopedic device; range of adjustability; range of motion; stiffness; strength; torsion

A4.13 Rationale

A4.13.1 Joints of various designs are used widely in external fixators. Both the types of elements connected and the pertinent directions of force, or moment, or both, transmission through joints are design and site specific. In many situations, elastic deformations at the joints between bridge elements, or between anchorage and bridge elements, account for a substantial fraction of the overall compliance of the fixator construct. Moreover, slippage between clamps and the bridge or anchorage elements they grip is often the major reason for overall structural failure of an external fixator.

A4.13.2 This test specification outlines a method by which the stiffness or strength, or both, of a joint can be measured, including both the connector body itself, and the one or more interfaces between the connector body and the bridge (or anchorage) elements so joined.

A4.13.3 The test specification also outlines a procedure by which the range of adjustability may be determined in specific degrees of freedom for which the joint's configuration can be adjusted by the end user. In the case of unlockable (dynamizable) joints, it outlines a method for determining the limits of motion permitted in the corresponding degrees of freedom.

A5. TEST METHOD FOR EXTERNAL SKELETAL FIXATOR PINS

A5.1 Scope

A5.1.1 This test method covers the procedure for determining the static bending strength and torsional strength of metallic pins used in external skeletal fixation systems. The described method is intended to provide a means of mechanically evaluating pins and not to define acceptable levels of performance. This test method is applicable only to pins made from materials exhibiting linearly elastic behavior. Pins are defined in Annex A1.

A5.1.2 *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.*

A5.2 Referenced Documents

A5.2.1 *ASTM Standards:*

A 938 Test Method for Torsion Testing of Wire[2]

E 4 Practices for Force Verification of Testing Machines[4]

F 1264 Specification and Test Methods for Intermedullary Fixation Devices[5]

A5.3. Terminology

A5.3.1 *Definitions of Terms Specific to This Standard:*

A5.3.1.1 *bending rigidity*, *n*—the resistance to bending of a pin tested in four-point bending, normalized to the cross-sectional properties of the working length, without regard for the length of the pin tested. This parameter is calculated as described in Guide F 1264 (EI_e). This theoretical equation is appropriate only for working lengths of constant cross section; it is not applicable to tapered pins.

A5.3.1.2 *bending stiffness*, *n*—the slope of Line *m-b* defined in A5.8.1.4.

A5.3.1.3 *bending yield strength*, *n*—the bending moment required to produce a 0.2 % permanent flexural strain in a pin tested as described in A5.8.1.4. If the pin fractures before the above-specified amount of permanent flexural strain is accrued, the maximum bending yield strength shall be defined as the bending moment occurring before or at the time of fracture.

A5.3.1.4 *maximum deformation*, *n*—in the four-point bending test of A5.8.1, the maximum vertical displacement measured at the point of load application while the load is applied.

A5.3.1.5 *permanent angular rotation*, *n*—in the torsion test of A5.8.2, the angle of rotation of the pin measured after the applied torque has been removed.

A5.3.1.6 *permanent deformation*, *n*—in the four-point bending test of A5.8.1, the vertical displacement of the point of load application after the applied loading has been removed.

A5.3.1.7 *thread runout*, *n*—the junction between the threaded and nonthreaded portions of the pin.

A5.3.1.8 *torsional rigidity*, *n*—a measure of the pin's normalized resistance to torsional shear when tested as described in A5.8.2. The value is calculated by dividing the torsional stiffness by the gage section length.

A5.3.1.9 *torsional stiffness*, *n*—the slope of line *m-b* defined in A5.8.2.4.

A5.3.1.10 *torsional yield strength*, *n*—in the torsion test of A5.8.2, the torque required to produce a permanent shear strain of 0.2 % in a pin tested as described in A5.8.2.4. If a pin fractures before the specified amount of permanent angular rotation is accrued, the torsional strength shall be defined as the maximum torque occurring before or at the time of fracture.

A5.4 Summary of Test Method

A5.4.1 External skeletal fixator pins are tested in static four-point bending by loading the pins to a specified deflection. The results of the test are displayed in the form of a bending moment versus deformation curve, from which the bending stiffness, and strength, if tested to failure, can be determined. Once the bending stiffness is determined, the bending rigidity can be calculated, as described in A5.3.1.1.

A5.4.2 External skeletal fixator pins are tested in torsion by gripping both ends of the pin in fixtures and holding one end stationary while applying torque to the other end. The results are displayed in the form of a torque versus angle of rotation curve, from which the torsional stiffness, and strength, if tested to failure, can be determined. Once the torsional stiffness is determined, the torsional rigidity can be calculated as described in A5.3.1.8.

A5.5 Significance and Use

A5.5.1 These benchtop tests are used to determine values for the mechanical response of external fixator pins under flexural loading conditions and under torsional loading conditions.

A5.5.2 The results obtained in these tests are not intended to predict the clinical efficacy or safety of the tested elements. The methods are intended only to measure the uniformity of the elements tested or to compare the mechanical performance of different pins.

A5.5.3 Since clinical failures often involve the threaded portions of the pin or the thread runout, it may be appropriate to perform bending tests (see A5.6.3.2), or torsional tests (see A5.6.4.2), or both, with working regions representing the corresponding portions of the pin.

A5.6 Test Apparatus

A5.6.1 Machines used for these tests shall conform to the requirements of Practices E 4.

A5.6.2 *Data Acquisition Device*—A suitable recorder to plot a graph of load versus load frame displacement, or torque versus load frame rotational displacement, on perpendicular axes. Optionally, this may include the use of computer-based digital sampling and output of the load and displacement signals.

A5.6.3 *Four-Point Bending Test*:

A5.6.3.1 The test configuration for the static four-point bending test is illustrated in Fig. A5.1.

A5.6.3.2 Since pins are available in a wide range of sizes, no single-testing geometry is appropriate in all circumstances; however, the following sizing criteria should be adopted. For testing the nonthreaded portion of the pin, the distance between

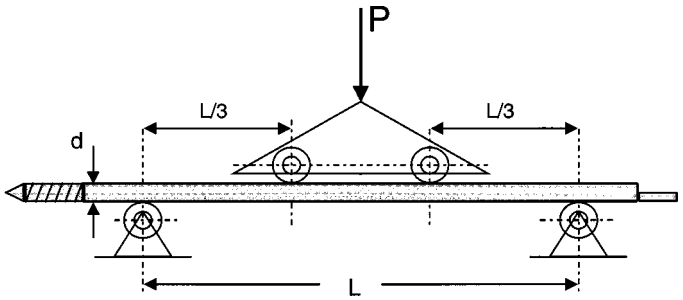


FIG. A5.1 Four-Point Bending Test for an External Skeletal Fixation Pin

the supports should be short enough that only a prismatic section of the pin is loaded; that is, the threaded portion of the pin plus at least a two-diameter length of the prismatic portion of the pin should overhang one outer (support) roller, and the keyed drive section and at least a two-diameter length of the prismatic portion of the pin should overhang the other outer (support) roller. For testing the threaded portion of the pin, the pin should be positioned such that its threaded portion completely spans the distance between the inner (loading) rollers. For testing to include the thread runout, the pin should be positioned such that the thread runout is positioned midway between the inner (loading) rollers. The diameter of the face of the rollers should be at least four times the diameter of the pin to insure negligible local deformation of the roller or the pin as a result of (Hertzian-like) contact stresses. The diameter of the roller face should be less than 1/10 the span length, so that roller/pin contact interface approximates point loading for purposes of beam flexure analysis.

A5.6.3.3 The load rollers will be placed at 1/3 points between the supports. The load shall be shared equally between both loading points.

A5.6.3.4 Deformation shall be measured as the displacement of the fixture applying the load.

A5.6.4 *Torsion Test*:

A5.6.4.1 A biaxial mechanical testing system is recommended for the torsion test.

A5.6.4.2 Two clamping heads, for example, collets, shall be used to clamp the pin. Care should be taken to not to damage the pin to the extent that failure initiates at the clamped surfaces during torsion. For testing the nonthreaded portion of the pin, the pin should be positioned in the clamps such that the free span of the pin between the clamps is prismatic and is at least two pin diameters from either the thread or the drive key. For testing the threaded portion of the pin, the pin should be positioned in the clamps such that the free span between the clamps is occupied only by the threaded portion of the pin. For testing the thread runout, the pin should be positioned in the clamps such that the junction between the threaded and nonthreaded portions of the pin lies mid way between the clamps.

A5.6.4.3 The clamping heads shall be affixed to the mechanical testing system, one to the test table and one to the torsional actuator.

A5.6.4.4 The pin and clamping heads should be aligned such that as the actuator rotates, negligible bending occurs.

A5.7 Test Specimen

A5.7.1 All tested pins should be representative of clinical quality products.

A5.7.2 If the pins to be tested have been used previously, the nature of such prior usage should be described appropriately.

A5.7.3 If the pin to be tested is a prototype, or under development, or both, the geometric and material information needed to characterize fully the pin should either be included in the report or detailed descriptive information should be referenced.

A5.8 Procedure

A5.8.1 *Four-Point Bending Test*:

A5.8.1.1 The pin should be placed into the test fixture (see Fig. A5.1). Quasistatic loads of progressively increasing magnitude should be applied, while recording the load P and corresponding deformation δ until either failure occurs or further deformation does not result in a corresponding increase in applied load.

A5.8.1.2 It is recognized that no specific rate is applicable to all situations; however, an input rate sufficient to attain in 30 s a pin flexural strain magnitude in the range of typical physiological usage, or of pin failure, shall be deemed quasistatic. The testing machine may be operated in either load or stroke control.

A5.8.1.3 The bending moment shall be computed as PL/6.

A5.8.1.4 On the bending moment versus deformation plot (see Fig. A5.2), lay off O-m on the abcissa from the origin of the curve to a point corresponding to a flexural strain of ϵ = 0.2 % the origin. Here, flexural strain is defined Mr/EI, where r is the pin radius. Draw a line parallel to the linear portion of the curve beginning as Point m and ending where the bending moment versus deformation curve is intersected, Point b. The location of this intersection corresponds to the bending moment, B, which is the bending yield strength.

A5.8.1.5 The bending stiffness is the slope of the Line m-b.

A5.8.1.6 The bending rigidity is defined as $(EI_e) = 0.0154\ L^3(F/y)$, where L is the distance between the support rollers and (F/y) is the slope of the Line O-m.

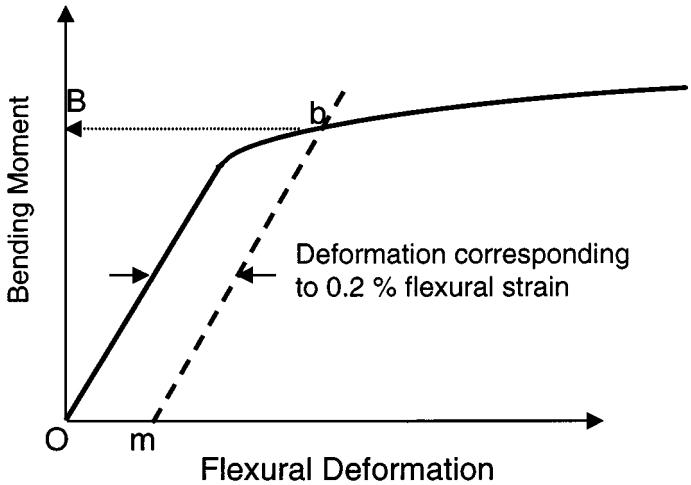


FIG. A5.2 Bending Moment Versus Flexural Deformation

A5.8.2 *Torsion Test*:

A5.8.2.1 Secure the pins in the clamping heads and affix the clamping heads to the mechanical test system table and torsional actuator such that the pin and clamping heads are aligned collinear with the axis of rotation of the actuator.

A5.8.2.2 Apply quasistatic torque via the torsional actuator and record the torque T and angle of rotation θ. The axial load on the pin should remain negligible at all times.

A5.8.2.3 It is recognized that no specific torsion rate is applicable to all situations; however, an input rate sufficient to attain in 30 s a pin shear strain magnitude in the range of typical physiological usage, or of pin failure, shall be deemed quasistatic. The testing machine may be operated in either torque or angular stroke control.

A5.8.2.4 Determine the torsional yield strength and stiffness as follows. On the torque versus angle of rotation plot (see Fig. A5.3), lay off O-m on the abcissa from the origin of the curve to a point corresponding to 0.2 % shear strain. Shear strain $\gamma = \theta\, r_{eff}/L_0$, where θ is the angle of rotation, r_{eff} is the effective radius, and L_0 is the free specimen length between the clamping heads. The effective pin radius may be taken as the root diameter of the threaded portion of the pin. For tests of nonthreaded pin portions, r_{eff} is the pin radius. Draw a line parallel to the linear portion of the curve beginning at Point m and ending where the torque versus angle of rotation curve is intersected, Point b. The location of this intersection corresponds to the Torque B, which is the torsional yield strength. The torsional stiffness is the slope of the Line M-B.

A5.8.2.5 The torsional rigidity is torsional stiffness divided by the free specimen length L_0.

A5.9 Report

A5.9.1 The report of the four-point bending test shall include the following information:

A5.9.1.1 Description of the pins, including manufacturer, part number, nomenclature, quality control or lot number, the material, overall length, unthreaded length.

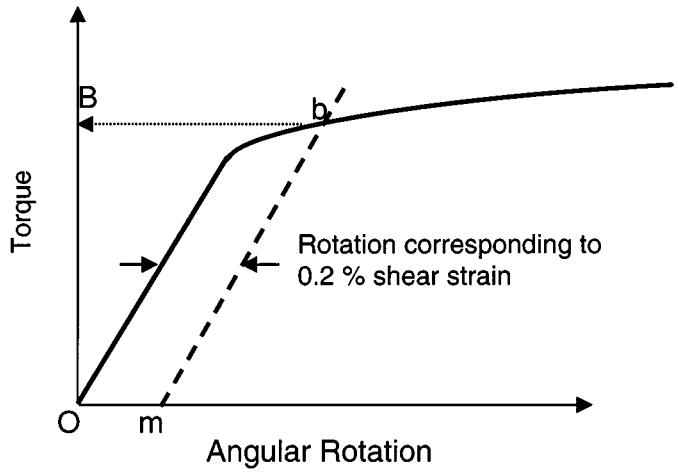


FIG. A5.3 Applied Torque Versus Angle of Rotation

A5.9.1.2 Description of the testing machine, including the make, model, and load range.

A5.9.1.3 Test rate, span length, and mode of control. Also, report whether the span segment tested was the threaded, nonthreaded, or thread-runout region of the pin.

A5.9.1.4 The number of pins tested and the means and standard deviations of the bending strength, bending rigidity, and bending stiffness.

A5.9.2 The report of the torsion test shall include the following information:

A5.9.2.1 Description of the pins, including manufacturer, part number, nomenclature, quality control or lot number, the material, overall length, unthreaded length.

A5.9.2.2 Description of the testing machine, including the make, model, and load range.

A5.9.2.3 Test rate, span length, and mode of control. Also, report whether the span segment tested was the threaded, nonthreaded, or thread-runout region of the pin.

A5.9.2.4 The number of pins tested and the means and standard deviations of the torsional strength, torsional rigidity, and torsional stiffness.

A5.10 Precision and Bias

A5.10.1 Data establishing the precision and bias to be expected from this test method have not yet been obtained.

11. Keywords

11.1 external fixation; four-point bending; orthopedic device; pins; rigidity; stiffness; strength; torsion

A5.12 Rationale

A5.12.1 Partially threaded transcutaneous pins are the most commonly used anchorage elements for external fixation. Normally, the threaded portion of a fixation pin is self-tapping and engages both bony cortices. Once inserted, these pins are loaded primarily in flexure. In many external fixation constructs, flexural deformation of the pins is responsible for much or most of the total axial and bending deformations of the overall construct. Pins experience torsional loading during the threading/insertion process and in resisting construct bending about axes parallel to pins (in a cluster).

A5.12.2 Besides heavily influencing deformations at the fracture site, pin deformation during loading is a major determinant of interfacial motion at the pin/bone interface, frequently a problematic site in terms of bone remodeling, pin loosening, and sepsis. Also, in some situations, the loads borne by the pins are so high that the pins themselves are at risk of failure either by plastic deformation of by breakage. This test method outlines benchtop flexural and torsional testing protocols useful for determining the flexural and torsional stiffnesses and strengths of these key fixator elements.

A6. TEST METHOD FOR EXTERNAL SKELETAL FIXATOR SUBASSEMBLIES

A6.1 Scope

A6.1.1 This test method covers procedures for determining the stiffness and strength of external skeletal fixator subassemblies, under force loadings (axial, medial-lateral shear, anterior-posterior shear), or under moment loadings (torsion, medial-lateral bending, anterior-posterior bending), or a combination thereof.

A6.1.2 *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.*

A6.2 Referenced Documents

A6.2.1 *ASTM Standards:*

D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials[3]

E 4 Practices for Force Verification of Testing Machines[5]

A6.3. Terminology

A6.3.1 *Definitions of Terms Specific to This Standard:*

A6.3.1.1 *subassembly, n*—that portion of an external fixator assembly specifically excluding the bony anchorage elements. Definitions of the terms used to describe various external skeletal fixator components are given in Annex A1.

A6.4 Summary of Test Method

A6.4.1 Subassemblies to be tested are assembled from individual bridge and connector elements. All geometric, material, and assembly parameters necessary to characterize the subassembly configuration unambiguously are recorded. The subassembly then is 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, which 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, and so forth.

A6.5 Significance and Use

A6.5.1 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.

A6.5.2 The results obtained in this test 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.

A6.5.3 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.

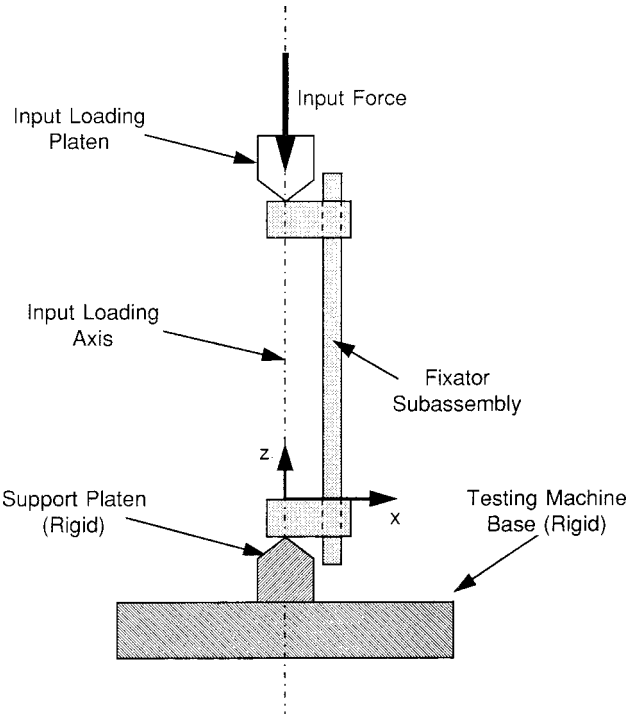
A6.6 Apparatus

A6.6.1 *Force, or Moment (or Both), Application Fixture*:

A6.6.1.1 The loading configuration is shown schematically in Fig. A6.1. 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.

A6.6.1.2 The subassembly undergoing testing is rigidly attached to two platens. One platen, termed the input platen, delivers the input load, or displacement, as a result of programmed motion of the actuator or crosshead of the testing machine. The other platen, termed the support or restraint platen, is affixed to the testing machine base, which in turn acts as a fixed support.

A6.6.1.3 Both the loading axis and the platen positions, orientations, and unrestrained degrees of freedom should be prescribed, or located, or both, with respect to a right-hand coordinate system defined with respect to the undeformed position of the subassembly being tested. Since positioning of the subassembly relative to anatomical orientations may vary from bone to bone, or with surgeon judgment, or both, the coordinate system should be defined relative to the major components of the subassembly. Normally, the axial direction will be associated with the longitudinal rod(s) or other longitudinal elements, and one of the transverse axes would be associated with the dominant direction of the anchorage elements.



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

FIG. A6.1 Schematic Test Configuration for Longitudinal (*z* Direction) Loading of an External Fixator Subassembly

A6.6.2 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 Practices E 4.

A6.6.3 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.

A6.7 Test Specimen

A6.7.1 All tested subassemblies should be assembled from elements representative of clinical quality products.

A6.7.2 If one or more of the elements in the frame to be tested has been previously used, the nature of such prior usage should be described appropriately.

A6.7.3 If any elements of the subassemblies to be tested are prototypes, or are under development, or both, the geometric and material information needed to characterize fully all such elements should either be included in the report, or a similarly detailed descriptive information should be referenced.

A6.7.4 The test specimens should be prepared in the manner in which they normally would be used clinically. For example, if a component normally would be sterilized in a particular manner before use, it should be sterilized similarly before mechanical testing. This is especially true for polymeric components and polymeric and metallic mechanisms used for connection or clamping.

A6.8 Procedure

A6.8.1 *Assembling the Subassembly to Be Tested*:

A6.8.1.1 Those bridge or connecting elements, or both, that are comprised of subcomponents first should be individually assembled according to manufacturer recommendations.

A6.8.1.2 The subassembly then is constructed according to the manufacturer's recommendations. Assembly forces or torques used to engage the clamps of the connecting elements should be measured and recorded. In cases using a noncalibrated, specialized assembly tool supplied by the manufacturer, for example, a ratchet wrench, the use of such a tool should be noted.

A6.8.2 *Mounting the Subassembly to Be Tested*:

A6.8.2.1 The subassembly then is affixed to the input and restraint platens. Normally, the sites of such gripping/attachment would be at the connectors where the subassembly would be coupled to anchorage elements for attachment to bone. For those subassembly degrees of freedom, which are to be constrained, rigid attachment to the platen should be ensured.

A6.8.3 *Stiffness or Strength Testing*:

A6.8.3.1 Stiffness or strength tests may be run under either load or displacement control.

A6.8.3.2 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.

A6.8.3.3 If single-cycle testing is to be performed, the specimen must be subjected to several preconditioning load cycles to demonstrate that the reported load/deformation curve is repeatable from cycle to cycle. Preconditioning should be continued until the apparent stiffness of the joint changes less than 5 % between subsequent cycles. Normally, about five preconditioning cycles are suitable for this purpose, with peak applied load within the elastic range, approximately 50 % of the expected physiologic service load or 50 % of the expected subassembly failure load, whichever is lower. Load/deformation curves for the preconditioning cycles should be recorded. Preconditioning cycle stiffnesses should be reported.

A6.8.3.4 The input load (or displacement) should be applied quasistatically. The rate(s) used should be reported. It is recognized that no specific rate is applicable to all situations; however, in this context, a quasistatic input rate should be interpreted 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. Input loading rates, which are in the range of those expected clinically may be desirable for testing components made of polymeric materials, that exhibit viscoelastic behavior, and for components that rely upon friction for fixation. A rationale should be provided for whatever input loading rate is used.

A6.8.3.5 For multicycle testing (fatigue or low cycle fatigue), the input loading frequency shall not exceed 5 Hz. Maximum and minimum values of the loading cycle, as well as the input waveform, should be included in the test report.

A6.8.3.6 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.

A6.8.3.7 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. The specific threshold or irrecoverable deformation constituting failure must be reported, and the rationale for that specific value stated.

A6.8.3.8 Input forces, or linear displacements, should be delivered either along the subassembly longitudinal axis (axial load), or perpendicular to the subassembly longitudinal axis (shear load). The line of action of the input force should be recorded, with respect to the subassembly based right-hand orthogonal coordinate system.

A6.8.3.9 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, the points and lines of application if the individual forces must be reported.

A6.8.4 *Data Recording*:

A6.8.4.1 The input load (N) or torque (N-mm) and the corresponding linear (mm) or angular (°) displacement of the input platen, or vice versa, should be recorded continuously. This may be done either as direct analog signals or using digital sampling at a rate sufficient to allow subsequent reconstruction

of a visibly smooth load/deformation curve mimicking a continuous analog tracing.

A6.8.4.2 Linear or angular displacements should be measured at the site of the input load platen.

A6.8.4.3 In some situations, it may be appropriate to record displacement in a direction other than that of the loading input, or vice versa. If this involves releasing one or more degrees of restraint at the input platen, this should be noted. Any additional sensors used for recording such coupled motion, or force/torque, components should be described, and their sampling points and measurement directions noted.

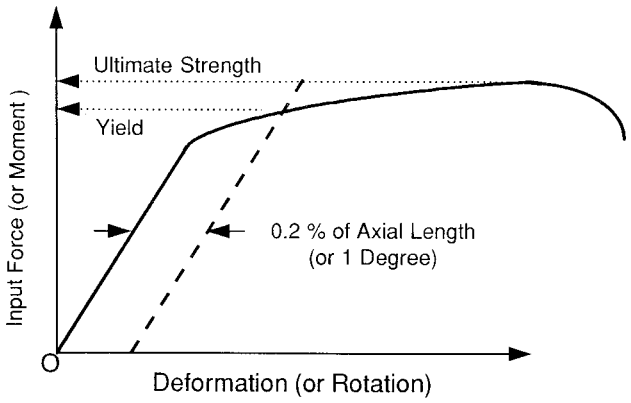
A6.9 Calculation or Interpretation of Results

A6.9.1 Tangent stiffness, units according to the chosen load and deflection configuration, such as, N/mm for force, N-mm/degree for moment, shall be calculated from the slope of the linear-most portion of the load/deflection curve, as apparent visually (see Fig. A6.2). If an objective slope determination technique, such as, curve fitting of a digitized tracing is used, this should be described. The load and deflection configuration (location of measuring elements and direction of the measured vector) must be defined clearly with respect to the loading axis of the test apparatus (see Fig. A6.1).

A6.9.2 Chord stiffness (units according to the chosen load and deflection configuration, such as, N/mm for force, N-mm/degree for moment) shall be calculated as the change in load (force or moment), divided by the change in the corresponding displacement (linear or angular), between two specific points on the load/deformation curve. The load and deflection configuration (location of measuring elements and direction of the measured vector) must be defined clearly with respect to the loading axis of the test apparatus (see Fig. A6.1).

A6.9.3 Ultimate strength (N or N-mm) shall be defined as the point of maximum force, or moment, acceptance.

A6.9.4 Yield strength (N or N-mm) shall be defined using the chord offset method (see Fig. A6.2). Toe regions of the load (moment) versus displacement (angulation) curve, which may occur during the initial loading of the subassembly, may be compensated for using the techniques described in Test Methods D 790.



NOTE—Stiffness is defined as the slope of the linear portion of the force/deformation curve.

FIG. A6.2 Typical Force/Deformation Curve, Illustrating Definitions of Ultimate Strength and Offset Yield Strength

A6.9.4.1 Normally, yield should be based on an irrecoverable deformation of 0.2 % of the axial length of the subassembly for force inputs, or 1° for moment inputs.

A6.9.4.2 Other permanent deformation thresholds may be appropriate, depending on the subassembly configuration. If alternative yield definitions are used, they should be included in the report, with appropriate justification.

A6.10 Report

A6.10.1 The test report shall include, but is not limited to, the following information:

A6.10.1.1 Identification of the individual elements comprising the subassembly. This should include manufacturer, part number, nomenclature, and where possible, the quality control or lot number. If the part is a prototype, geometrical and material descriptions shall be included.

A6.10.1.2 Configuration of the subassembly. This should include a drawing, or photograph of the subassembly, or both, using multiple orthogonal views (antero-posterior view, medial-lateral view, superior-inferior view) as necessary to define unambiguously the relative positions and orientations of the individual elements comprising the subassembly. All physical dimensions, or element orientations within the subassembly, or both, that can be varied by the end user must be unambiguously specified, for example, clamp positions along rod elements, angle between rods connected by an adjustable clamp. For subassembly elements whose physical dimensions, or orientations, cannot be varied by the end user, or both, it is recognized that detailed dimensional, or material information, or both, may not be practical or appropriate to report when testing overall subassembly behavior. At a minimum, however, reference to public domain documentation reporting that specific information must be included. The assembly force or torque used to engage any connector grip mechanism(s) should be reported. If assembly is performed using noncalibrated specialty instruments often provided by manufacturers, such as ratchet drives, this should be reported and reference made to documentation reporting the actual force or torque delivered by such specialty instruments, if available.

A6.10.1.3 Test machine (manufacturer, model) and configuration of the subassembly relative to the test machine. A drawing, or photograph of the subassembly, or both, within the test machine setup should be provided. The positions of the load application platens must be identified. All physical dimensions, whether or not end user variable, which influence the load (or moment) delivered to the subassembly by the testing machine, must be specified. Constrained versus unconstrained degrees of freedom at the two platen/subassembly interfaces must be identified.

A6.10.1.4 Loading rate, and for fatigue tests, the number of cycles, maximum and minimum loads, and the waveform.

A6.10.1.5 Subassembly stiffness (tangent, or secant, or both) in the specific direction(s) tested.

A6.10.1.6 If the subassembly is loaded to failure, both the strength and the specific mode of failure, for example, slip at a particular clamped interface or yield of a specific bridge element, should be specified. If the specific mode of failure cannot be ascertained by gross observation, the technique(s) used to identify the mode or site of failure should be reported.

A6.11 Precision and Bias

A6.11.1 Data establishing the precision and bias to be expected from this test method have not yet been obtained.

A6.12 Rationale

A6.12.1 The modularity of most external fixation devices affords a great deal of variability in how subassemblies can be constructed. In many instances, it is desirable to compare the effective stiffness or strength of alternative subassembly configurations that can be assembled from a specific set of elements, such as perturbations of end-user-controlled variables, such as the distance between two connection clamps attached to a rod element. Also, there are many instances in which it is desirable to compare the effective stiffness or strength of similarly conceived subassemblies built up from different individual components, for example, choosing different rod diameters from within a given manufacturer's fixator set or assembling conceptually similar subassemblies using different manufacturers' fixator sets.

A6.12.2 Normally, the subassembly itself is the stiffest and strongest part of an overall external fixator assembly or construct. Also, the mechanical behavior of the subassembly, per se, is of interest because intrinsic subassembly properties do not depend upon the specifics how the subassembly is connected (via anchorage elements) to the skeletal elements being fixated, provided of course, that those anchorage elements connect to the subassembly at comparable locations. That is, many attributes of the mechanical behavior of an overall fixator assembly/construct can be influenced substantially by the structural characteristics of the subassembly itself without needing to confront anatomic or clinical constraints limiting the configuration(s) of anchorage elements.

A6.12.3 Because of the wide variety of fixator size ranges and anatomic sites, it is inappropriate to standardize the geometry or kinetics of subassembly loading tests. Rather, this test method emphasizes unambiguous specification of the subassembly being tested, clear identification of the site at which loading is applied and deformation is measured, and a formal definition of the subassembly's stiffness, or strength, or both, for each combination of load/deformation measured.

A7. TEST METHOD FOR EXTERNAL SKELETAL FIXATOR-BONE CONSTRUCTS

A7.1 Scope

A7.1.1 This test method covers procedures for determining the stiffness, strength, and repetitive loading performance characteristics of external skeletal fixator-bone constructs when subjected to force loading (axial, medial-lateral shear, anterior-posterior shear) and moment loading (torsion, medial-lateral bending, anterior-posterior bending).

A7.1.2 This test method establishes a universal fixator-bone construct's minimum configuration and set of laboratory tests for evaluating the external fixator device's (EFD) basic performance characteristics.

A7.1.3 *Units*—Unless otherwise stated, the values stated in SI units are to be regarded as standard.

A7.1.4 *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.*

A7.2 Referenced Documents

A7.2.1 *ASTM Standards:*

D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials[3]

E 4 Practices for Force Verification of Testing Machines[4]

E 122 Practice for Choice of Sample Size to Estimate the Average Quality of a Lot or Process[7]

E 467 Practice for Verification of Constant Amplitude Dynamic Loads and Displacements in an Axial Fatigue Testing Machine[4]

E 1823 Terminology Relating to Fatigue and Fracture Testing[4]

E 1942 Guide for Evaluating Data Acquisition Systems Used in Cyclic Fatigue and Fracture Mechanics Testing[4]

A7.3. Terminology

A7.3.1 *Definitions*—Unless otherwise specified, the terms used to describe various external skeletal fixator components are defined in Annex A1. Unless otherwise defined in this method, the terminology to mechanical testing that is used in this method will be in accordance with the definitions of Terminology E 1823.

A7.3.2 *Definitions of Terms Specific to This Standard:*

A7.3.2.1 *angular displacement (θ), (°), n*—the relative change in the angle of the moment application point at the beginning of the test and the current position as shown in Fig. A7.1.

A7.3.2.2 *D (mm), n*—the diameter measurement of the bone analog model as illustrated in Fig. A7.2.

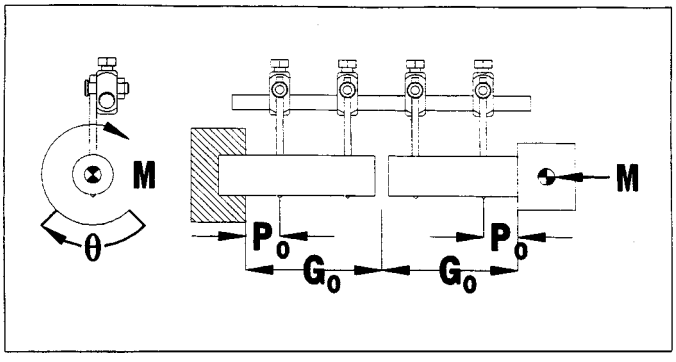


FIG. A7.1 Torsion Test Configuration

[7] *Annual Book of ASTM Standards*, Vol 14.02.

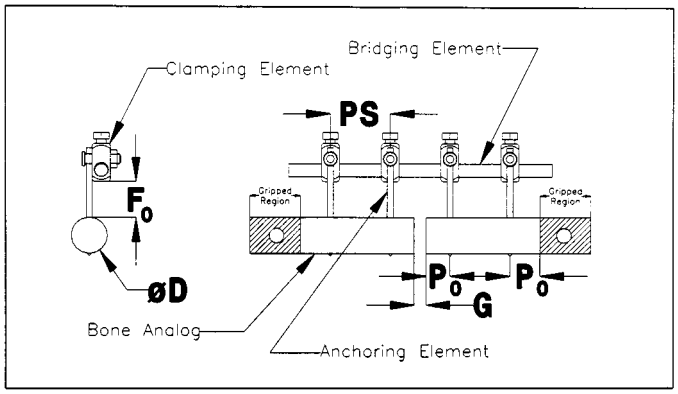


FIG. A7.2 Typical Fixator-Bone Construct

A7.3.2.3 *failure*, *n*—the point when the construct experiences either irrecoverable deformation or has reached a deformation limit. This can be a result of the destructive failure of an element, for example, plastic bending of a rod or pin or from slippage at an interconnection between individual components. 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.

A7.3.2.4 *fixator-bone construct*, *n*—the combination of an EFD and the bone analog to which it is anchored.

A7.3.2.5 *fracture gap offset (G_o), (mm)*, *n*—the distance between the plane at the center of the fracture gap and the gripping (or loading) locations that are illustrated in Fig. A7.1 and Figs. A7.3-A7.5. If different fracture gap offset values are used in the same test construct, identify each offset with a unique subscript label.

A7.3.2.6 *frame offset (F_o), (mm)*, *n*—the minimum clearance between the periosteal surface of the bone analog and any frame elements when measured normal to the bone analog surface (see Fig. A7.2).

A7.3.2.7 *gap size (G), (mm)*, *n*—the minimum clearance between the distal end of the proximal bone analog segment and the proximal end of the distal bone analog segment (see Fig. A7.2).

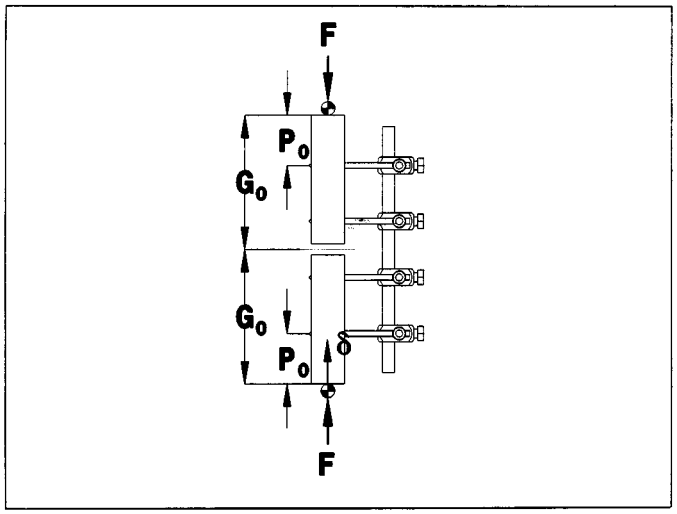


FIG. A7.3 Axial Load Test Configuration

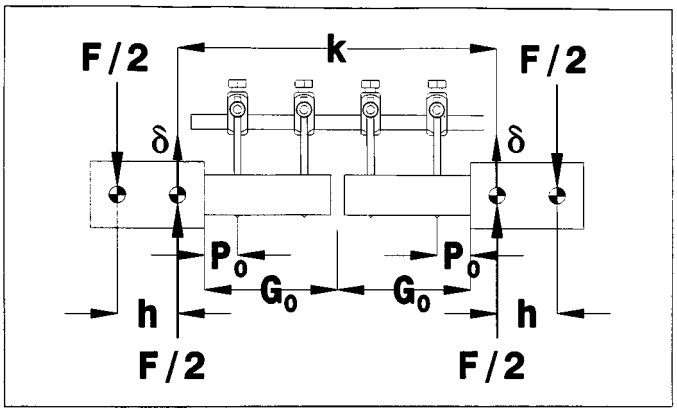


FIG. A7.4 Four-Point Bend Test Configuration

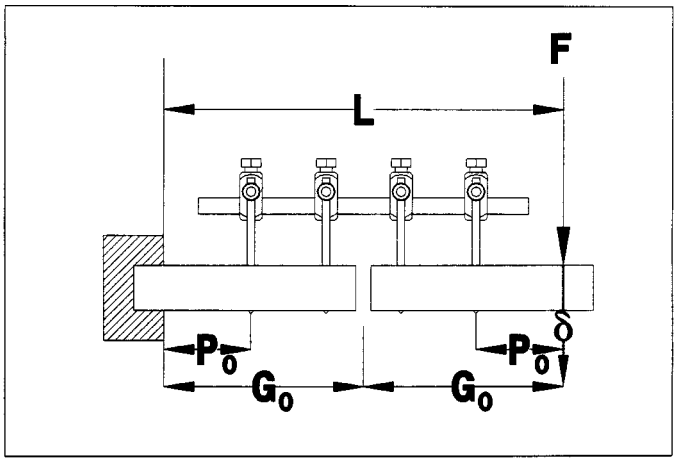


FIG. A7.5 Cantilever Bend Test Configuration

A7.3.2.8 *inner pin span (PS_I)*, (mm), *n*—the longitudinal distance from the center of the most distal pin on the bone analog's proximal end to the center of the most proximal pin on the bone analog's distal end within a given bone analog (see Fig. A7.6).

A7.3.2.9 *level arm (L), (mm)*, *n*—the distance between either the test block anchor point or section of interest and the position of the load application point as illustrated in Fig. A7.5.

A7.3.2.10 *linear displacement (δ), (mm)*, *n*—the relative change in the position of the load point at the beginning of the

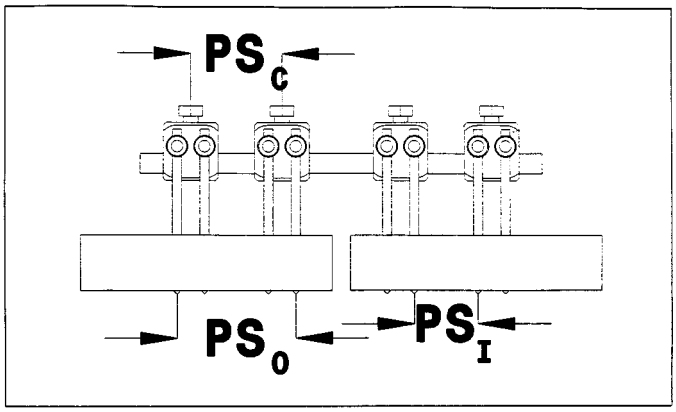


FIG. A7.6 Pin Cluster Illustration

test and the current position as defined for the given test configuration.

A7.3.2.11 *loading span (k), (mm), n*—the distance between the two moving loading attachment point axis for the four-point bend test as illustrated in Fig. A7.4.

A7.3.2.12 *outer pin span (PS_o), (mm), n*—the longitudinal distance from the center of the most proximal pin on the bone analog's proximal end to the center of the most distal pin on the bone analog's distal end within a given bone analog (see (Fig. A7.6).

A7.3.2.13 *pin cluster span (PS_c), (mm), n*—the longitudinal distance from the center of the proximal-most and distal-most pins within a given pin cluster (see Fig. A7.6).

A7.3.2.14 *pin offset (P_o), (mm), n*—the minimum linear distance between either the ends of the bone analog elements or test fixture gripping locations and the nearest anchor element as shown in Figs. A7.1-A7.5. If different anchor element offset values are used in the same test construct, identify each offset with a unique subscript label.

A7.3.2.15 *pin span (PS), (mm), n*—the longitudinal distance from the proximal pin to the distal pin within a given bone analog for a fixator-bone construct using only two pins in the given bone analog (see Fig. A7.2).

A7.3.2.16 *secant stiffness, (units according to the chosen loading configuration, for example, N/mm for force, N· m/° for moment), n*—the difference in load (or moment) divided by the change in displacement between two specific points on the construct's response curve (see Fig. A7.7). The load and deflection configuration (location of measuring elements and direction of the measured vector) must be clearly defined clearly with respect to the loading axis of the test apparatus.

A7.3.2.17 *support span (h), (mm), n*—the distance between the fixed support attachment point axis and the nearest loading attachment point axis for the four-point bend test as illustrated in Fig. A7.4.

A7.3.2.18 *tangent stiffness, (units according to the chosen loading configuration, for example, N/mm for force, N· m/° for moment), n*—calculated from the slope of the linear-most portion of the load versus deformation curve, as apparent visually (Fig. A7.6). The load and deflection configuration (location of measuring elements and direction of the measured vector) must be defined clearly with respect to the loading axis of the test apparatus. Describe the use of any objective slope determination techniques, for example, curve fitting of a digitized tracing) that are implemented when determining the tangent stiffness.

A7.3.2.19 *yield load (or moment), N or N·m), n*—determined using the secant offset method (Fig. A7.7). The standard method uses an offset value that is based on an irrecoverable deformation of 0.2 % of the gap size for force tests, or 1° for moment tests. Under some circumstances, other permanent deformation thresholds may be more appropriate relative to the construct configuration being tested. Include in the final report, with appropriate justification, the use of alternative yield definitions. Toe regions of the load (moment) versus displacement (angulation) curve, which may occur during the initial loading of the construct, may be compensated for using the techniques described in Test Methods D 790 Annex 1.

A7.3.2.20 *ultimate load (or moment), N or N·m), n*—the maximum reaction force (or torque) experienced by the construct during a static strength test. The load and deflection configuration (location of measuring elements and direction of the measured vector) must be defined clearly with respect to the loading axis of the test apparatus.

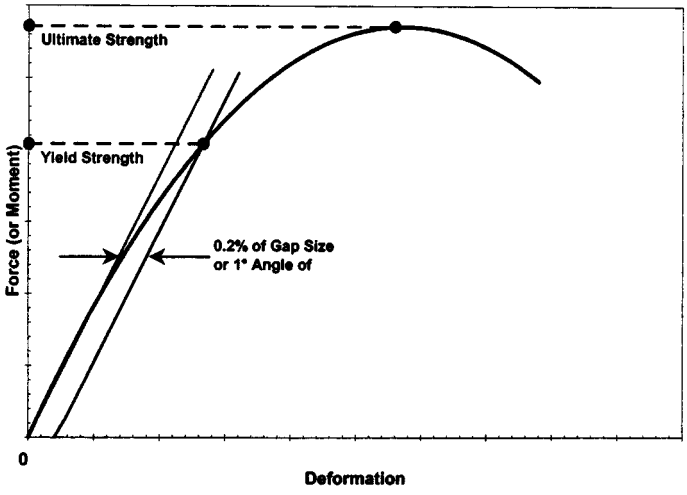


FIG. A7.7 Typical Fixator-Bone Construct Response Curve

A7.4 Summary of Test Method

A7.4.1 Fixator systems are assembled from individual bridge and connector elements. The assembled fixator system is anchored to upper and lower sections of a bone analog, producing a fixator-bone construct that simulates a segmental defect fracture. All geometric, material, and assembly parameters necessary to characterize the fixator configuration unambiguously are recorded. The fixator-bone construct is then mounted within the testing machine and subjected to a specific loading condition. For the static tests, the fixator-bone construct's reaction to the applied displacement (either linear or angular) is recorded which allows for the calculation of the fixator's stiffness and strength, when applicable, for the specific testing mode. For the dynamic test, the fixator-bone construct's ability to survive the application of repeated loading cycles is determined and reported.

A7.5 Significance and Use

A7.5.1 These laboratory tests are used to determine values for the stiffness and strength (when applicable) of an external fixation system when subjected to either force or moment loading.

A7.5.2 A dynamic axial loading test method is defined in this method to determine if any of the EFD's interconnections will loosen over time. In the event that a typical fatigue test is desired, carefully define the testing conditions so that the data provided are relevant to the issue being studied.

A7.5.3 This test method defines testing requirements that use a "minimal" EFD configuration for either a specific fracture indication that is dictated by the EFDs being evaluated or the universal indications that are specified in the method. The "minimal" configuration used in this method is that which is either specified by the manufacturer's surgical technique or by the requirements specified in this method. The user may

elect to test other fixator system configurations using the methodology found in this specification.

A7.5.4 The results obtained in these tests are not intended to predict the clinical efficacy or safety of the tested fixator. The methods are intended only to measure the uniformity of the fixators tested or to compare the mechanical performance of different fixators.

A7.5.5 The test method may not be appropriate for all types of external skeletal fixator applications. Furthermore, the minimum recommended test series may not be adequate to evaluate performance characteristics fully that are unique to a given fixator system; therefore, the user is cautioned to consider the appropriateness of the method in view of the materials and designs being tested and their potential application.

A7.6 Apparatus

A7.6.1 *Test Fixture*:

A7.6.1.1 Use rigid test fixtures that are able to support the construct adequately for the test being performed and do not influence the final test results.

A7.6.1.2 This test specification concentrates on testing EFDs with the construct constrained as illustrated in Fig. A7.1 and Figs. A7.3-A7.5. Since no single universal set of constraints or boundary/loading conditions may be appropriate for all evaluations, the constraints or boundary/loading conditions may be modified depending upon the construct being tested. Document the rationale behind alternative loading constraint conditions that were adopted in the test report.

A7.6.1.3 The input loading axis is designated as either the line of application in the case of force input or the axis about which a moment is applied in the case of moment input.

A7.6.1.4 The construct undergoing testing is attached to two platens. One platen, termed the input platen, delivers the input displacement (or load) caused by the programmed motion of the actuator or crosshead of the testing machine. The other platen, termed the support or restraint platen, is affixed to the testing machine base, which in turn acts as a fixed support.

A7.6.2 *Test System*:

A7.6.2.1 Use a rigid mechanical test machine that is capable of a generating the forced displacement of the test sample's supporting (gripping) points at a constant displacement rate.

A7.6.2.2 Machines used for testing shall conform to the requirements of Practices E 4 and, when applicable, Practice E 467. The loads used for the test shall be within the loading range of the test machine, as defined in Practices E 4.

A7.6.2.3 Monitor the linear (angular) displacement of the input platen with a calibrated displacement (angle) transducer that has an accuracy of ± 0.5 % of the selected full-scale range.

A7.6.2.4 In some situations, it may be appropriate to record displacements in a direction other than that of the loading input (or vice versa). Sensors used for recording such coupled motion components should be described, and their sample points and measurement directions noted. Monitor these secondary displacements with calibrated transducers that have an accuracy of ± 0.5 % of the selected transducer's full-scale range.

A7.6.3 *Data Acquisition Systems*:

A7.6.3.1 Automatically record the test parameters with either an analog or a digital recorder.

A7.6.3.2 A suitable analog recorder would be capable of continuously monitoring the output from the test machine's load (moment) transducer and the displacement transducer to produce a load (moment) versus displacement curve.

A7.6.3.3 Alternatively, a multichannel analog-to-digital recording device with storage capabilities may be used to record the test's progress. The analog-to-digital hardware should meet the requirements of Guide E 1942 and be capable of collecting the necessary data at rates up to 1 kHz. Under any circumstance, the recorder must be able to reconstruct subsequently the load versus deformation curve to determine stiffness and strength parameters.

A7.7 Sampling

A7.7.1 The sample size used for static tests shall be determined according to the methods defined in Practice E 122 for any given loading condition. If insufficient information is available to determine a suitable sample size in accordance with Practice E 122, then test a minimum sample size of five for any given loading condition.

A7.7.2 For multicycle dynamic studies, test at least three constructs at any given load or moment level. If the study's goal is to generate a fatigue curve, then evaluate the fatigue properties for at least three different maximum load (or moment) levels for a specific loading condition. One of the three maximum load (or moment) levels selected for such studies should result in all three constructs reaching the fatigue runout cycle limit. Guidance and recommendations for selecting suitable sample sizes for fatigue studies used to develop a *P-N (M-N)* diagram can be found in the literature **(1, 2)**.[8]

A7.8 Test Specimen

A7.8.1 All tested fixators should be assembled from elements representative of clinical quality products.

A7.8.2 Select anchoring elements that have a sufficient threaded length so that they will at least pass through the test block.

A7.8.3 If one or more of the elements in the fixator to be tested has been used previously, the nature of such prior usage should be described appropriately.

A7.8.4 Record either the geometric and material information necessary to characterize fully any prototype elements that are contained in the tested fixator or provide references to similarly detailed descriptive information.

A7.8.5 Prepare all fixator system components for testing with the same methods that they would normally be prepared clinically. For example, if a component would normally be sterilized in a particular manner before use, it should be sterilized similarly before mechanical testing. This is true especially for polymeric components and polymeric and metallic mechanisms used for connections or clamping.

A7.8.6 The bone analog can be either a solid right circular cylinder or a thick-walled hollow cylinder of a size representative of the anatomic bone on which the fixator to be tested normally would be mounted (see Table A7.1).

[8] The boldface numbers in parentheses refers to the list of references at the end of this standard.

TABLE A7.1 Basic Fixator-Bone Construct Parameters

Test Construct Configuration Parameter	Fixator Size Classification		
	Large (that is, femur, tibia, and so forth)	Small (that is, forearm, wrist, and so forth)	Mini (that is, finger, and so forth)
Pin span, *PS* (mm)	90	45	18
Frame offset, F_o (mm)	50	25	10
Gap size, *G* (mm)	20	10	5
Bone analog diameter, *D* (mm)	30	15	6
Pin offset, P_o (mm)	20	10	5
Tightening torque (N·m)	10.0	5.0	2.5

A7.8.7 The material to be used for the bone analog will be such that elastic deformations within the two individual pieces of the bone analog can be considered negligible compared to elastic deformations in the fixator. Normally, this condition can be achieved if the stiffness of the bone analog in three-point bending (N/mm) is more than 100 times the axial compressive stiffness (N/mm) of the overall fixator-bone construct.

A7.8.8 Ensure that the bone analog material chosen is sufficiently tough so that the anchorage elements (usually pins) will remain tightly embedded throughout the test.

A7.8.9 Reuse of bone analogs should be avoided, unless it can be demonstrated that the test/retest variability generated is no greater than the variability of similarly conducted tests with fresh unused bone analogs.

A7.9 Construct Assembly

A7.9.1 The EFD construct being evaluated is attached to two bone analog test blocks. Prepare the typical "minimal" test construct (see Fig. A7.2) for testing in the following manner. The illustrated EFD configuration is considered the typical "minimal" test construct since it is a four-pin (two per bone analog) and clamp single-bar unilateral construct.

A7.9.2 Be sure to measure and record assembly forces or torque values that are used to engage the clamps of the connecting elements. Record the use of any noncalibrated specialized assembly tools supplied by the manufacturer, for example, a ratchet wrench.

A7.9.3 Install the anchoring elements into the test block using the insertion techniques, templates, and so forth, recommended by the manufacturer. If other procedures are used, this should be reported. Ensure that the anchoring elements are aligned, as they would be oriented for the clinical situation. Unless otherwise specified in the manufacturer's surgical technique, affix the anchoring elements along the centerline of the test block. Position the anchoring elements so that the anchor element offset is either in compliance with the manufacturer's surgical technique or is no less than four anchoring element diameters away from the ends of the test blocks.

A7.9.4 Loosely assemble multicomponent bridge, or connecting elements, or both, according to manufacturer's recommendations. Avoid tightening any interconnections any more than is necessary to ease the fixator-bone construct's assembly.

A7.9.5 Assemble the subassembly (frame) according to the manufacturer's recommendations leaving any interconnection loose that will affect the fixator-bone construct's alignment. Install the subassembly on the anchoring elements and position it so that the frame offset meets the requirement listed in Table A7.1. Tighten only those connecting element interconnections that are necessary to maintain the frame offset for the remainder of the fixator-bone construct's assembly process.

A7.9.6 Align the test blocks so that their longitudinal axes are coincident and positioned so that the gap size adheres to the requirements listed in Table A7.1.

A7.9.7 Tighten all EFD interconnections either to the manufacturer's recommendations or to the recommended tightening torque that is listed in Table A7.1.

A7.9.8 Check and record the fixator-bone construct's alignment before testing.

A7.10 Procedure

Construct Mounting

A7.10.1 Verify that the loading axis, input and restraint platen positions, orientations, and restrained and unrestrained degrees of freedom meet the requirements of the particular investigation. Record these parameters with respect to a right-hand coordinate system defined with respect to the undeformed position of the construct being tested.

A7.10.2 Input linear displacements (or forces) should be delivered either along the bone analog longitudinal axis (axial load) or perpendicular to the bone analog longitudinal axis (shear load). The line of action of the input displacement should be recorded, with respect to the fixator-based right-hand orthogonal coordinate system.

A7.10.3 Input angular displacements (or moments) should be delivered either by a torque actuator or by an applied force couple. These moments should be either about the symmetry axis of the bone analog or about an axis perpendicular to the input-loading axis. If the moment is delivered by a force couple system, the points and lines of application if the individual forces must be reported. Typical way to achieve this might be four-point bending or eccentric force (cantilever).

A7.10.4 Because of the inherent variability of available fixator systems, use the following hierarchy to determine the alignment and subsequent loading orientation designations for the tests.

A7.10.4.1 The fixator system is indicated for a specific anatomical indication with a fixed anatomical orientation. Align the test construct relative to the direction of the applied load for the given tests according to the fixator system's alignment relative to the anatomical axes for the indication being evaluated.

A7.10.4.2 One fixator system within the group being evaluated is indicated for a specific anatomical indication with a fixed anatomical orientation. Align all test constructs relative to the direction of the applied load for the given tests according to each fixator system manufacturer's recommended alignment relative to the anatomical axes for the indication being evaluated.

A7.10.4.3 All fixator systems being evaluated are universally indicated for multiple indications. The axes will be aligned according to the major axes of the major construct components as follows. The axial axis will be oriented with the longitudinal elements rods(s). The transverse axis will be oriented parallel to the longitudinal axis of the anchorage

elements. The lateral axis will be oriented normal to both the transverse and axial axes.

A7.10.5 Position the test construct in the test apparatus so that the fracture gap offset and anchor element offset parameters are equivalent for the series of tests being performed.

A7.10.6 Affix the construct to the input and restraint platens.

A7.10.7 The sites used as construct gripping/attachment locations should be on the bone analog and located at least three pin diameters away from the outermost sites of anchorage element attachments.

Construct Conditioning

A7.10.8 Subject constructs destined for single-cycle static tests to several quasistatic preconditioning load cycles to demonstrate that the reported load versus deformation curve is repeatable from cycle to cycle.

A7.10.9 Preconditioning should be continued until the apparent stiffness of the construct changes less that 5 % between subsequent cycles.

A7.10.10 Normally, about five preconditioning cycles are suitable for this purpose, with peak applied load within the elastic range, approximately 50 % of the expected physiological service load or 50 % of the expected construct failure load, whichever is lower.

A7.10.11 Record the resulting load versus deformation curves for the preconditioning cycles and the preconditioning cycle stiffness for each preconditioning cycle.

Static Strength or Stiffness Tests

A7.10.12 Single-cycle static tests may either be restricted to the elastic regime or taken to a failure point.

A7.10.13 Run single-cycle static stiffness or strength tests in displacement control (either linear or angular). Tests may be run in load control as long as the construct's response is of a linear nature.

A7.10.14 The minimum series of static tests for any given fixator-bone construct should include the following types of tests.

A7.10.15 *Axial Load Test*:

A7.10.15.1 Axially load the test construct through spherical load points as illustrated in Fig. A7.3. This test configuration results in a minimally constrained condition during the axial load test.

A7.10.15.2 For this test configuration, displacement is defined as the relative change in the straight-line distance between the loading points (see Fig. A7.3). Monitor this distance directly with the displacement transducer. The reaction force is measured by the force transducer and shall be the force vector that is aligned with the direction of the displacement vector.

A7.10.16 *Bend Tests*—This test method tests the fixator-bone construct in bending with loading occurring in the two principle anatomical (or local relative) planes for a given fracture indication. For typical long bone indications (femur; tibia, and so forth), this would be bending on both the *M-L* and *A-P* planes. For a universal fixator system, this would be bending about both the transverse and longitudinal axes.

A7.10.16.1 *Four-Point Bend Test*:

A7.10.16.1.1 The four-point bend test is used primarily used to evaluate fixator systems that are symmetrical about the fracture gap plane. A constant bending moment is generated in the test construct because of the forced displacement of the load points as illustrated in Fig. A7.4; therefore, this test normally would not be used to evaluate a fixator system that does not normally experience a uniform bending moment when clinically applied, that is, a system that bridges a joint space.

A7.10.16.1.2 For this test configuration, displacement is defined as the relative change in the vertical distance between the loading points and the support points (see Fig. A7.4). Monitor this distance directly with the displacement transducer. The reaction force is measured by the force transducer and shall be the force vector that is aligned with the direction of the displacement vector.

A7.10.16.2 *Cantilever Bend Test*:

A7.10.16.2.1 This test is used primarily for fixator systems that are not symmetrical about the fracture gap plane. Additionally, this test normally would not be used for the evaluation of a fixator system that would normally experience a uniform bending moment when clinically applied.

A7.10.16.2.2 A variable bending moment is generated in the test construct as a result of a load applied at a distance *L* (mm) from the rigidly anchored end of the test construct (see Fig. A7.5). The test construct should be orientated so that the anatomical proximal end is rigidly anchored and the anatomical distal end is unconstrained.

A7.10.16.2.3 For this test configuration, displacement is defined as the relative change in the vertical position of the load application point (see Fig. A7.5). Monitor this distance directly with the displacement transducer. The reaction force is measured by the force transducer and shall be the force vector that is aligned with the direction of the displacement vector.

A7.10.17 *Torsion Test*:

A7.10.17.1 A moment is applied to the test construct about the axis of the bone analog segments as illustrated in Fig. A7.1. The test construct is orientated so that the anatomical proximal end is rigidly anchored and the anatomical distal end is unconstrained.

A7.10.17.2 For this test configuration, displacement is defined as the relative change in the angular position of the test system's grips about the test machine's drive axis (see Fig. A7.1). Monitor this position directly with the displacement transducer. The reaction moment is measured by the torque transducer and shall be the moment vector that is oriented in the direction of the displacement vector.

A7.10.17.3 Load the construct in a quasistatic manner at a constant rate. Use a rate that is sufficient to attain in approximately 30 s either a load (or moment) magnitude that is in the range of typical physiologic usage or that is sufficient to cause failure. Alternatively, rates that are in the range of those expected clinically may be desirable for testing components made of polymeric materials that exhibit viscoelastic behavior and for components which rely upon friction for fixation. A rationale should be provided for whatever input rate is used and the rate(s) should be reported.

A7.10.17.4 Continuously record the reaction load (or

torque) in response to the applied linear (or angular) displacement of the input platen.

A7.10.17.5 Continue the test until the construct has met the specified failure criteria.

Multicycle Dynamic Tests

A7.10.18 These types of tests should be run in either load or torque control.

A7.10.19 Restricted multicycle dynamic tests to loading conditions that are within the EFD's elastic regime.

A7.10.20 The input loading frequency should be limited to a frequency that does not result in dynamic heating of any test construct component. Typically, a limit of five cycles per second (5 Hz) is sufficient to prevent heating and still generate test results in a timely manner. Alternatively, rates that are in the range of those expected clinically (1 Hz) may be necessary for testing components made of polymeric materials, which exhibit viscoelastic behavior, and for components, which rely upon friction for fixation. A rationale should be provided in the final report for the test frequency used for these types of devices.

A7.10.21 The standard multicycle dynamic test is a dynamic axial loading test (see Fig. A7.3). The test construct is exercised with a fully reversed tension and compression ($R = -1.0$) true sinusoidal loading waveform. Set the runout cycle limit for the standard test at 50 000 cycles.

A7.10.22 Record the loading cycle's maximum and minimum values, the input waveform shape, and the test frequency for inclusion in the final report.

A7.10.23 Continue the test until the construct has met the specified failure criteria or until the runout cycle limit has been reached.

A7.10.24 Record the final cycle count and failure mode (if applicable) of the dynamic test for inclusion in the final report.

A7.11 Calculation or Interpretation of Results

Static Strength or Stiffness Tests

A7.11.1 Using the load (or moment) versus deformation curve, determine the tangent stiffness and secant stiffness, as applicable, according to the definitions found in A7.3.

A7.11.2 On the load (or moment) versus deformation curve, determine the yield load (or moment) and ultimate load (or moment), as applicable, according to the definitions found in A7.3.

A7.11.3 Perform the following additional analyses for bend-type tests.

A7.11.4 *Cantilever Bend Test*:

A7.11.4.1 Calculate the bending (tangent or secant) stiffness in the following manner:

$$\text{Bending Stiffness} = \text{Stiffness} \cdot L \qquad \text{(A7.1)}$$

where:

L = lever arm length (as illustrated in Fig. A7.5).

A7.11.4.2 Calculate the yield bending moment in the following manner, when applicable:

$$\text{Yield Bending Moment} = \text{Yield Load} \cdot L \qquad \text{(A7.2)}$$

A7.11.4.3 Calculate the ultimate bending moment in the following manner, when applicable:

$$\text{Ultimate Bending Moment} = \text{Ultimate Load} \cdot L \qquad \text{(A7.3)}$$

A7.11.5 *Four-Point Bend Test*:

A7.11.5.1 Calculate the bending (tangent or secant) stiffness in the following manner:

$$\text{Bending Stiffness} = \frac{\text{Stiffness} \cdot h^2\,(2h + 3k)}{12} \qquad \text{(A7.4)}$$

where:

h = loading span distance (as illustrated in Fig. A7.4) and

k = support span distance (as illustrated in Fig. A7.4).

A7.11.5.2 Calculate the yield bending moment in the following manner, when applicable:

$$\text{Yield Bending Moment} = \frac{\text{Yield Load} \cdot h}{2} \qquad \text{(A7.5)}$$

A7.11.5.3 Calculate the ultimate bending moment in the following manner, when applicable:

$$\text{Ultimate Bending Moment} = \frac{\text{Ultimate Load} \cdot h}{2} \qquad \text{(A7.6)}$$

A7.11.6 Calculate the mean and standard deviation of the tangent stiffness, secant stiffness, yield load (or moment), and ultimate load (or moment) for each group of fixator-bone constructs tested.

Multicycle Dynamic Tests

A7.11.7 Plot the maximum load (or moment) versus cycles to test termination data on a semi-log graph. Various techniques may be used to estimate the mean or median fatigue lives, statistical differences between groups, curve fits of the fatigue data, probability of survival curves, and so forth. **(3-7)**.

A7.11.8 If determining median fatigue load (or moment) at a specific cycle count, it is recommended that the fatigue load (or moment) be determined as the median fatigue load (or moment) (50 % probability of survival), using a technique or criteria described in the literature **(1-3, 6, 7)**.

A7.12 Report

A7.12.1 The test report shall include the following, at a minimum:

A7.12.2 Identification of the individual elements comprising the fixator, which should include the manufacturer, part number, nomenclature, and where possible, the quality control or lot number. If the part is a prototype, provide geometrical and material descriptions.

A7.12.3 A description of the fixator-bone construct's configuration.

A7.12.3.1 The geometry and material composition of the bone analog used.

A7.12.3.2 Include a drawing, or photograph, or both, of the construct, using multiple orthogonal views (anterior-posterior, medial-lateral, and superior-inferior views) as necessary to define unambiguously the relative positions and orientations of the individual elements comprising the fixator.

A7.12.3.3 The physical dimensions, or element orientations, or both, within the fixator that can be varied by the end-user must be unambiguously specified. Typically, this would include the following information: fracture gap offset, frame offset, gap size, inner pin span, outer pin span, pin cluster span, pin offset, pin span. Additional optional information would

include the position of clamps along the rod elements or pins, the angle between rods connected by an adjustable clamp and unsupported pin length.

A7.12.3.4 For fixator elements whose physical dimensions, or orientations, or both, cannot be varied by the end user, it is recognized that detailed dimensional, or material information, or both, may not be practical or appropriate to report when testing overall construct behavior. At a minimum, however, reference to public domain documentation reporting that specific information must be included.

A7.12.3.5 Description of any prior usage for any fixator element that was tested.

A7.12.3.6 Alternative procedures that were used while installing the anchoring elements in the test blocks.

A7.12.3.7 The assembly force or torque used to engage any connector gripping mechanism(s). If assembly is performed using noncalibrated specialty instruments often provided by manufacturers, for example, ratchet drives, this should be reported, and reference made to documentation reporting the actual force or torque delivered by such specialty instruments, if available.

A7.12.3.8 The construct's alignment before testing.

A7.12.4 Number of constructs tested for each test configuration and the rationale for the sample size selected.

A7.12.5 A description of the test machine (manufacturer, model).

A7.12.5.1 Include the description of any secondary transducers that were used to record construct response data that is presented in the final report.

A7.12.6 A description of the testing configuration(s).

A7.12.6.1 Report the loading axis, input and restraint platen positions, and restrained and unrestrained degrees of freedom for each test configuration.

A7.12.6.2 Report the construct's orientation relative to the test machine's loading axis for each test configuration.

A7.12.6.3 A drawing, or photograph, or both, of the construct within the test machine setup should be provided.

A7.12.6.4 Rationale for the use of alternative or modifications to the defined test configurations.

A7.12.7 Description of the test environment if other than the recommended room temperature laboratory air environment.

Static Tests

A7.12.8 Pictures of the failure surfaces of any components that failed during the study.

A7.12.9 The loading rate used during static tests with a corresponding rationale.

A7.12.10 The load versus deformation curves for the preconditioning cycles and the preconditioning cycle stiffness for each preconditioning cycle.

A7.12.11 The load versus deformation curves for each test performed.

A7.12.12 Alternative methods that were used to determine the stiffness or yield point. Also, include any methods that were used to compensate for toe regions found in the construct's response curve.

A7.12.13 The tabulated construct stiffness (tangent, or scan, or both) in the specified directions tested including the mean and standard deviation for each data set.

A7.12.14 The tabulated yield load (or moment) data in the specified directions tested including the mean and standard deviation for each data set.

A7.12.15 *Failure-Type Tests*:

A7.12.15.1 The specific threshold of irrecoverable deformation constituting failure and the rationale for the specific value selected.

A7.12.15.2 The failure definition used and the rationale for the method selected.

A7.12.15.3 The tabulated ultimate load (or moment) data in the specified directions tested including the mean and standard deviation for each data set.

A7.12.15.4 Any failure modes observed during the tests, for example, slip at a particular clamped interface or yield of a specific bridge element. If the specific mode of failure cannot be ascertained by gross observation, the technique(s) used to identify the mode or site of failure should be reported.

Multicycle Dynamic Tests

A7.12.16 Test frequency, waveform shape, and runout cycle limit for multicycle dynamic tests. Include a rationale for the test frequency used while testing constructs that contain polymeric fixator components that exhibit viscoelastic behavior or components that rely upon friction for fixation.

A7.12.17 Tabular listing that summarizes the maximum and minimum load and the number of cycles until test termination for the specified directions tested.

A7.12.18 Description of the failure mode and failure location for each construct that failed.

A7.12.19 The semi-log diagram of the maximum load (or moment) versus number of cycles to test termination. Uniquely identify constructs that have not failed before reaching the runout cycle limit.

A7.12.20 Regression analysis results for the maximum load (or moment) versus number of cycles to failure data, when applicable.

A7.12.21 When applicable, include the results of any fatigue data analyses conducted on the final study results. Include descriptions of any analytical or statistical techniques used when interpreting the fatigue data.

A7.13 Precision and Bias

A7.13.1 *Precision*—Data establishing the precision of the test method have not yet been obtained.

A7.13.2 *Bias*—No statement of bias can be made, since no acceptable reference values are available, nor can they be obtained since this test is a destructive test.

14. Keywords

14.1 bend testing—orthopedic medical devices; fatigue testing—orthopedic medical devices; orthopedic medical devices—external fixation devices; test methods—surgical devices

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 This specification is intended to provide useful and consistent information related to the terminology, performance, test methods, and application of external skeletal fixation devices. A rationale for the importance of particular performance characteristics and a reference to applicable test methods is given in Section 6. Some of the applicable test methods are given in the annexes. Currently, test methods for connectors, in-plane compression of ring elements, joints, anchorage pins, and subassemblies are provided in Annex A2, Annex A3, Annex A4, Annex A5, and Annex A6, respectively.

X1.2 The orthopedic surgeon should be able to choose the size, design, orientation, and configuration of an ESFD, and the manner of preparation of the bone, appropriate to the usage of a fixator for each individual patient. To do so, the surgeon must have confidence that the geometry of the individual components of the fixator and its subassemblies has a specific, known meaning, which is quantifiable and reliable regardless of the manufacturer or design. The mechanical behavior and material properties also must be described in a reliable, known manner, which is irrespective of the manufacturer or design. To accomplish this uniformity of designations, the terminology, dimensions, mechanical properties, material properties, and test methods for obtaining and reporting these parameters must be standardized.

X1.3 Because of the wide variety of ESFDs currently available, and the many assemblages that are possible as a result of the modularity of these devices, a wide variety of testing protocols is needed. This specification provides an overall framework within which several test methods for individual elements, subassemblies of elements, or entire ESFD assemblies are registered in the form of annexes. As additional test methods are developed, it is contemplated that they will be incorporated as new annexes.

X2. RATIONALE FOR ANNEX A7

X2.1 The modularity of most external fixation devices affords a great deal of variability of how fixators can be constructed; therefore, it is necessary to develop a standard test method that will evaluate any possible fixator configuration in a consistent and repeatable manner so that a surgeon will have useful information available for comparing various fixation devices.

X2.2 In many instances, it is desirable to compare the effective stiffness or strength of alternative fixator configurations (deviations from the manufacturer's recommended configuration) that can be assembled from a specific set of elements; therefore, this test method was developed with flexibility built into it.

X2.3 Normally, elastic flexure of anchorage elements is the greatest source of compliance in the overall fixator construct. Clinically, however, large apparent fixator compliance can also result from loose anchorage elements. This test procedure is not designed to document anchorage element loosening or to identify factors responsible for loosening; therefore, the choice of bone analog material and the method used to insert anchorage elements should ensure sound purchase of the anchorage elements throughout construct testing.

X2.4 Because of the variety of fixator size ranges and anatomic sites, it is inappropriate to standardize completely the geometry or kinetics of construct loading tests. This test method, therefore, emphasizes the unambiguous documentation of the construct being tested. This is accomplished by clearly identifying the site at which loading is applied and deformation is measured and a formal definition of the construct's stiffness, or strength, or both for each combination of load/deformation measured.

X2.5 A dynamic axial loading test method is defined in this test method instead of a typical fatigue test. The anticipated outcome for a typical fatigue test is the generation of a fatigue crack, which leads to the eventual failure of a component within the fixator system. Unfortunately, this type of failure is not a typical clinical failure of fixator systems. The typical cyclic loading clinical failure mode of fixator systems is a degradation of the interconnection strength at the bone/anchoring element interface. Since this type of failure cannot be consistently reproduced in the laboratory, this specification does not attempt to evaluate this failure mode. The only purpose then to perform cyclic loading tests would be to determine if any of the interconnections loosened over time; therefore, the standard dynamic test method stipulates a maximum runout cycle limit of only 50 000 cycles. In the event that a typical fatigue test is required, the testing conditions should be defined corresponding to the particular questions that need to be answered.

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