Designation: F1541 – 02 (Reapproved 2015)

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

This standard is issued under the fixed designation F1541; 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 standard. No other units of measurement are included in this 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:*[2]

A938 Test Method for Torsion Testing of Wire

D790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials

E4 Practices for Force Verification of Testing Machines

F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

F90 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)

F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

F366 Specification for Fixation Pins and Wires

F543 Specification and Test Methods for Metallic Medical Bone Screws

F544 Reference Chart for Pictorial Cortical Bone Screw

[1] This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.21 on Osteosynthesis.

Current edition approved Sept. 1, 2015. Published October 2015. Originally published as F1541 – 94. Last previous edition approved in 2011 as F1541 – 02 (2011)ε1. DOI: 10.1520/F1541-02R15.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

Classification (Withdrawn 1998)[3]
F1058 Specification for Wrought 40Cobalt-20Chromium-16Iron-15Nickel-7Molybdenum Alloy Wire and Strip for Surgical Implant Applications (UNS R30003 and UNS R30008)
F1264 Specification and Test Methods for Intramedullary Fixation Devices
F1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)
F1713 Specification for Wrought Titanium-13Niobium-13Zirconium Alloy for Surgical Implant Applications (UNS R58130)

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 that 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 by 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 the 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

[3] The last approved version of this historical standard is referenced on www.astm.org.

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:*[2]

F366 Specification for Fixation Pins and Wires

F543 Specification and Test Methods for Metallic Medical Bone Screws

F544 Reference Chart for Pictorial Cortical Bone Screw Classification (Withdrawn 1998)[3]

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).

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 shall 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,