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Standard Terminology Relating to Spinal Implants[1]

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1. Scope

1.1 This terminology covers basic terms and considerations for spinal implant devices and their mechanical analyses.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E6 Terminology Relating to Methods of Mechanical Testing

E1150 Definitions of Terms Relating to Fatigue (Withdrawn 1996)[3]

3. Terminology

Definitions Related to Spinal Implant Devices

anchor, *n*—components that are directly attached to the bony elements of the spine (sacrum, lamina, pedicle, vertebral body, spinous process, transverse process, the pelvis, or ribs).

assembly, *n*—a complete implant configuration (not including spine, pelvis, ribs, or substitute material) as intended for surgical use.

band, *n*—a flexible anchor component with a noncircular cross section that connects the bony elements of the spine, pelvis, or ribs to each other or to other implant components using a knot or similar tying mechanism, forming a locked, closed loop.

bolt, *n*—an anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of threads with the lead threads accommodating a nut, thus sandwiching the bony element or implant component between the nut or washer and bolt head or other fixed stop.

bolt interconnection, *n*—an interconnection having an implant component sandwiched between two nuts or between a nut and fixed stop.

cable, *n*—a multi-strand, flexible longitudinal element designed primarily to resist axial tension loading.

clamp, *n*—an interconnection component whose mechanism to secure the longitudinal element is through a squeezing action.

DISCUSSION—For example, crimps, wedges, set screws.

component, *n*—any single element used in an assembly.

construct, *n*—a complete implant configuration attached to and including the spine, pelvis, ribs or substitute material as intended for surgical use.

expansion anchor, *n*—a component that forms a connection to bony element by means of a mechanism which enlarges once the component is inserted into the bony elements.

hook, *n*—an anchoring component that fastens to the spine by means of a curved blade passed under or over lamina, transverse or spinous processes or into an anatomic or surgically created notch or opening.

hook blade, *n*—that portion of a spinal hook that is placed under, over, or into a bony structure to provide attachment.

hook body—that portion of a spinal hook that connects the hook blade to the longitudinal element.

hybrid longitudinal element, *n*—a longitudinal element consisting of two or more types of longitudinal elements of different size or cross-section manufactured into a single element.

interbody spacer, *n*—a structure (biologic or synthetic) to replace (partially or totally) the vertebral body or intervertebral disk(s), or both.

interconnection, *n*—the mechanical interface or connection mechanism between at least two components or between components and bony elements of the spine, pelvis, or ribs.

interface, *n*—one of the two mating surfaces, lines or points of contact within an interconnection between two components, between any component and bone, or between two bony elements.

[1] This terminology is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.25 on Spinal Devices.

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

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

intervertebral body fusion cage, *n*—a hollow device which contains graft material.

intervertebral body fusion devices, *n*—a structure which is placed in the disc space between two adjacent vertebral bodies to provide support for eventual arthrodeses of the two adjacent vertebral bodies.

longitudinal element, *n*—a component whose long axis is parallel, or nearly so, to the long axis of the spine.

motion segment, *n*—two adjacent vertebrae, the intervening disc, and the associated ligamentous structures.

partial replacement disc—a structure intended to restore a portion of the support and motion or a portion thereof, between adjacent vertebral bodies.

plate, *n*—a longitudinal element asymmetrical in the transverse plane and designed to resist tension, compression, bending, and torsion.

post, *n*—a non-threaded anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of a non-threaded hole in the bony element.

replacement disc, *n*—a structure intended to restore support and motion between adjacent vertebral bodies.

rod, *n*—a longitudinal element symmetrical in the transverse plane designed to resist tension, compression, bending, and torsion.

screw, *n*—an anchor component that connects to the bony elements of the spine, pelvis, or ribs by means of threads.

screw interconnection, *n*—an interconnection having an implant component sandwiched between the screw head (or screw thread) and bony element or other implant components.

sleeve interconnection, *n*—an interconnection in which an implant component passes through any opening that limits motion in one or more planes.

staple, *n*—an anchor component that connects the bony elements of the spine, pelvis, or ribs to each other or to other implant components by using at least two interconnected posts.

subassembly, *n*—any portion of an implant assembly that is composed of two or more components.

subconstruct, *n*—any portion of an implant construct that is composed of two or more components including the spine, pelvis, ribs, or substitute structure.

transverse element, *n*—a component or subassembly that links longitudinal members together.

vertebral body replacement device, *n*—a structure which is designed to restore anatomic position and support to a section of spine lacking one or more vertebral bodies and intervening disc(s).

vertebral span, *n*—the number of vertebra that are spanned by the longitudinal element, including the vertebrae containing anchor components.

wire, *n*—a single strand flexible anchor component with a circular cross section that connects the bony elements of the spine, pelvis, or ribs to each other or to other implant components. A series of wire components can be bound together to form a cable (see **cable**).

Definitions Related to Spinal Implant Testing Defined in Other Documents, or Established Terminology

DISCUSSION—In certain instances, a value for moment or load can be substituted for *stress* when describing fatigue life. This is true in cases in which the actual stress values are unknown or not easily obtainable. The moment or load can be substituted when comparing devices assigned to perform the same mechanical function. The value for load or moment thus determined is subject to the same conditions as those that apply to *stress* in this terminology standard. However, whenever possible, *stress* should be the standard employed.

fatigue, *n*—the process of progressive localized permanent structural change occurring in a material subjected to conditions that produce fluctuating stresses and strains at some point or points and that may culminate in cracks or complete fracture after a sufficient number of fluctuations.

DISCUSSION—See Definitions E1150.

fatigue life, *n*—the number of loading cycles, *N*, of a specified character that a given specimen sustains before failure of a specified nature occurs.

DISCUSSION—See Definitions E1150

fatigue strength at N Cycles, S_n [FL^{-2}], *n*—a value of stress for failure at exactly *N* cycles as determined from an *S-N* diagram. The value S_n thus determined is subject to the same conditions as those that apply to the *S-N* diagram.

DISCUSSION—The value of S_n which is commonly found in the literature is the value of S_{max} (*maximum stress*) or S_a (*stress amplitude*) at which 50 % of the specimens of a given sample could survive *N* stress cycles in which S_m (*mean stress*) = 0. This is also known as the median fatigue strength for *N* cycles (see Definitions E1150).

fatigue test, *n*—a test designed to evaluate the cyclic load properties of a material, component, interconnection, subconstruct, construct, subassembly, or assembly.

load ratio, R, A, *n*—in fatigue loading, the algebraic ratio of the two loading parameters of a cycle.

DISCUSSION—The most widely used ratios are:

$$R = \frac{\text{Minimum Load}}{\text{Maximum Load}} = \frac{P_{\min}}{P_{\max}} \quad (1)$$

or

$$\frac{S_{\min}}{S_{\max}} \quad (2)$$

or

$$R = \frac{\text{Valley Load}}{\text{Peak Load}} \quad (3)$$

and

$$A = \frac{\text{Loading Amplitude}}{\text{Mean Load}} = \frac{Pa}{Pm} \quad (4)$$

or

$$\frac{Sa}{Sm} \quad (5)$$

or

$$A = \frac{(\text{Maximum Load} - \text{Minimum Load})}{(\text{Maxium Load} + \text{Minimum Load})} = \frac{(P_{max} - P_{min})}{(P_{max} + P_{min})} \quad (6)$$

S-N diagram, *n*—a plot of stress against the number of cycles to failure. The stress can be maximum stress S_{max}, minimum stress S_{min}, stress range S or S_r, or alternating stress S_a. The diagram indicates the *S-N* relationship for a specified value of S_m (*mean stress*) *A*, or *R*(*load or stress ratio*), and a specified probability of survival. For *N*, a log scale is almost always used. For *S*, a linear scale is used most often, but a log scale is sometimes used.

DISCUSSION—See Definitions E1150.

static test, *n*—single cycle loading tests designed to evaluate the mechanical properties of materials, components, interconnections, subconstructs, constructs, subassemblies, or assemblies.

DISCUSSION—The mechanical properties can include stiffness, flexibility, failure loads and stresses, and yield and ultimate strengths defined in the associated test standard, that is, the properties associated with elastic and inelastic reactions when force is applied or those that involve a relationship between stress and strain.

stress, S, *n*—the intensity at a point in a body of the forces or components of force that act on a given plane through the point.

DISCUSSION—Stress is expressed in units of force per unit area (pounds-force per square inch, megapascals, and so forth). (See Terminology E6.)

4. Coordinate System Related to the Application of Spinal Implant Devices

4.1 The coordinate system used in the testing of spinal implant devices is a system of three orthogonal axes that are defined in terms of the standard anatomic planes that they are perpendicular to, for example, transverse (horizontal or axial), coronal (frontal), and sagittal (median). Translations are also defined in terms of standard clinical directions, for example, ventral (anterior), dorsal (posterior), cranial (cephalad or superior), caudal (inferior), lateral, or medial. All rotations follow the right hand rule and are defined using current clinical terminology, for example, right or left side bending, flexion, extension, or twist. In addition, translations and rotations should be broken down into their accordant anatomic components.

4.2 It is recommended that the origin of the axes be located in a rigid structure such as bone. In addition, the orientation of the coordinate system, the designation of the three axes and location of the origin should be reported.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 Where available, the standard terms used in Definitions E1150 or Terminology E6 were used.

X1.2 The coordinate system proposed is based on standard engineering practices for defining an orthogonal coordinate system. For clinical relevancy, anatomic or clinical terms are recommended. The selection of this coordinate system was made to avoid the differences in the myriad coordinate systems used in the current published literature and by various institutions, for example, International Organization for Standardization (ISO), Department of Transportation, Armed Services, and so on.