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Testing criteria for spinal implants: recommendations for the standardization of in vitro stability testing of spinal implants

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Abstract New implants and new surgical approaches should be tested in vitro for primary stability in standardized laboratory tests in order to decide the most appropriate approach before being accepted for clinical use. Due to the complex and still unknown loading of the spine in vivo a variety of different test loading conditions have been used, making comparison of the results from different groups almost impossible. This recommendation was developed in a series of workshops with research scientists, orthopedic and trauma surgeons, and research and development executives from spinal implant companies. The purpose was to agree on in vitro testing conditions that would allow results from various research groups to be compared. This paper describes the recommended loading methods, specimen conditions, and analysis parameters resulting from these workshops.

Key words Spine · Biomechanics · Implant testing · In vitro testing · Test standard

Introduction

Spinal implants fall under the Medical Devices Directive regulatory laws (93/42/EEEC). For this reason the German Society for Spinal Surgery (Gesellschaft für Wirbelsäulenchirurgie) resolved to create a European Standard for the testing of spinal implants. Toward this end, a series of workshops was held in Ulm, Germany, beginning in June, 1996, to discuss with research scientists, orthopedic and trauma surgeons, and research and development executives from spinal implant companies the basis for such a standardization.

Due to increasing experience and widening capacity in spinal surgery, today more and more implants are being developed for surgical treatment of spinal injury, disc prolapse, pathological curvature like scoliosis, and tumors. The success of operative procedures involving these spinal implants can be defined by their ability to achieve primary biomechanical stability of the affected levels.

New implants and new surgical approaches therefore should be tested for primary stability in standardized laboratory tests before being accepted into clinical use, in order to decide the most appropriate approach. Unfortunately, the in vivo loads on the spine, and especially the distribution of load within individual structures, are still unknown.

Nonetheless it is possible to perform a comparison of new implants against those for which reasonable clinical experience is already available. This may allow an estimate of the expected clinical success.

The most reliable comparison of the stabilization capacity of various spinal implant systems is provided by testing under controlled loading conditions, which can be achieved in vitro. In such tests it is possible to measure directly reaction loads and motions within the spine with virtually unrestricted technology. Thus individual structures like the disc, ligaments, and vertebral bodies can be studied in isolation or in connection with other structures. It is important for these in vitro tests, which involve highly specialized loading and measurement apparatus, that standard, calibrated loading conditions be provided.

Because of the potential complexity of simulating in vivo loads with in vitro testing, there are still no convincing test criteria to evaluate the stability of spinal implant systems. Thus, the foregoing suggestions for an in vitro test standard shall be understood to be a recommendation. This is based on simplified, uniform loading conditions, which would better allow the results of various groups working in this field to be compared. This recommendation is based on generally accepted methods described by Goel and Panjabi [3–5].

Purpose and scope

Before being put into clinical practice new implants and surgical approaches should be tested through calibrated in vitro methods for primary stabilization in the main anatomical directions, includ-

ing flexion/extension, lateral bending, and axial rotation. Eventually, as these standards develop, devices and techniques shall also be evaluated under shear loading, compression, muscle forces, and other representative in vivo loads. To decide the best approach in a given clinical situation, in vitro evaluation involving intact, injured, or degenerated specimens with the device implanted provide the most realistic option.

It is assumed that the instrumentation shall be implanted in accordance with the manufacturers instructions. Artifactual differences in implant performance may result when the specimens used in testing vary widely in bone density, ligamentous integrity, or disc viability.

It should be noted that this recommendation does not concern dynamic testing of spine implants under cyclic loading conditions. This recommendation also does not concern strength evaluations of spinal implants.

Reference to other standards and norms

The Society for Spine Surgery: Subcommittee for Test Criteria of Spinal Implants is also supporting the National Institute of Standardization (DIN) in reviewing the following proposals for test standards:

ISO proposal "Mechanical testing of spinal implantable devices":
Part 1 Spinal implant testing: Terminology, rationale, and indexing to parts 2–5
Part 2 Static and fatigue test methods for spinal implant assemblies using corpectomy models
Part 3 Static and fatigue test methods for interconnection mechanisms and subassemblies of spinal implants
Part 5 Static and fatigue test method for interbody fusions devices

ISO proposal "Static and Fatigue Test Methods for Spinal Artificial Disc".

They are based on the ASTM standards also currently in development. The only currently approved standard for this type of testing is ASTM F 1582-95 Standard terminology relating to spinal implants.

A further accepted standard concerning the coordinate system suggested in this proposal is: ISO/DIS 2631, Mechanical vibration and impacts : evaluation of the effect of whole body vibration in the human; general requirements [Part 1 (08/95)].

Concepts, terminology and definitions

Functional spinal unit or motion segment: Two adjacent vertebrae with the intervening disc and ligaments intact. It is the smallest unit representing the general mechanical behavior in a given region of the spine.

Intact specimen: A fresh spine test length with complete and intact ligaments and disc with at least one functional spinal unit.

Injured or defect specimens: Spine segments with an existing or created disturbance of the ligaments, bony tissue, or discs.

Construct: The spine test length comprised of the specimen instrumented with the implant of interest.

Spinal loading simulator: A special test apparatus in which spinal specimens can be mounted and tested under defined loading conditions.

Coordinate system: Three-dimensional, orthogonal, right-handed coordinate system with the following axis designations: *X* forward or ventral, *Y* to the left, and *Z* above or cranial (Fig. 1).

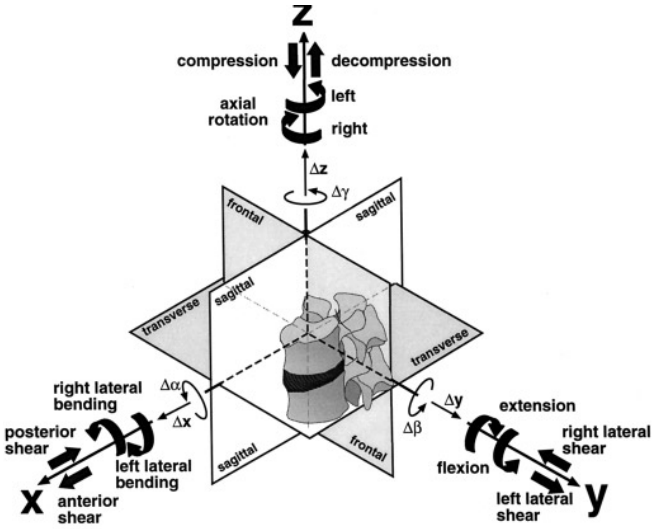

Fig. 1 Definition of the three-dimensional coordinate system (according to ISO 2631). All possible load and motion components are illustrated. The arrows of the motion components $\Delta\alpha$, $\Delta\beta$, $\Delta\gamma$, Δx, Δy, Δz represent the positive direction

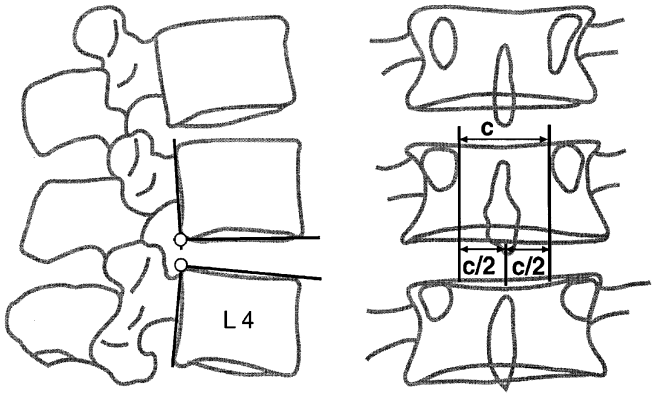

Fig. 2 Definition of suggested local coordinate systems on lateral (*left*) and anterior/posterior (*right*) radiographs

The transverse plane of the spine corresponds to the x-y plane of the coordinate system, the sagittal plane to the *x–z* plane, and the frontal plane to the *y–z* plane.

This definition is consistent with that of ISO 2631 (VDI 2057) and has been adopted by the Scoliosis Research Society [8].

Global coordinate system: The origin of the global coordinate system shall lie in the middle of the underside of the lower mounted end of the specimens. The specimen shall be aligned such that the *x–y–z* axes match those of the whole, upright body. For example, a lumbar segment shall be aligned such that the L3–4 disc lies horizontally.

Local coordinate system: The origin of the local coordinate system for each vertebra shall lie in a biomechanically relevant point within the vertebra. In most cases the suitable origins within the segment of interest would be the mid-point in the frontal plane of the posterior margins of the two adjacent vertebral body endplates (Fig. 2).

In some cases a more general local coordinate system may be more appropriate. Historically, for instance, the middle of the ver-

tebral body has been used. The origin of the local coordinate system must be accurately determined and its error reported.

Primary loading directions: Regardless of the type of loading applied to the spine, the reaction loads can be described in terms of the three forces and three moments acting at a descriptive point, such as the base of the specimen (Fig. 2). With the appropriate definition of the coordinate system the loading components shall correspond to the following: lateral bending to the right/left is a pure moment in the +/– M*x* direction; flexion/extension is a pure moment in the +/– M*y* direction; and axial rotation to the left/right is a pure moment in the +/– Mz direction; anterior/posterior shear is a force in the +/– F*x* direction; left/right lateral shear is a force in the +/– F*y* direction; and distraction/compression is a force in the +/– Fz direction.

Relative motion: The three-dimensional motion of one vertebral body relative to another determined by transformation of one of the local coordinate systems onto another.

Primary motions and coupled motions: The motion in the same direction as that in which the load is applied is the primary motion, and the motions in the other planes are the coupled motions.

Preconditioning: Loading precycles applied to the specimen or construct to minimize viscoelastic behavior and achieve a measure of reproducibility in its biomechanical behavior.

Neutral zone (NZ): The neutral zone is a measurement of the laxity of the spinal specimen. It describes the range over which the specimen moves essentially free of applied loading, for instance under its own weight (Fig. 3). NZ is defined as the difference in angulation at zero load between the two phases of motion.

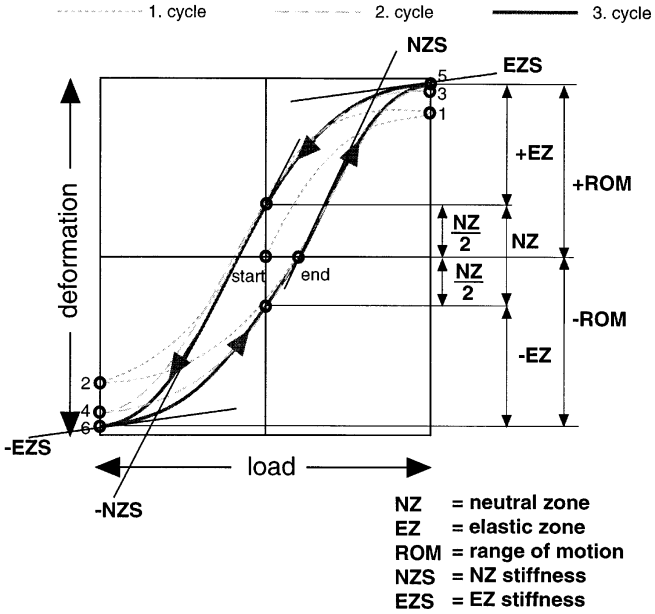

Fig. 3 Typical load–displacement curve (cycle 1–3) with continuously changing load with definitions of the parameters (ROM, EZ, NZ, NZS, EZS). Positive load indicates right lateral bending (+M*x*), flexion (+M*y*), or left axial rotation (+Mz) and negative load indicates left lateral bending (–M*x*), or extension (–M*y*), or right axial rotation (–Mz)

Elastic zone (EZ): The deformation measured from the end of the neutral zone to the point of maximal loading is defined as the elastic zone.

Neutral position: The hysteresis curve will produce two points at zero load, one for each phase of motion (forward and backward or left and right). The neutral position is defined as the calculated mid-point between these two points of deformation at zero load.

Range of motion (ROM): The range of motion describes the sum of the neutral zone and the elastic zone in one direction of motion (e.g., flexion, or axial rotation to the right).

Neutral zone stiffness (NZS): The stiffness characterizing the relatively lax deformation of the specimen or construct. Stiffness is a measurement of the mechanical resistance of a specimen. It is defined as the quotient of the loading to the deformation. Because the load deformation characteristics of the specimens are nonlinear it is important to provide the points at which the stiffness is calculated (e.g., NZS and EZS in Fig. 3).

Elastic zone stiffness (EZS): The stiffness characterizing the elastic deformation of the specimen or construct.

Sigmoidity (NZS/EZS): A measure of the non-linearity of the mechanical characteristics of the specimen or construct.

Engery dissipation: The area enclosed by the load–deformation curve. It describes the viscoelastic and/or plastic behavior of the specimen or construct.

Instability: A specimen, when injured or degenerated, is considered unstable when the neutral zone or the range of motion deviates significantly from the normal intact condition. This may result from a change in stiffness characteristics or from degeneration across a motion segment.

Apparatus

Spinal loading simulator

A spinal loading simulator should fulfill the following requirements:

1. The specimen shall be able to move freely in all six degrees of freedom.
2. The simulator shall be capable of simulating the six loading components separately. This includes flexion/extension moments, lateral bending moments right and left, torsion left and right, and axial compression, tension, and shear in the sagittal and frontal planes.
3. All possible loading combinations shall be provided.
4. Loading shall be applied either continuously or in stepwise fashion.
5. The specimen shall be loaded in the positive and negative directions continuously (forward–backward or left–right) in order to obtain load–displacement curves that reflect the full cycle of motion in a given direction.

Motion measurement system

The motion measurement system shall be able to determine the 6 motion components for the three-dimensional relative motion between the two vertebrae of interest. This includes the three translations *x*, *y*, *z* and the three rotations α, β, γ. The relative motion between the given transducers eventually must be transformed to the local coordinate system and referenced to the anatomical point of

interest. The measurement error of the motion measurement system both in translation and in rotation shall be reported.

Other transducers

Transducers used to investigate other parameters (e.g., intradiscal pressure or strain of the ligaments) should not by their application change the biomechanical properties of the specimen (e.g., an increase in local stiffness).

Specimens

The results of biomechanical testing are most reliable when the tests are performed directly on living subjects or on freshly prepared human cadaveric specimens. However, the availability of cadaveric specimens for in vitro tests is for various reasons very limited. In some applications, specimens from other species may be considered.

Human cadaveric specimens

Naturally, the most readily available specimens are those from elderly individuals, often with one or more levels in various states of degeneration. This contrasts with the intended environment for spinal instrumentation, which normally is implanted into younger, biologically healthier spines. Tests with degenerated and osteoporotic specimens allow only limited conclusions to be drawn and thus shall be discussed. Specimens with notable injury or tumors should be excluded from the study.

Identification

The specimens must be readily identifiable in storage and be marked according to age, gender, weight, size, and cause of death. The quality of the bone should be noted according to findings from frontal and lateral plain radiographs, or preferably to quantitative measures from CT or MRI data.

Specimens of other species

It appears from recent studies [11, 13] that the use of calf and sheep spines as models for human spines in the testing of implant stability may be valid if the parameter of primary interest is range of motion. Similarities among these species, however, are more consistent biomechanically than they are anatomically in some regions [2, 10]. It is thus advisable to make anatomical and biomechanical comparisons to human specimens to be able to appropriately discuss the relevance of the results.

When using other species, the race and age of the animal should also be noted. The mechanical properties of the specimen may be highly dependent upon the breed of the animal.

Handling of the specimen

Safety precautions

Working with human cadaveric specimens now poses very serious risks of infection due to the epidemiological developments of AIDS, Hepatitis and other infectious diseases. This has necessitated safety precautions in laboratory practices [1].

Storage

1. The specimen shall be removed fresh from the expired body and the bulk of the muscle mass dissected away as quickly as possible. The specimen then shall be sealed in double or triple plastic bags.
2. The specimen shall remain frozen at –20 to –30 °C then be thawed out several hours before testing. Freezing and thawing out at room temperature has been reported to have little effect on the biomechanical behavior of bone and disc [6]. Nevertheless the time spent in the thawed condition shall be reported, as over time this can affect the specimen's properties.
3. Formalin-fixed specimens shall not be used at all, as it has been shown that this storage method drastically alters the specimen's biomechanical properties [12].

Preparation

The specimen shall be thawed out and prepared in its final form at room temperature shortly before testing. The specimen should be void of musculature and have all ligamentous and bony structures intact. The cranial and caudal segments shall be potted in a suitable polymeric or low-melting-point alloy in order to ensure that the specimen can be mounted into the simulator with a well-defined and reliable positioning load. Anchoring of the specimen in the potting medium may be improved with screws set partly into the specimen and several thread-pitches and the screw head jutting into the potting.

Length of specimens

The length of the specimen must match the intended use of the implant. Additionally, at least one free segment on either end of the construct length shall be included. Exceptions include implants that are anchored to the sacrum or occiput.

Defect conditions

When performing biomechanical tests to evaluate the stabilization characteristics of surgical techniques used in the reconstruction of the injured or diseased spine, such compromised conditions shall be closely simulated. This is especially important for comparing various stablization approaches and necessitates standardization and reproducibility of the defect.

A bony defect, produced with oscillating saws or osteotomy chisels, should represent the clinical situation. For the worst case scenario, a full corpectomy is recommended.

Test conditions

Test duration

Tests should not be performed over more than 20 h of room temperature exposure, as the properties of the specimens will begin to change beyond this (Nolte, personal communication, [9]).

Temperature

Tests shall be performed between 20° and 30 °C. Higher temperatures (for example, body temperature) accelerate the cellular autolytic process and thus shorten the possible test duration through compromise of the specimen's biomechanical properties.

Moisture condition

The specimens must be protected against drying out during the tests. This can be achieved with a 100% humidity chamber. However, a simpler and similarly effective method may be used by wrapping the specimens loosely in plastic, food-packaging wrap or moistened gauze. Spraying the specimen intermittently with 0.9% saline further assures its moist condition, although a slight increase in salinity may result from the evaporation of the solution. Experience indicates this problem is of less concern than the gross preservation of the moisture condition of the specimen and is likely negligible [9]. However, full immersion also has a strong effect on the specimen's behavior [7, 9]. The stability of this condition is important to simulate the physiological environment, and perturbations can change the motion characteristics especially of the disc.

Loading rate

Specimens can be deformed at rates between 0.5° and 5.0°/s without a considerable effect on the results [9]. Much slower rates may introduce creep effects and much faster rates may amplify the effect of the mechanical system inertia. If loading is applied stepwise, the time between load stepping and motion measurement at each interval shall be reported.

Test planning

Deciding protocol

Before performing the experiment, the protocol shall be clearly decided, following from the experimental design. The order in which each test step is performed as well as the measurement parameters shall be determined in accordance with relevant standards.

Recommendations

The following considerations are recommended for most tests. In general, the test shall be performed using only the spinal region intended for clinical use of the implant, as other regions may produce unreliable results.

Testing of intact specimen

The inherent motion properties of the intact specimen shall be determined before testing the stabilizing capacities of the implant systems or the effect of defects in order to provide an individual basis for normalization and to assure that mechanically defective specimens are excluded prior to implant testing. Also, this better enables a comparison with data in the literature.

Testing of defined defect

Reproducible defects shall be created with a scalpel in the disc and ligaments, and with an oscillating saw or osteotomy chisel within the bony structures, as closely as possible in accordance with clinical practice.

Implant test order

Implant tests shall include several competing systems for comparison. A “gold standard” or at least a device in common clinical use shall be included in the implant test series to allow a determination of the efficacy especially of newer implant systems in relation to those already existing. When using a given specimen to test more than one device, the implants, if practically feasible, shall be mounted to the specimens and tested in random order. In experiments involving an implant series with various screw sizes, for instance, the test order rather should follow the ascending screw size. This order, the reasons for it, and the effects from it shall be reported and discussed.

Number of specimens

For each implant, at least six specimens shall be tested to allow (in most cases) reasonably conclusive statistical analysis to be performed. When implant groups are formed with distinct specimens, the groups shall be carefully matched for age, bone mineral density, and other parameters likely to influence the spinal biomechanical properties.

Testing

Preliminary testing

Preliminary testing allows estimation of the variability in the data and thus helps determine the appropriate number of specimens needed for the experiment. It also allows the control parameters, like load or displacement magnitude and rate, to be decided for the chosen test environment.

It is important to make a thorough analysis of the preliminary test data to arrive at reliable methods of implantation, defect simulation, loading protocol, data collection, software application, and analysis, all of which commonly undergo notable changes through the preliminary testing process.

Mounting of specimen

Generally, the caudal end of the specimen is fixed rigidly at the base of the spinal loading simulator with an orientation approximating that in situ and matching the global coordinate system of the test apparatus. In lumbar spine testing, for instance, the midplane of the L3–4 segment shall be aligned horizontally.

Preconditioning of specimen

Biomechanical in vitro tests of spines normally shall be performed over at least three cycles in the three primary test directions, each cycle including both positive and negative directions. The first two cycles serve as precycles to precondition the construct (e.g., wire cerclage) so as to minimize the viscoelastic effect of the specimens. The load displacement behavior of the first two cycles can still be clearly distinguished, whereas the difference between the second and third cycles is considerably reduced. The third cycle in many cases is nearly identical with all subsequent cycles. For this reason the third cycle generally is recommended for analysis. However, it is recommended that during pretrials, the cycles be repeated until a reproducible result is achieved. In any case, the rate of loading and the number of preconditioning cycles shall be reported.

Loading of specimen

The loading of the spine in vivo is complex and the absolute values of the loading components are not well understood. The loading furthermore varies from one individual to another with a strong dependence on the level of activity and particular movements of the person.

The in vitro tests for intact specimens described herein are generally well within the elastic range of the specimens. This allows

multiple tests involving several loading cases and, in some cases, several implants. The amplitude of loading depends on the region and condition of the tested specimen. The loading for a given test series should be at least as high as that needed to achieve the normal range of motion for the given specimens.

Standard loading is defined as pure moments applied at the cranial or caudal end without preload in flexion/extension, axial rotation, and lateral bending. When using pure moment loading in the lumbar spine, an amplitude of ± 7.5 Nm is suggested; for the thoracic spine, ± 5 Nm; for the cervical spine, ± 1 Nm at C1–2 and otherwise, ± 2.5 Nm. When testing osteoporotic spinal specimens these values are recommended to be reduced by one-half. For the reporting of data, the amplitude of the loading should be exactly described.

Other loads may be additionally tested, including combinations of moments and/or compression and sagittal or lateral shear. Complex loading may be applied using, for instance, muscle force simulation by pneumatic/hydraulic cylinders acting through cables attached to representative points in the bone structures. Regardless of the protocol used, a six-component load cell shall be fixed into the base structure of the loading apparatus to record the net reaction at the caudal end of the specimen. The loading protocol will vary according to region and thus shall be described in detail.

Protocol definition

A well-defined protocol, relying on the developments of preliminary testing, shall be formulated prior to experimental testing. Deviations from this protocol shall be clearly reported. The protocol must provide the following, in sufficient detail to assure its reproducibility:

1. Assignment of project title and number
2. Specimen data, including sex, age, weight, cause of death (see Specimen; Identification)
3. Preparation methods
4. Test series order
5. Torque and distraction magnitudes for screws, clamps, and hooks
6. Test apparatus drawings and functional description
7. Preconditioning of specimens
8. Environmental conditions (temperature, humidity)
9. Control parameters (loading magnitude and speed)
10. Test duration

Calibration

The calibration of the various test apparatus, including measurement transducers, shall be appropriate to the chosen test parameters and environmental conditions and be valid at the time of testing.

Analysis

Relative motion from transformation of data

The motion of one vertebra relative to another, either neighboring or remote, shall be defined through three angles – α, β, γ – and three translations – x, y, and z – of a defined movement point and shall correspond to one of the two relevant local coordinate systems. Right/left lateral bending is +/– α; flexion/extension is +/– β; and left/right axial rotation is +/– γ (Fig. 2).

In most cases, analyzing the data in terms of projected angles onto the planes of the global coordinate system suffices to describe the motion of the specimen. If reporting the motion in terms of Euler angles, the sequence of angles shall be reported.

Because the critical motion component in the stabilization characteristics of an implant may well be a translation, the choice of anatomical reference point warrants careful consideration and shall be accurately described. An historical default reference point, which, however, is not commonly relevant to the clinical situation, is the middle of the vertebral body (see Concepts, terminology and definitions; Local coordinate system; Fig. 1).

Biomechanical parameters

When continuous loading is used, hysteresis load–deformation curves result (Fig. 3) and often are very individual to the specimen or construct tested. It is customary with such results to plot load on the *x*-axis, or abscissa, and angulation on the y-axis, or ordinate. If all three cycles are plotted on a graph, it is recommended to show the first cycle with a dotted line, the second with a dashed line, and the third with a thick, solid line. The third cycle, or that which through preliminary testing has been shown to represent the fully conditioned specimen, is used for analysis.

The standard spinal implant biomechanical parameters are defined as: (1) neutral zone (NZ); (2) range of motion (ROM); (3) elastic zone (EZ); (4) neutral zone stiffness (NZS); and (5) elastic zone stiffness (EZS). These are defined for each of the two test directions, forward and backward or left and right.

Statistics

The significance of the differences in implant stabilization characteristics shall be indicated by appropriate non-parametric statistical tests and reported in detail.

Presentation of results

The raw data shall be reduced for reporting purposes to representative values, like mean/median, range, and standard deviation. These may be given in tabular or graphical form. When the experiment is comparative, at least the graphical form is recommended.

The results involving constructs or defects in some cases may be normalized to the intact results to minimize the variability in the data and improve the power of the statistics.

Report

The report shall contain the following:

1. Protocol and description of the test method, including the loading apparatus and measurement devices (see Testing, Mounting, Preconditioning and Loading of specimen)
2. Estimate of the error of the system regarding load application and transduction as well as motion measurement
3. Number of specimens and other parameters described in Specimens; Specimens of other species
4. Noting of loosening of implants or conspicuous laxity or suspected points of mechanical failure as well as permanent deformation of the specimens following testing; the relevance of the implant to these changes shall be described
5. Reduction of the raw data into presentable form; description of statistical tests used and results of analysis (see Analysis; Statistics)
6. Dates of testing and signatures of persons responsible for project and report
7. Name and address of institute where the work was performed

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