Designation: F3295 – 18

Standard Guide for Impingement Testing of Total Disc Prostheses[1]

This standard is issued under the fixed designation F3295; 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 standard is intended to provide guidance on the evaluation of wear and fatigue characteristics of total disc prostheses under cyclic impingement conditions.

1.2 This guide describes impingement testing of devices with articulating components. The user is cautioned that the methods described herein are intended to produce an impingement condition which may or may not be indicative of clinical performance and which may or may not be consistent with the intended use of the device, and that this should be considered when interpreting the data. Clinically, total disc prostheses should always be implanted per labeling and the manufacturer's instructions for use.

1.3 Impingement has been observed in retrievals among several total disc prosthesis designs; however, impingement is not necessarily associated with device or clinical failure. It is the intent of this guide to investigate possible impingement-induced wear and mechanical failure modes associated with device design, as well as potential mechanical failure modes associated with clinical events such as subsidence, malpositioning, and improper implant sizing. Note that mechanical failure may or may not be associated with functional failure.

1.4 It is recommended that the user define the bearing and non-bearing features of the intervertebral disc (IVD) prosthesis and evaluate the performance of the IVD prosthesis under Mode 1 wear by using Guide F2423 or ISO 18192-1 prior to use of this guide. This standard is not intended to provide guidance on Mode I testing.

1.5 The goal of this guide is to evaluate impingement in IVD prostheses regardless of the intended region of the spine (cervical or lumbar), material or material combinations (ceramic, metal, polymer), and bearing type (fixed or mobile).

1.6 It is the intent of this guide to enable comparison of IVD prostheses with regard to wear and fatigue characteristics when tested under the specified conditions.

1.7 The values stated in SI units are to be regarded as the standard with the exception of angular measurements which should be reported in degrees.

1.8 *The use of this standard may involve the operation of potentially hazardous equipment. 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.9 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E4 Practices for Force Verification of Testing Machines

E1402 Guide for Sampling Design

E1488 Guide for Statistical Procedures to Use in Developing and Applying Test Methods

F561 Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids

F1714 Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices

F1877 Practice for Characterization of Particles

F2423 Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses

2.2 *ISO Standard:*[3]

ISO 18192–1 Implants for surgery—Wear of total intervertebral spinal disc prostheses—Part 1: Loading and displacement parameters for wear testing and corresponding environmental

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

[1] This guide 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] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.1.1 *axial force, n*—the resultant force $F_{axial\ force}$ applied to the IVD prosthesis along the *Z*-axis that simulates the *in vivo* axial force. Based on a healthy disc, the primary component would be an axial compressive force, F_Z, in the direction of the negative global *Z*-axis, and it would pass through the center of rotation of the IVD prosthesis.

3.1.2 *coordinate system/axes, n*—global *XYZ* orthogonal axes are defined following a right-handed Cartesian coordinate system in which the *XY* plane is to bisect the sagittal plane angle between superior and inferior surfaces that are intended to simulate the adjacent vertebral end plates. The global axes are stationary relative to the IVD prostheses's inferior end plate fixture, which in this standard guide is also considered to be stationary with respect to the test machine's frame. Lower case letters, *xyz*, denote a local, moving orthogonal coordinate system attached to the superior end plate-fixturing with directions initially coincident with those of the global *XYZ* axes, respectively. The 3D motion of the superior relative to inferior end plate-fixture is specified and is to be measured in terms of sequential Eulerian angular rotations about the *xyz* axes, respectively (*z*, axial rotation; *x*, lateral bending; and *y*, flexion-extension).

3.1.2.1 *origin, n*—center of the global coordinate system, located at the initial position of the IVD's instantaneous center of rotation (COR). Note that some articulating devices do not have a fixed center of rotation, but instead have either a mobile center of rotation or multiple distinct centers of rotation, depending on the direction of movement. In this case the origin should be explicitly defined by the user with a rationale for that determination.

3.1.2.2 *X-axis, n*—positive *X*-axis is a global fixed axis relative to the testing machine's stationary base and is to be directed anteriorly relative to the specimen's initial unloaded position.

3.1.2.3 *Y-axis, n*—positive *Y*-axis is a global fixed axis relative to the testing machine's stationary base and is directed laterally relative to the specimen's initial unloaded position.

3.1.2.4 *Z-axis, n*—positive *Z*-axis is a global fixed axis relative to the testing machine's stationary base and is to be directed superiorly relative to the specimen's initial unloaded position.

3.1.2.5 *x-axis, n*—positive *x*-axis is a fixed axis relative to the IVD prosthesis and a moving axis relative to the global coordinate system and is directed anteriorly relative to the prosthesis.

3.1.2.6 *y-axis, n*—positive *y*-axis is a fixed axis relative to the IVD prosthesis and a moving axis relative to the global coordinate system and is directed laterally relative to the prosthesis.

3.1.2.7 *z-axis, n*—positive *z*-axis is a fixed axis relative to the IVD prosthesis and a moving axis relative to the global coordinate system and is directed superiorly relative to the prosthesis.

3.1.2.8 *device neutral position, n*—the device position where the user considers the local *xyz* coordinate system initially parallel to those of the global *XYZ* axes coordinate system, defined by the user. Device neutral position is often the position when the device endplates are parallel to one another.

3.1.3 *device range of motion (ROM), n*—the maximum amount of angular displacement that an IVD prosthesis can undergo from the device neutral position to the point at which initial impingement occurs around a defined global axis. For example, if a device impinges at 15° from the device neutral position in flexion and 20° from the device neutral position in extension, the device range of motion can be defined as +15°/-20° in flexion-extension.

3.1.4 *functional failure, n*—permanent deformation or wear that renders the IVD prosthesis assembly ineffective or unable to resist force/motion or any secondary effects that result in a substantial alteration of clinically relevant motions or the motions intended by the design of the device.

3.1.5 *impingement, n*—contact between two components, resulting in a restriction of motion (Fig. 1).

3.1.5.1 *impingement conditions, n*—the angles determined to produce impingement in the device in flexion-extension, lateral bending and axial rotation.

3.1.5.2 *impingement test parameters, n*—the test inputs for rotations and forces which create the intended impingement conditions and are used for impingement testing.

3.1.5.3 *initial impingement angle* (A in Fig. 2), *n*—the angular displacement in a given plane, with respect to the device neutral position, at which impingement initially occurs, usually indicated by a sharp change in moment.

3.1.5.4 *impingement moment, n*—the moment (N-m) measured or applied at the point of impingement (POI). It may be determined as the product of the applied axial force and impingement moment arm.

3.1.5.5 *maximum impingement angular displacement, n*—the greater of the two angular displacement test parameters (farthest from the device neutral position); it is the ultimate angle plus 2.0°.

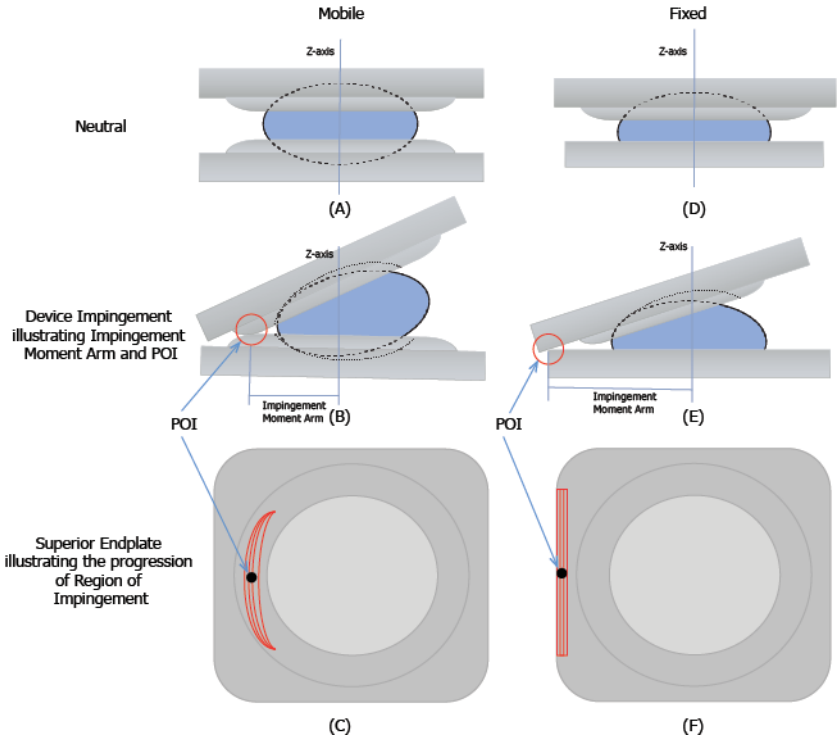
3.1.5.6 *minimum impingement angular displacement, n*—the lesser of the two angular displacement test parameters (that closer to the device neutral position). It is 2.0° less than the initial impingement angle.

3.1.5.7 *impingement moment arm, mm* (Fig. 1b and Fig. 1e), *n*—the distance in the *x-y* plane from the *z*-axis of the device to the POI.

3.1.5.8 *impingement region* (Fig. 1C and Fig. 1F), *n*—physical area on the device components where the impingement wear scar develops as a result of repeated loading and motion cycles.

3.1.5.9 *point of impingement (POI)* (Fig. 1C and Fig. 1F), *n*—the theoretical location on the IVD prosthesis's *x-y* plane where impingement occurs with respect to the origin.

3.1.5.10 *theoretical ultimate moment* (M_t in Fig. 2), *n*—the mathematical product of the axial force to be applied during the impingement wear test (Table 1) and the distance in the *x-y* plane from the *z*-axis of the device to the POI (mm); for example, for a cervical IVD prosthesis with a POI 9.0 mm from the *z*-axis, M_t = (100 N) (9.0 mm) / (1000) = 0.9 Nm.



A-C show an example of a mobile bearing disc at its neutral position (A), impinged position (B), and its superior endplate with impingement region indicated (C). D-F show an example of a fixed bearing disc at its neutral position (D), impinged position (E), and its superior endplate with impingement region indicated (F). The dashed arcs show the geometry of the bearing (black) and the endplate (gray). For B and E the point of impingement (POI) and impingement moment arm are indicated. For C and F, the impingement region is illustrated as a series of overlapping regions indicating the expected progression of the impingement region over the duration of the test and reinforcing the concept that there is an angular range over which the impingement region develops. The concept for the point of impingement has also been indicated in B,C and E,F and is provided as a purely theoretical representation for the purpose of defining the impingement moment arm.

FIG. 1 Schematic of Impingement Modes for Two Total Disc Prostheses

3.1.5.11 *ultimate angle, n*—the angular displacement associated with the theoretical ultimate moment, in degrees (A_u in Fig. 2).

3.1.6 *intervertebral disc (IVD) prosthesis, n*—non-biologic structure intended to restore the support and motion or a portion thereof, to the space between adjacent vertebral bodies. Also referred to as *total disc prosthesis*.

3.1.7 *kinematic profile, n*—relative motion between adjacent vertebral bodies that the IVD prosthesis is subjected to while being tested.

3.1.8 *force profile, n*—loading that the IVD prosthesis is subject to during testing.

3.1.9 *mechanical failure, n*—failure associated with a defect in the material (for example, fatigue crack) or of the bonding between materials that may or may not produce functional failure.

3.1.10 *wear, n*—progressive loss of material from the device(s) or device components as a result of relative motion at the surface with another body as measured by the change in mass of the IVD prosthesis.

3.1.11 *fluid absorption, n*—fluid absorbed by the device material during testing.

3.1.12 *interval net volumetric wear rate VR_i during cycle interval i (mm^3/million cycles), n*—$VR_i = WR_i / \rho$, where ρ = mass density (for example, units of g/mm^3) of the wear material.

3.1.13 *interval net wear rate WR_i during cycle interval i (g/million cycles), n*—$WR_i = ((NW_i - NW_{i-1} /$ (number of cycles in interval i)) $\times 10^6$.

3.1.13.1 *Discussion*—For $i = 1$, $NW_{i-1} = 0$.

3.1.14 *net wear NW_i of wear specimen (g), n*—$NW_i = (W_0 - W_i) + (S_i - S_0)$; loss in weight of the wear specimen corrected for fluid absorption at end of cycle interval i.

3.1.15 *net volumetric wear NV_i of wear specimen (mm^3), n*—$NV_i = NW_i / \rho$ at end of cycle interval i where ρ = mass density (for example, units of g/mm^3) of the wear material.

3.1.16 *weight S_i of soak control specimen (g), n*—S_0 initial and S_i at end of cycle interval i.

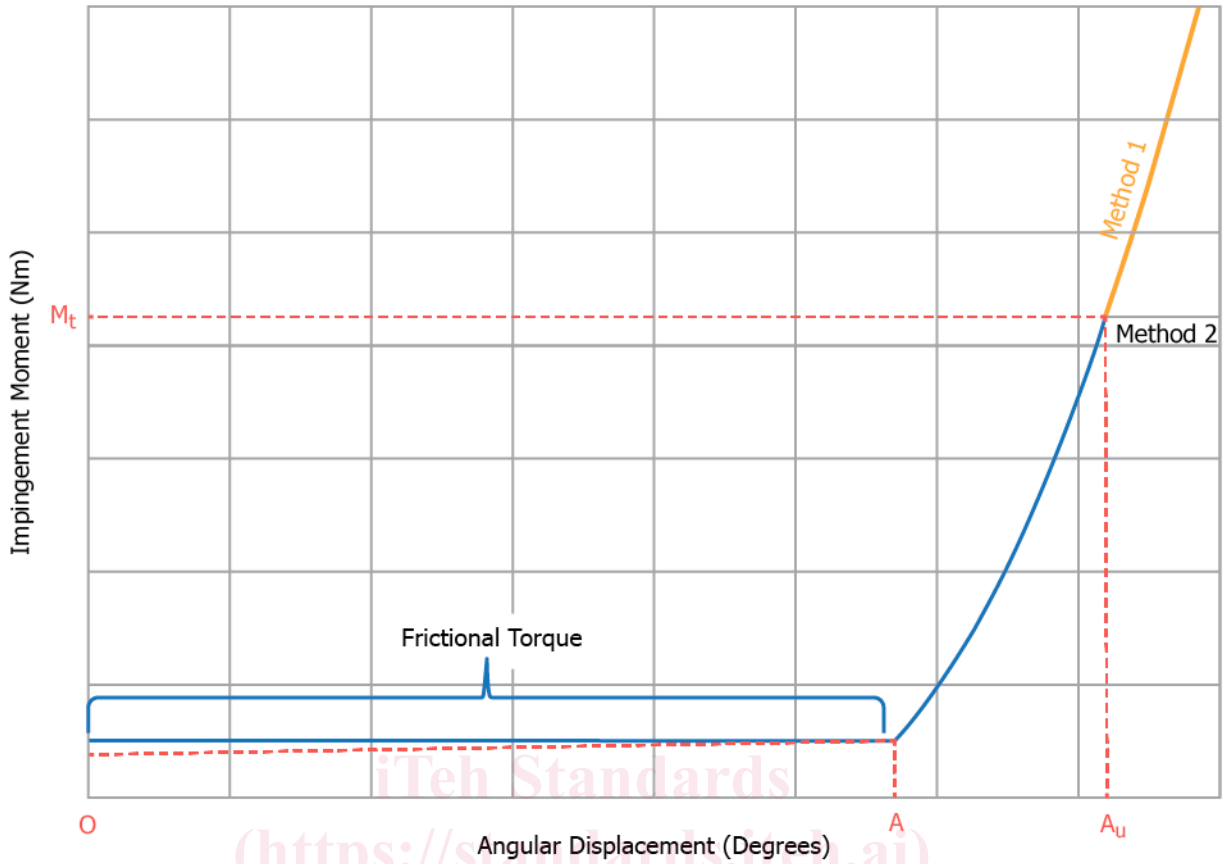
3.1.17 *weight W_i of wear specimen (g), n*—W_0 initial and W_i end of cycle interval i.

4. Summary of Guide

4.1 This guide provides a generic approach for developing impingement test parameters for total disc or IVD prostheses, summarizing the key steps in the process of developing, conducting, and interpreting results from an impingement test (Fig. 3).

5. Background, Significance and Use

5.1 This guide can be used to develop test parameters for evaluating fatigue and wear behavior of IVD prostheses under impingement loading. It must be recognized, however, that



In this plot, the horizontal blue line represents constant, low frictional torque expected as the device is rotated through its range of motion. The sloping dashed line OA shows increasing torque that may be an indicator of COR misalignment. Point A represents the initial impingement angle (A). The arc between the initial impingement angle (A) and the ultimate angle (A_u) and theoretical ultimate moment (M_t) illustrates the sharp upward torque experienced during impingement. Beyond the ultimate angle (A_u) and theoretical ultimate moment (M_t) the curves for Quasistatic Test Method 1 (see 10.1) and Quasistatic Test Method 2 (see 10.2) diverge.

FIG. 2 Impingement Moment versus Angular Displacement Plot Showing Two Theoretical Curves for Impingement Under Quasistatic Conditions

TABLE 1 Force and Motion Parameters for Cervical and Lumbar IVD Prostheses[A]

	Axial Force, (N)	Minimum Impingement Angular Displacement, (°)	Maximum Impingement Angular Displacement, (°)	Axial Rotation Displacement Control, (°)[B]
Cervical	100	Initial impingement angle, less 2.0°	Ultimate Angle (A_u) plus 2.0°	± 6°
Lumbar	1200	Initial impingement angle, less 2.0°	Ultimate Angle (A_u) plus 2.0°	± 2°

[A] The values provided are based on Guide F2423 (axial force) and ISO 18192-1 (axial rotation) or determined through quasistatic test as described in Sections 7 – 10.
[B] It may be determined by the user that incorporating axial rotation is unnecessary to achieve clinically relevant impingement wear and damage. Additionally, the magnitude for axial rotation provided is a starting point for defining test parameters; the user may choose alternate angular limits if justified by other means (e.g., retrieval analysis, scientific literature, etc.).

there are likely many possible impingement conditions for a given IVD prosthesis.

5.2 The user should attempt to determine the clinically relevant and geometrically possible impingement conditions and dictated by the design and impingement wear test parameters that may result in wear and fatigue damage for the IVD prosthesis. The user should also attempt to select the device size which will represent a worst case for the impingement conditions and parameters selected.

5.3 The user should reference and utilize existing sources of information to identify the impingement test parameters that produce the clinically relevant impingement wear and damage for their IVD prosthesis. Prior clinical experience with the device design may aid in the development of impingement test parameters through analysis of device retrievals and radiographs. However, prior clinical experience with the IVD being tested should not be considered as a prerequisite for performing impingement testing.

5.4 This guide details a three-step process for assessing device impingement under a selected set of conditions:

5.4.1 The user selects previously identified impingement conditions, one at a time, or clinically observed conditions.

5.4.2 The user selects the worst-case size of device to apply the selected conditions.

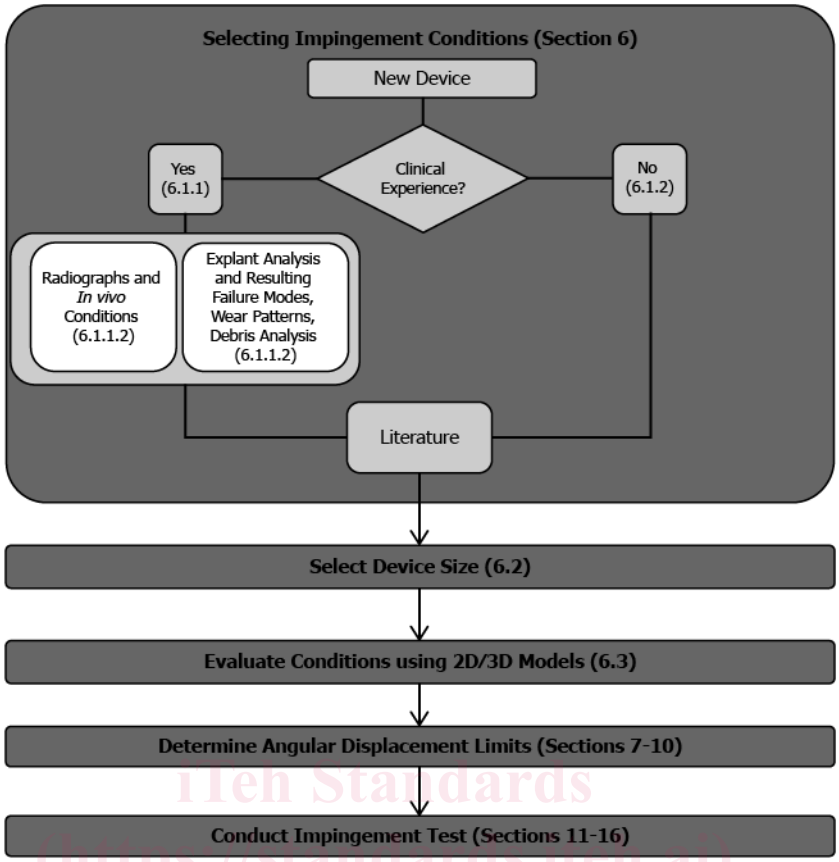


FIG. 3 Work Flow for Running the Impingement Test

5.4.3 Solid modeling and the quasistatic test method should be employed to assess the impingement condition and determine the impingement test parameters – most importantly, the angular displacement limits to be used in the impingement wear test.

5.4.4 The impingement wear test is then conducted using the impingement test parameters.

5.5 This guide serves to evaluate devices with various designs, materials (i.e., metal-on-metal versus polymer-on-polymer), and stiffness in the impingement region using the same axial force and angular displacement control.

5.5.1 In the case where the device has no limit in a given direction or does not allow motion in a given direction, a rationale for excluding that condition should be provided (e.g., intended design or function of the device).

5.6 Impingement occurs over a range between an initial and an ultimate angle rather than at a discrete angle and location because both design (e.g., mobile bearings) and material combinations (e.g., inclusion of polymeric materials) may lead to compliance, deformation and wear, which in turn may lead to a change in the angular displacement at which contact occurs over the course of the test. A range of angular displacement is therefore prescribed to ensure that the impingement region is fully loaded during each impingement cycle.

5.7 The suggested test parameters in Table 1 have been provided with the objective of minimizing Mode I wear at the bearing surface while providing sufficient motion to fully offload the bearing surface for each cycle. Given that the intended function of the devices is typically to articulate, it may be impossible to fully eliminate Mode 1 wear at the intended bearing interface.

5.8 The point of impingement (POI) is a simplification for the purpose of determining an impingement moment arm and thus calculating the theoretical ultimate moment (M_t). M_t may be useful for comparing device designs.

5.9 The contribution of axial rotation to impingement damage is still under-studied. However, retrieval analysis has provided evidence that it may contribute to impingement damage. Many total disc replacements are unconstrained in axial rotation. Therefore, unlike flexion-extension or lateral bending where a moment versus angular displacement response can be readily developed, axial rotation will have a near-zero moment response. The axial rotation parameters provided in Section 15 are based on the Mode 1 wear test methods and should be assessed and altered if justification (e.g., wear patterns from retrievals, scientific literature, etc.) exists.

6. Selection of Impingement Conditions

6.1 Select the relevant impingement conditions in accordance with the guidance provided in this section.

6.1.1 If the IVD prosthesis to be tested has been studied clinically and information on impinged devices is reported, these data may be utilized to develop clinically relevant

impingement test parameters. Specifically, retrieval and radiographic analyses are the two main sources of information obtained from the clinical study that may aid in the development of the test parameters.

6.1.1.1 If clinical information is available, radiographs may be analyzed to select and justify the impingement test parameters. Radiographs from patients for whom devices show probable impingement may provide further insights into the conditions that led to impingement. Motion modes that lead to impingement may be noted. Relative alignment of components (e.g., relative angulation or translation of endplates) may be noted.

6.1.1.2 If retrievals are available, the objective of the impingement study should be to replicate clinical impingement wear and damage. Clinical retrievals of the IVD prosthesis, if available, should be analyzed for evidence of impingement. Retrievals that demonstrate evidence of impingement provide insights into the motion mode(s) most likely to lead to impingement. Impingement wear scars on the retrieved device may be analyzed in an attempt to determine impingement wear and damage mechanisms.

6.1.2 Existing clinical data should not be considered as a prerequisite to performing impingement testing. In such cases, a review of the scientific literature (e.g., **[1-4]**[4]), device modeling, and quasistatic testing may need to be more extensive to determine the impingement conditions.

6.1.3 Impingement may occur in a variety of conditions including, but not limited to, flexion, extension, lateral bending, axial rotation, and anterior, posterior or lateral translation, shear, and combinations of the aforementioned motions.

6.1.3.1 Extension and flexion are most commonly associated with impingement; thus impingement at both the posterior and anterior aspects of the device should be explored and considered.

6.1.3.2 Lateral bending impingement has also been reported in the literature. The user should attempt to determine if their IVD prosthesis is more susceptible to lateral bending impingement and to consider testing in this motion mode if relevant.

6.1.3.3 Impingement may not occur in axial rotation for devices unconstrained in this motion mode, but when coupled with other motion modes, axial rotation may contribute to clinically relevant impingement wear and damage.

6.1.3.4 Anterior-posterior and/or lateral translation of components should be considered and potentially incorporated into the test method if the device has a mobile core. In addition, clinical impingement may result from translations of the device endplates with respect to one another (e.g., anterior migration of the inferior endplate). Such modes should be explored and considered.

6.1.3.5 Shear may play a role in the impingement mechanics of IVDs **[5]**; thus the user should consider the role of shear in inducing impingement.

6.2 The user should attempt to define the worst-case device size for the selected impingement conditions. The following guidance is provided to assist in selecting the worst-case device once a set of impingement test conditions has been selected:

6.2.1 Devices are typically produced in a range of sizes or configurations. Therefore the user should consider which device size or configuration would result in the greatest extent and magnitude of wear and damage. To determine the worst case will require the user to consider contact stress and contact area for the selected impingement conditions and parameters.

6.2.2 Select the design and size combination that allows the least device ROM for the conditions selected.

6.3 Once a set of impingement conditions and worst case device(s) have been selected, the user should determine the device range of motion using solid models. The user should also define the impingement moment arm and POI and associated M_t (see 3.1.5.10 for calculation).

6.3.1 Rotate and translate the device virtually using the models. Specifically, rotate the device from the device neutral position until impingement occurs.

7. Summary of Quasistatic Test Methods

7.1 The quasistatic bench test is performed to determine the response of the device to increasing angular displacement. The angular displacement limits for the impingement test are determined based on the results of quasistatic testing (Fig. 2).

7.2 Two test methods are described in Section 9. The two methods are expected to produce reasonably equivalent results but have not been studied for direct comparison. The user may select either method for testing the quasistatic performance of their device based on the availability of the required equipment for each method. Other methods which are reasonably expected to produce equivalent results are also acceptable.

7.3 Both methods are conducted using load frames equipped with torsional actuators to apply angular rotation. Method 1 uses fixtures to constrain the device and a torsional actuator to apply angular displacement. Method 2 uses an axial actuator and fixtures to constrain the device and a torsional actuator that is perpendicular to the axial actuator to apply angular displacement. Other load frames and fixtures that are reasonably expected to produce equivalent results are also acceptable.

8. Quasistatic Test Specimens

8.1 All components of the IVD prosthesis shall be previously unused parts only; no implants shall be retested. All implants shall be production quality parts. Any deviations from the intended marketed product shall be noted in the final report.

8.2 It is permissible to exclude features that may either interfere with obtaining accurate results, may obstruct or hinder proper support or clamping of the device, and/or may otherwise prevent the device from being tested, provided that exclusion of the feature does not alter the results of the test. For example, bone-implant interface features such as coatings or keels may be omitted, unless they are relevant to the investigation.

8.3 It is suggested that a sample size of three be used to perform the quasistatic test. For additional guidance on experimental design, see Guides E1488 and E1402.

[4] The boldface numbers in parentheses refer to the list of references at the end of this stndard.