Designation: F2624 – 07

# StandardTest Method for Static, Dynamic, and Wear Assessment of Extra-Discal Spinal Motion Preserving Implants[1]

This standard is issued under the fixed designation F2624; 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 test method is intended to provide test methods for the static, dynamic, and wear testing of extra-discal motion preserving implants. These implants are intended to augment spinal stability without significant tissue removal while allowing motion of the functional spinal unit(s).

1.2 Wear is assessed using a weight loss method and a dimensional analysis for determining wear of components used in extra-discal spinal motion preserving procedures, using testing medium as defined in this test method (6.1).

1.3 This test method is not intended to address any potential failure mode as it relates to the fixation of the device to its bony interfaces.

1.4 It is the intent of this test method to enable comparison of motion preserving, extra-discal implants with regard to kinematic, functional, and wear characteristics when tested under the specified conditions. It must be recognized, however, that there are many possible variations in the *in vivo* conditions. A single laboratory simulation with a fixed set of parameters may not be universally representative.

1.5 This test method is not intended to address facet arthroplasty devices.

1.6 This test method prescribes the use of pure angular rotations for assessing the mechanical characteristics of extra-discal motion preserving implants. This test method does not, however, prescribe methods for assessing the mechanical characteristics of the device in translation (for example, anterior/posterior translation), though this type of linear motion may be clinically relevant.

1.7 In order that the data be reproducible and comparable within and between laboratories, it is essential that uniform procedures are established. This test method is intended to facilitate uniform testing methods and data reporting for extra-discal motion preserving implants.

1.8 Without a substantial clinical retrieval history of spinal, motion preserving extra-discal implants, actual loading profiles and patterns cannot be delineated at the time of the writing of this test method. It therefore follows that the motion profiles specified by this test method do not necessarily accurately reproduce those occurring *in vivo*. Rather this method provides useful boundary/endpoint conditions for evaluating implant designs in a functional manner.

1.9 This test method is not intended to be a performance standard. It is the responsibility of the user of this test method to characterize the safety and effectiveness of the device under evaluation.

1.10 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.

1.11 The values stated in SI units are to be regarded as the standard with the exception of angular measurements, which may be reported in either degrees or radians.

1.12 *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]

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

F1717 Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

F1877 Practice for Characterization of Particles

F2003 Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air

[1] This test method 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.

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

## 3. Terminology

3.1 All terminology is consistent with the referenced standards, unless otherwise stated.

3.2 *Definitions:*

3.2.1 *center of rotation (COR)*—the point about which the simulated vertebral bodies rotate in performing the range of motion (ROM) specified in this test method.

3.2.2 *coordinate system/axes*—three orthogonal axes are defined following a right-handed Cartesian coordinate system. The *XY*-plane is to bisect the sagittal plane between superior and inferior surfaces that are intended to simulate the adjacent vertebral end plates. The positive *Z*-axis is to be directed superiorly. Force components parallel to the *XY*-plane are shear components of loading. The compressive axial force is defined to be the component in the negative *Z*-direction. Torsional load is defined to be the component of moment about the *Z*-axis.

3.2.3 *degradation*—loss of material or function or material properties due to causes other than that associated with wear.

3.2.4 *extra-discal motion preserving device or implant*—a non-biologic structure, which lies entirely outside the intervertebral disc space and is intended to at least partially support the motion/load between adjacent vertebral bodies. In this test method, this definition does not include facet arthroplasty devices.

3.2.5 *fluid absorption*—fluid absorbed by the device material during testing or while implanted *in vivo*.

3.2.6 *functional failure*—permanent deformation or wear that renders the extra-discal motion preserving implant assembly ineffective or unable to adequately resist load/motion or any secondary effects that result in a reduction of clinically relevant motions or the motions intended by the design of the device.

3.2.7 *functional spinal unit (FSU)*—two adjacent vertebrae, including the intervertebral disc, and all adjoining ligaments between them, specifically excluding all other connective tissues such as muscles (Ref **(1)**).[3]

3.2.8 *interval net volumetric wear rate—$VR_i$ during cycle interval i (mm³/million cycles)*:

$$VR_i = \frac{WR_i}{\rho} \tag{1}$$

*where:*

ρ = mass density (for example, units of g/mm³) of the wear material.

3.2.9 *interval net wear rate—$WR_i$ during cycle interval i (g/million cycles)* :

$$WR_i = \frac{(NW_i - NW_{i-1})}{(\#\text{ of cycles in interval } i)} \times 10^6 \tag{2}$$

Note, for $i = 1$, $NW_{i-1} = 0$.

[3] The boldface numbers in parentheses refer to a list of references at the end of this standard.

3.2.10 *kinematic profile*—the relative motion between adjacent vertebral bodies that the extra-discal motion preserving device is subjected to while being tested.

3.2.11 *mechanical failure*—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.

3.2.12 *net volumetric wear—$NV_i$ of wear specimen (mm³)*:

$$NV_i = \frac{NW_i}{\rho} \tag{3}$$

at end of cycle interval *i*.

*where:*

ρ = mass density (for example, units of g/mm³) of the wear material.

3.2.13 *net wear—$NW_i$ of wear specimen (g)*:

$$NW_i = (W_0 - W_i) + (S_i - S_0) \tag{4}$$

Loss in weight of the wear specimen corrected for fluid absorption at end of cycle interval *i*.

3.2.14 *origin*—the center of the coordinate system is located at the center of rotation of the testing fixture.

3.2.15 *run-out (cycles)*—the maximum number of cycles that a test needs to be carried to if functional failure has not yet occurred.

3.2.16 *wear*—the 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 components of the implants. Or in the case of a non-articulating, compliant device, wear is defined simply as the loss of material from the device. Note that bone interface components of the device are excluded from this definition (see 5.2.2, 5.2.4, and 5.2.5).

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

3.2.18 *weight $W_i$ of wear specimen (g)*—$W_0$ initial and $W_i$ at end of cycle interval *i*.

3.2.19 *X-axis*—the 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.

3.2.20 *Y-axis*—the 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.

3.2.21 *Z-axis*—the 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.

## 4. Significance and Use

4.1 This test method is designed to quantify the static, dynamic, and wear characteristics of different designs of extra-discal motion preserving implants using testing medium (see 6.1) for simulating the physiologic environment at 37°C. Wear is assessed using a weight loss method in addition to dimensional analyses. Weight loss is determined after subjecting the implants to dynamic profiles specified in this test

method. This information will allow the manufacturer or end user of the product to understand how the specific device in question performs under the test conditions prescribed in this test method.

4.2 This test method is intended to be applicable for extra-discal motion preserving implants. These implants augment the motion/load bearing characteristics between adjacent vertebral bodies, and thereby fully or partially support and transmit motion by means of an articulating joint or by use of compliant materials. Ceramics, metals, or polymers, or combinations thereof are used in implant design, and it is the goal of this test method to enable a comparison of the static, dynamic, and wear properties generated by these devices, regardless of material and type of device.

## 5. Apparatus

5.1 *Implant Components*—The extra-discal motion preserving device may comprise a variety of shapes and configurations. Some known forms include screws which rigidly purchase the vertebral bodies coupled with flexible, elastic members; other forms may include rigid members coupled in a semi-constrained manner (for example, screws, and rods connected with a universal joint with defined motion limitations). Forms of these devices which employ hooks that engage posterior spinal elements are also envisioned; these devices may support extension loading only or loads in both flexion and extension.

5.2 *Spinal Testing Apparatus:*

5.2.1 *Test Chambers*—In case of a multi-specimen machine, each chamber shall be isolated to prevent cross-contamination of the test specimens. The chamber shall be made entirely of non-corrosive components, such as acrylic, plastic, or stainless steel, and shall be easy to remove from the machine for thorough cleaning between tests.

5.2.2 For wear testing, the test chamber also must isolate the spinal motion preserving device/construct from wear centers created by the testing fixtures.

5.2.3 For all testing, the actuator of the testing machine is connected to the superior testing block. The user must determine the appropriate degrees of freedom for the device depending on its intended use (see 5.2.6).

5.2.4 *Component Clamping/Fixturing*—Since one of the purposes of the test is to characterize the wear properties of the extra-discal motion preserving device, the method for mounting components in the test chamber shall not compromise the accuracy of assessment of the weight loss or stiffness variation during the test. For example, implants having complicated surfaces for contacting bone (for example, sintered beads, hydroxylapatite (HA) coating, plasma spray) may be specially manufactured to modify that surface in a manner that does not affect the wear simulation.

5.2.5 The device should be securely (rigidly) attached at its bone-implant interface to the test fixtures.

5.2.6 The extra-discal motion preserving construct mated with the testing fixture shall be constrained with the appropriate degrees of freedom for the intended use. For example, some devices may only be intended to provide stability in one motion, which would dictate that the test fixture may be constrained in all other motions. Other devices, which provide stability along multiple degrees of freedom, would necessitate having more degrees of freedom incorporated into the testing fixture. The user shall determine and justify the appropriate degrees of freedom of the test fixture.

5.2.7 Blocks are to be made from polyacetal homopolymer (minimum ultimate tensile strength shall be no less than 61 MPa). The simulated spinous process is to be made from 304 series stainless steel (minimum ultimate tensile strength shall be no less than 500 MPa). See Note 1.

NOTE 1—304 stainless steel is used for the simulated spinous process for rigidity purposes to enable the user to more accurately characterize the mechanical performance of the extra-discal motion preserving implant.

5.2.7.1 The simulated spinous process is only needed if the implants are intended to be attached to the spinous process *in vivo*.

5.2.7.2 The simulated spinous process must be manufactured in such a way as to be rigidly attached to the polyacetal homopolymer block. Modifications are allowed to conform to device design and the manufacturer's intended use of the extra-discal implant. Note that if wear is expected between the implant and the spinous process, the user should consider altering the surface finish of the simulated spinous process to offer a more appropriate test model for assessing the mechanical characteristics of the implant.

5.2.8 Fig. 1 and Fig. 2 are of an extra-discal motion preserving implant attached to simulated vertebral bodies (Fig. 3) and testing fixtures. Note that the represented testing fixtures, which attach to the simulated vertebral bodies and the testing instrument, are for illustrative purposes only. The user must design the appropriate fixtures for the device being tested and means by which they are rigidly fixed to the testing instrument.

5.2.9 *Range of Motion (ROM):*

5.2.9.1 Axial compressive loads/motions are applied in the direction of the negative *Z*-axis.

5.2.9.2 Flexion loads/motions are generated by positive rotation about the *Y*-axis.

5.2.9.3 Extension loads/motions are generated by negative rotation about the *Y*-axis.

5.2.9.4 Lateral bend loads/motions are generated by positive and negative rotation about the *X*-axis.

5.2.9.5 Torsional loads/motions are generated by positive and negative rotation about the *Z*-axis.

5.2.9.6 *Center of Rotation (COR)*—See X1.6 for a discussion on the COR. Since the COR will vary in accordance with device design and intended use, it is impossible to artificially specify the coordinates of the COR for testing. Therefore, the COR must be determined by the end user of this test method for the specific device being tested. The user should specify the COR based on the expected *in vivo* COR.

5.2.10 *Frequency:*

5.2.10.1 Test frequency is to be determined and justified by the user of this test method and shall not exceed 2 Hz without adequate justification ensuring that the applied motion (load) profiles remain within specified tolerances and that the construct's wear and functional characteristics are not significantly affected.

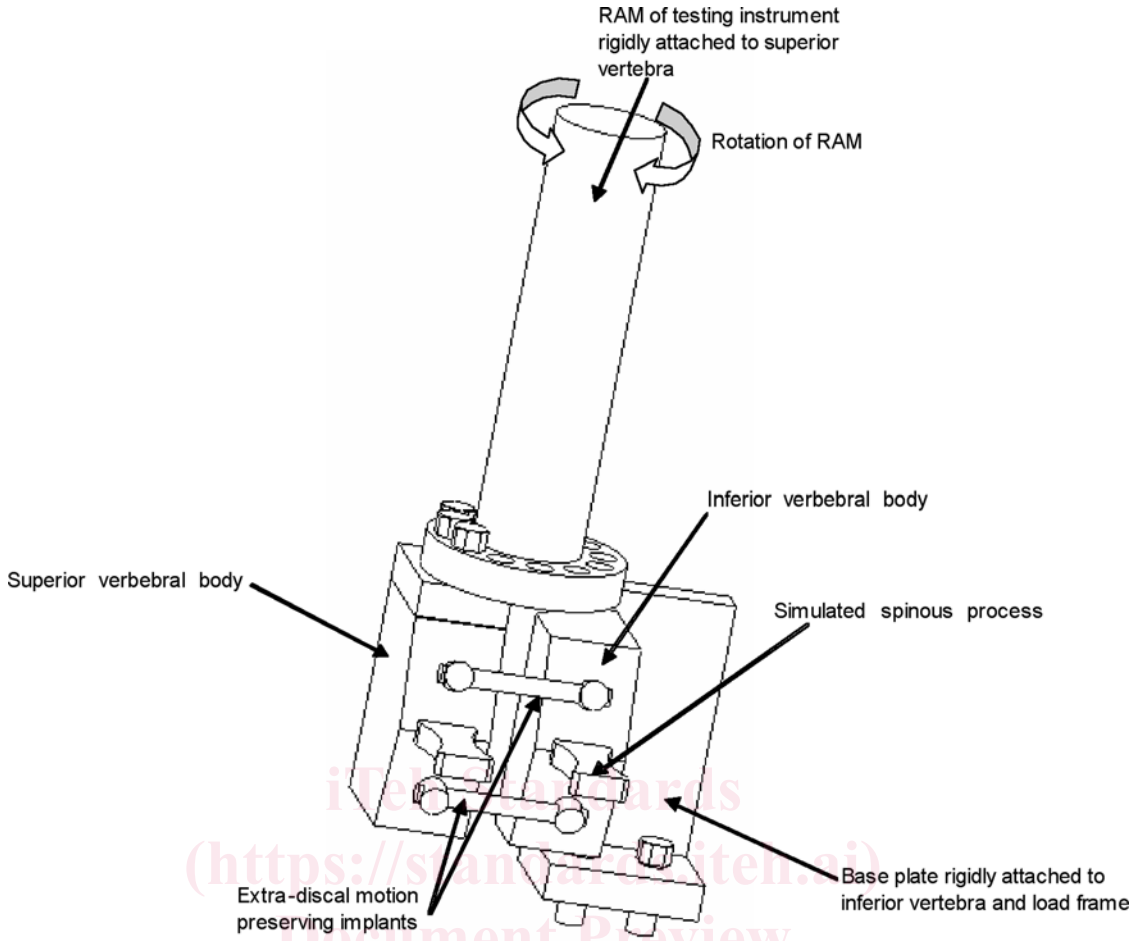



**FIG. 1 3-D View of Extra-Discal Motion Preserving Implants in One Representative Testing Configuration**

5.2.11 *Cycle Counter:*

5.2.11.1 One complete motion is the entire range from starting position, through the range of motion and returning to the starting position. Cycles are to be counted using an automated counting device.

## 6. Reagents and Materials

6.1 *Testing Medium:*

6.1.1 If the device does not have articulating surfaces or surfaces that move relative to one another, then a solution containing 0.9 % saline shall be used as the testing medium.

6.1.2 If the device contains articulating surfaces, or surfaces that move relative to one another, the device shall be tested in a testing medium containing bovine serum diluted to a protein concentration of 20 g/L in deionized water. The user should reference Guide F2423 for more information on the use of serum in the testing medium.

6.1.2.1 To retard bacterial degradation, freeze and store the serum until needed. In addition, the testing medium should contain suitable antibiotics or antimycotics, or both, to prevent bacterial and fungal growth, respectively. Penicillin-streptomycin (0.15 % per volume) and amphotericin B (0.25 % per volume) are recommended. Note that, if possible, the user should avoid using sodium azide (0.2 % per volume) as an antimicrobial reagent, due to its chemical toxicity.

6.1.2.2 It is recommended that ethylene-diaminetetraacetic acid (EDTA) be added to the testing medium containing serum at a concentration of 20mM to bind calcium in solution and minimize precipitation of calcium phosphate onto the bearing surfaces. The latter event has been shown to strongly affect the friction and wear properties, particularly of polyethylene/ceramic combinations. The addition of EDTA to other testing mediums should be evaluated.

6.1.3 The bulk temperature of the testing medium shall be maintained at 37 ± 3°C unless otherwise specified.

6.1.4 The user is cautioned that internal heating of the implant may cause localized temperatures to fall outside the 37 ± 3°C of the testing medium. Internal local temperatures may depend on a number of factors including but not limited to joint friction, material hysteresis, conductivity of the device-fixture materials, design, and test frequency. Localized elevated temperatures may have an effect on the mechanical as well as wear properties of the implant. If the device experiences localized elevated temperatures, the user must describe

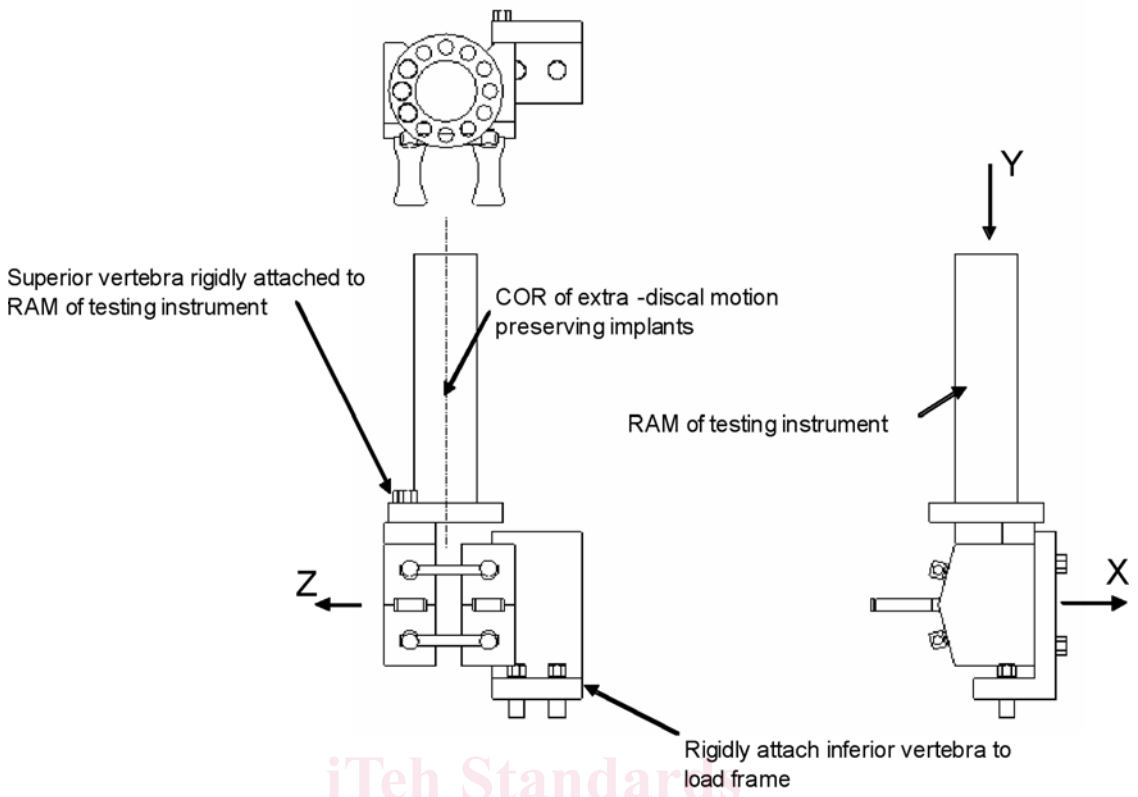



**FIG. 2 Extra-Discal Motion Preserving Implants in One Representative Testing Configuration**



the effect the selected frequency and resultant localized temperature have on the test results, or justify that the effects are physiologically relevant. Refer to X1.5 for further information.

## 7. Sampling Test Specimens

7.1 It is suggested that a minimum sample size of five be used for the static tests and two to be used for each load or motion in the dynamic/wear testing of the device. However, it should be noted that, as for any experimental comparison, the total number of needed specimens will depend on the magnitude of the difference to be established, the repeatability of the results (standard deviation), and the level of statistical significance desired.

7.2 The test assemblies (that is, extra-discal implant components in the tested configuration) shall be labeled so they can be traced and must be kept in a clean environment to avoid contamination. The test assembly can be disassembled to facilitate examination of surface conditions.

7.3 Polymeric specimens may require pre-conditioning, as device stiffness may depend on temperature or hydration, or both, of the polymer. In addition, the user may also wish to consider the effects of polymer aging on the mechanical properties of the device (the user should reference Practice F2003 for more information.)

## 8. Preparation of Apparatus

8.1 The functional surface of the implantable form of the device to be tested is produced using equivalent manufacturing methods as the implantable form of the construct, including sterilization.

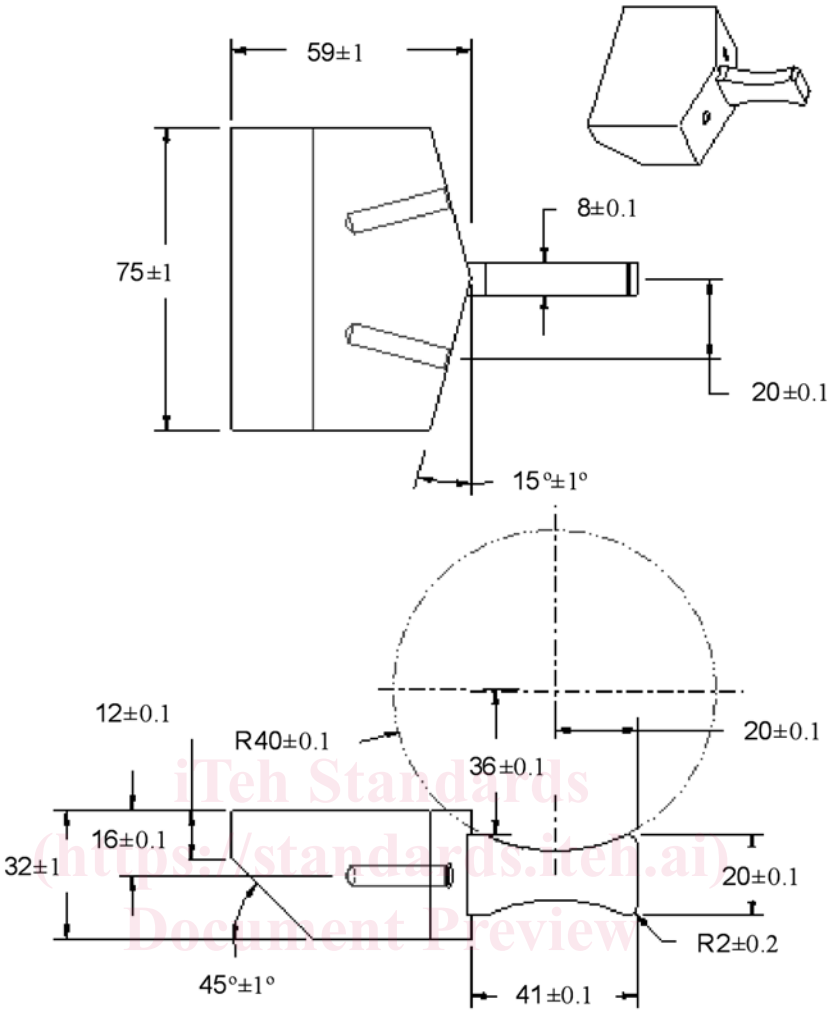
8.2 It is permissible to exclude non-functional features that may interfere with obtaining wear/functional measurements. For example, bone implant interfaces such as HA, plasma-spray titanium, and beads may be omitted since they may abrade the fixtures and thus produce unwanted mixture of functional and not-functional component wear particles (see 5.2.2).

8.3 The requirements of Guide F1714, Section 5 on "Specimen Preparation" shall be followed.

## 9. Procedure

9.1 Not all devices are designed to resist loading in all motions specified in this test method. The user must therefore determine which motion profiles are appropriate for a given device.

9.2 Angular motions shall be controlled with an accuracy of ±0.5°, and loads shall be controlled with an accuracy of ± 5 % of the maximum load.




NOTE 1—All dimensions are in mm.

**FIG. 3 Simulated Vertebral Body Testing Block**



9.2.1 Mount the extra-discal motion preserving device to the polyacetal homopolymer blocks (Fig. 1, Fig. 2, and Fig. 3). Install the anchors in accordance with the manufacturer's instructions. Note that modifications to the blocks may be required to adapt the test blocks to the extra-discal motion preserving device.

9.2.2 In order to account for the axial preload the device would be subjected to *in vivo* in the neutral position, the test blocks/fixture shall be designed such that the implant, for static, fatigue and wear testing, is subjected to a nominal axial load of 300 N ($F_Z$) when the implants are in the neutral position.

NOTE 2—Note the rationale for a 300 N axial load. Assuming an approximate 1000 N load (based on intradiscal pressure measurements made by A. Nachemson (**2, 3**)) axially on the spinal column, one can equally assume that approximately ⅓ of this load is resisted by the posterior elements yielding approximately 300 N of load, which would be applied to the extra-discal elements described in this test method.

Note that this is only possible for devices that can resist compressive forces. The user must determine the appropriate methodology to exert this axial preload on the device. As an example, the user may design a *Z*-direction axial offset for the position of the axis of rotation such that the device, in its final assembled form, is being compressively loaded with 300 N. Note that other preloads may be appropriate with proper justification. For example, certain devices may be assembled *in vivo* with tensile preload forces; in this case, the application of appropriate tensile forces on the device in the final assembled form on the test blocks would be necessary.

9.2.3 The distance between the simulated endplates of the vertebral bodies shall be 20 mm (**4, 5**)[3] (that is, simulated disc space height) in the final assembled configuration. (See Note 3.) Other distances may be appropriate if justified.

NOTE 3—Assuming a normal distribution of anterior disc space heights in the population, 20 mm is within three standard deviations of the mean and represents an upper limit for anterior intervertebral disc space heights of the reported L4-L5 and L5-S1 intervertebral disc space heights (**4, 5**).

9.3 *Procedure for Static Tests*—Evaluate only the load parameters in the relevant direction.

9.3.1 *Static Flexion Test:*

9.3.1.1 Load the test apparatus with a pure moment (+*Y* rotation) at a rate up to a maximum of 60°/min.