Designation: ~~F2345 – 03 (Reapproved 2013)~~ F2345 – 21

Standard Test Methods for Determination of ~~Static and~~ Cyclic Fatigue Strength of Ceramic Modular Femoral Heads[1]

This standard is issued under the fixed designation F2345; 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 These test methods cover the evaluation of the ~~static and~~ cyclic fatigue strength of ceramic modular femoral heads, mounted on a cone as used on the femoral stem of the total hip arthroplasty.

1.2 These test methods were primarily developed for evaluation of ceramic ~~(Specifications~~(Specification F603~~ and~~, ISO ~~F1873)~~ 6474-1, ISO 6474-2, ISO 13356) head designs on metal cones but may have application to other materials.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 *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~~ safety, health, and ~~health~~environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *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

F603 Specification for High-Purity Dense Aluminum Oxide for Medical Application

~~F1873 Specification for High-Purity Dense Yttria Tetragonal Zirconium Oxide Polycrystal (Y-TZP) for Surgical Implant Applications (Withdrawn 2007)[3]~~

~~F1875 Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface~~

2.2 *Other Documents:*

DIN 4768 Determination of Surface Roughness R_a, R_z, and R_{max} with Electric Stylus Instruments; Basic Data[3]

ISO 6474-1 Implants for surgery—Ceramic materials—Part 1: Ceramic materials based on high purity alumina[4]

~~FDA Guidance Document~~ISO 6474-2 ~~for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems~~

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[1] ~~This~~These test ~~method is~~methods are under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and ~~is~~are the direct responsibility of Subcommittee F04.22 on Arthroplasty.

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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 Beuth Verlag GmbH (DIN—DIN Deutsches Institut fur Normung e.V.), Burggrafenstrasse 6, 10787, Berlin, Germany.

[4] Available from ~~Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857.~~American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

(draftImplants for surgery—Ceramic materials—Part 2: Composite materials based on a high-purity alumina matrix Jan. 10, 1995)with zirconia reinforcement[4]

ISO 7206-10 Implants for surgery—Partial and total hip-joint prostheses—Part 10: Determination of resistance to static load of modular femoral head[4]

ISO 13356 Implants for surgery—Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)[4]

3. Terminology

3.1 *Definitions:Definitions of Terms Specific to This Standard:*

3.1.1 *bore*—conical blind hole in the surface of the modular femoral head.

3.1.2 *bore angle*—included angle of the conical surface of the bore (Fig. 1).

3.1.3 *circularity*—deviations of taper cross section from a perfect circle.

3.1.4 *cone*—the proximal end of the femoral component fabricated as a truncated right cone and metal truncated right-circular cone (male component) used to engage with a mating conical bore (female component) of the modular femoral head.

3.1.5 *cone angle*—included angle of the conical surface of the cone (Fig. 12).

3.1.6 *femoral neck-axis*—centerline or axis of symmetry of the femoral cone.

3.1.7 *head size*—nominal spherical diameter of the head (generally standardized, but not limited to 22, 26, 28, 32, 36, 40, and 3644 mm for total hips.)

3.1.8 *installation load*—the force, applied at 0° from the femoral neck axis,neck-axis and used to settleconnect the head on the coneand neck components prior to testing.

3.1.9 *load axis*—line of action of the compressive force applied to the femoral head.

3.1.10 *load axis angle*—the measured angle "L" between the line of action of the applied force and femoral neck axis (see Fig. 5).

3.1.11 *load magnitude*—the peak (absolute value) compressive force of the applied constant amplitude cyclic force.

3.1.12 *load rate*—rate of applied compressive force.

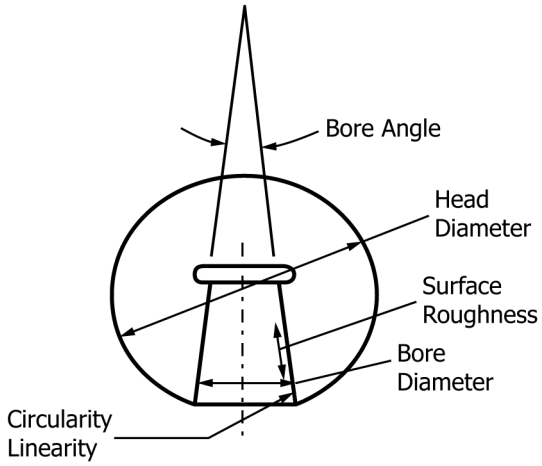

FIG. 1 Geometrical Design Criteria for Modular BallHead

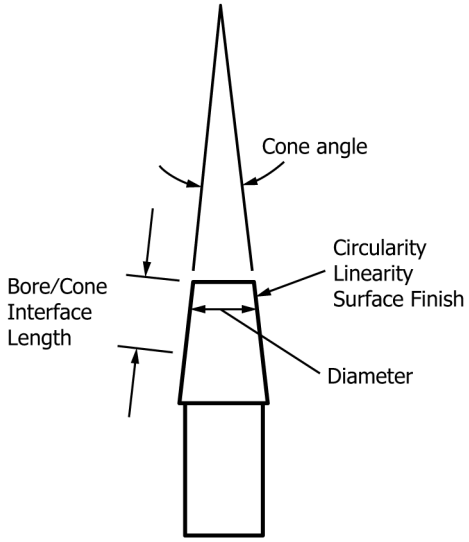

FIG. 2 Geometrical Design Criteria for Mating Conical Fit

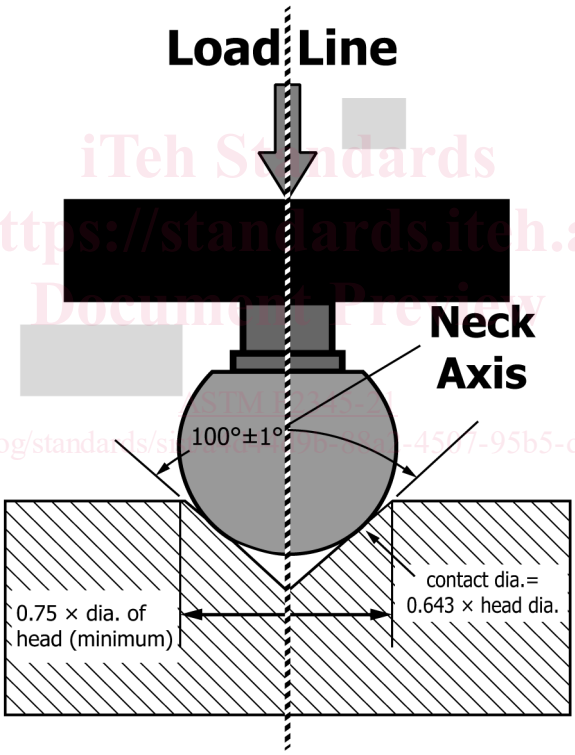

FIG. 3 Loading in a Metal Cone

3.1.13 *stroke rate*—~~the~~nominal rate of ~~the stroke displacement~~movement of the moving component of the ~~force applicator.~~test machine.

3.1.14 *surface finish*—measured roughness of the surface of the taper cone or head bore as determined by DIN 4768.

3.1.15 *test frequency*—the rate of cyclic repetition of fatigue loading in cycles per second.

3.1.16 *THR*—total hip replacement.

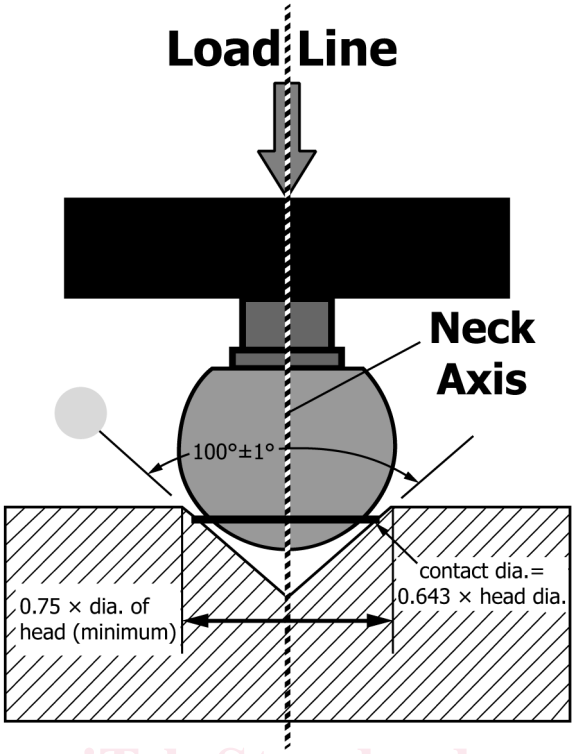

FIG. 4 Loading Through a Copper Ring

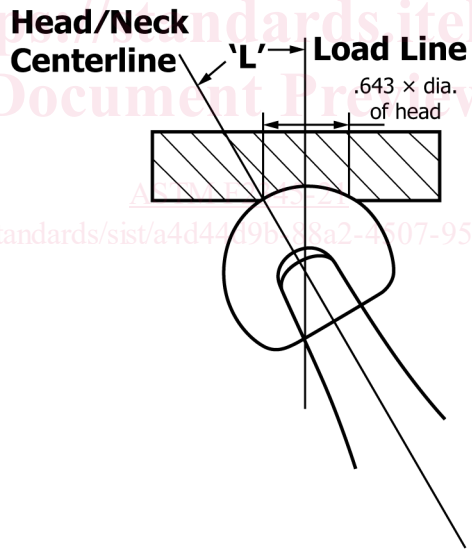

FIG. 5 Pictorial Example of the Load Angle "L"

4. Significance and Use

4.1 These test methods can be used to determine the effects of head and cone materials, design variables, manufacturing, and other conditions on the ~~static and~~ cyclic load-carrying ability of modular femoral heads mounted on the cones of femoral stem prostheses.

4.2 The loading of modular femoral heads *in vivo* will, in general, differ from the loading defined in these methods. The results obtained here cannot be used to directly predict *in-vivo* performance. However, these methods are designed to allow for comparisons between the fatigue performance of different ceramic modular femoral head designs, when tested under similar conditions.

4.3 These test methods may use actual femoral prostheses or neck-cone models of simplified geometry with the same geometrical and material characteristics as in the implants. In either case, the matching metallic cone region of the test specimen selected shall be of the same material, tolerances, and ~~finishing~~finish as the final femoral stem prosthesis.

~~4.3 The static test data may yield valuable information about the relative strengths and merits of different head and cone designs for particular applications. Due to the high forces anticipated for this type of destructive test (>40 kN), the boundary conditions and load levels far exceed possible *in vivo* loading parameters and therefore may not necessarily be applicable as a quantitative indicator of expected *in vivo* device performance.~~

4.4 In the fatigue test methods, it is recognized that actual loading *in vivo* is quite varied, and that no one set of experimental conditions can encompass all possible variations. Thus, the test methods included here represent a simplified model for the purposes of comparisons between designs and materials. These test methods are intended to be performed in ~~air.~~physiological solution.

4.5 The test data may yield valuable information about the relative strengths of different head and cone designs.

5. Apparatus

5.1 The loading fixtures should be capable of sustaining static forces up to the anticipated fracture level. The ~~static loading fixtures may require load capacity up to 200 kN in some circumstances. The~~ fatigue tests should use fixtures with fatigue load capacity up to 50 kN.

5.2 The fixtures shall be constructed so that the line of force application passes through the center of the femoral head.

5.3 Due to the high forces anticipated in this type of cyclic, potentially destructive test, appropriate shielding of the modular ball test site is recommended.

6. Equipment Characteristics

6.1 ~~Generally, the static tests should be performed on either mechanical (power screws) or hydraulic (servo-hydraulic) load frames with adequate load capacity (up to 200 kN).~~ The fatigue tests should generally be performed on hydraulic (servo-hydraulic) load frames with adequate load capacity (up to 50 kN). The test equipment should meet the requirements outlined in Practices E4.

6.2 The varying force, as determined by suitable dynamic verification, should be maintained at all times to be within ±2 % of the largest compressive force being used for the duration of the test.

7. Procedure

7.1 *Sample Characterization:*

7.1.1 Femoral heads and cones shall be characterized by the manufacturer and shall fulfill the manufacturer's requirements of actual implants, according to 6.1 and 6.3 of ISO 7206-10.

7.2 *Sample Assembly:*

7.2.1 Following normal laboratory cleaning procedures to remove any debris or other surface contaminants, the head and cone are assembled on a suitable test machine. A suggested procedure for cleaning and drying of the specimens is given in Appendix X1. Any cleaning procedures used should be consistent with typical manufacturing practices.

~~7.1.2 The stem taper cones are mounted at 0° load angle (L = 0°). An assembly force of 2 kN is used to mount the femoral ball and achieve a standard head/cone reference position prior to all tests.~~

7.2.2 ~~Pre-assembly of the head on the taper should be conducted under stroke or load control at a rate that will consistently produce the required 2 kN assembly load with less than 50 N of overshoot. One of the following loading conditions for assembly is suggested:~~Follow the assembly procedure according to 7.2 of ISO 7206-10.

~~7.1.3.1 A loading rate of 500 N/s ± 100.~~

~~7.1.3.2 A stroke rate of 0.04 mm/s.~~

7.3 *General Test Requirements:*

7.3.1 The tests are performed at ~~room temperature in air.~~37 °C in physiological solution (for example, Ringer's solution). The tests can be performed at room temperature, if it is shown that such temperature change does not influence the test results significantly. Several weeks of soaking components made from inorganic materials like metal alloys or ceramics in physiological solution is not necessary.

7.3.2 New test cones and femoral heads shall be used for each test. Note that it is imperative that components that survive the test should not be used for clinical purposes after testing.

7.3.3 The load axis angle "L" shall be maintained within ±1° for all test samples.

NOTE 1—Precautions should be taken to protect the test operator from injury by fragments should the specimen shatter when under load or when disassembling or when storing the specimen after removal of the force from unfractured specimens.

~~*7.3 Static On Axis Test Method:*~~

~~7.3.1 The load axis angle "L" is 0°.~~

~~*7.3.2 Number of Test Specimens*—A minimum of five specimens is recommended for a test group.~~

~~7.3.3 The femoral head may be loaded through a hardened (minimum 150 HB) metal 100 ± 1° cone with a minimum surface diameter of 0.75 times the head diameter (Fig. 3) or alternatively, the contact surface may be protected by means of a copper ring (Fig. 4). A suggested minimum thickness for the copper ring is 1.25 mm and it should extend about 2.25 mm on either side of the contact diameter. The diameter of contact for the applied force should be approximately 0.643 times the head size.~~

~~7.3.4 The conical metal loading fixture may be damaged if the test fractures the sample. It shall be examined after each test fracture and be discarded if damaged. If a copper ring is used for the contact, a new ring shall be used for each test.~~

~~7.3.5 Use of one of the following loading conditions are recommended:~~

~~7.3.5.1 Position control with a stroke rate of 0.04 mm/s (0.0015 in./s) or,~~

~~7.3.5.2 Load control with a loading rate of 1 kN/s (224.8 lb/s) or less.~~

7.4 ~~*On Axis*~~ *On-Axis Fatigue Test Method:*

7.4.1 The maximum test frequency shall not exceed 30 Hz.

7.4.2 The load axis angle "L" is ~~0°.~~0 ± 1°.

7.4.3 *Number of Test Specimens*—A minimum of five specimens is recommended for a test group.

7.4.4 The femoral head may be loaded through a hardened metal 100 ± 1° cone (Fig. 3) or alternatively, the contact ring may be protected by means of a copper ring (Fig. 4~~). A suggested minimum thickness for the copper ring is 1.25 mm and it should extend about 2.25 mm on either side of the contact diameter. The diameter of contact for the applied force should be the head diameter multiplied by the cosine of 50° or 0.643 times the head diameter.~~) in accordance with ISO 7206-10.

7.4.5 The conical metal loading fixture may be damaged if the test fractures the sample. It should be examined after each test fracture and be discarded if damaged. If a copper ring is used for the contact surface, a new ring should be used for each ~~test.~~test specimen.

7.4.6 The fatigue force shall have a sinusoidal waveform applied from the force magnitude to a minimum that is 10 % of the load magnitude.

7.4.7 The cyclic forces should be applied until 10 million cycles without failure of the components or until fracture has occurred.

7.5 ~~*Off Axis*~~ *Off-Axis Fatigue Test Method:*

7.5.1 The maximum test frequency shall not exceed 30 Hz.

7.5.2 The load axis angle "L" is ~~30°.~~30 ± 1°.

7.5.3 A polymeric spherical concave component with the same segment diameter ~~as suggested in~~0.643 times the ~~7.4.3~~head diameter should be used (Fig. 5). The segment diameter should not change during the test.

7.5.4 The fatigue force shall have a sinusoidal waveform applied from the force magnitude to a minimum that is 10 % of the load magnitude.

7.6 *Post-Fatigue Burst Test Method:*

7.6.1 Following the on-axis fatigue test or off-axis fatigue test, respectively, a burst test according to ISO 7206-10 in air and at ambient conditions shall be performed to determine the static strength of the femoral heads remaining after the cyclic fatigue loading.

NOTE 2—The post-fatigue burst test should be done within a reasonable time interval (for example, one or two days) after the fatigue test loading has been completed.

8. Report

8.1 The ~~minimum required~~ report shall identify the manufacturer(s), head size, femoral head material, the definition of failure used in the test, the cone material, and the description of the cone and taper geometries.

8.2 The report shall also describe the test ~~equipment and all test parameters.~~method, test frequency, the peak force, the load axis angle "L," load amplitude, and a description of the loading contact for each sample. The report shall also contain information about the time interval between the fatigue test and the post-fatigue burst test.

~~8.2.1 For the static test, the control mode, the loading rate, and a description of the loading contact.~~

~~8.2.2 For the fatigue tests, the test frequency, the peak force, the load axis angle "L," load amplitude, and a description of the loading contact for each sample.~~

8.3 *Test ~~Results:~~ Results—*

~~8.3.1 For the static test, the maximum failure force for each sample is required. Reporting of the mean failure force, standard deviation, and range is also recommended.~~The number of cycles completed by the sample and whether the sample failed. A statement justifying the number and kinds of samples should be included.

~~8.3.2 For the fatigue test methods, the number of cycles completed by the sample and whether the sample failed. A statement justifying the number and kinds of samples should be included (FDA Guidance Document).~~

8.4 Additional optional information characterizing the bore and cone dimensions and tolerances (Figs. 1 and 2) would be desirable to better interpret the test results. This information may include, but is not limited to the following: cone type, head bore angle, head bore major/minor diameters, bore surface roughness (R_a, R_z per DIN 4768), cone angle, cone diameter, cone surface roughness (R_a, R_z per DIN 4768), length of mating interface between the bore and cone, and method of femoral ball sterilization.