Designation: F2345 – 21

Standard Test Methods for Determination of 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 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 (Specification F603, ISO 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, health, and 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

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]

ISO 6474-2 Implants for surgery—Ceramic materials—Part 2: Composite materials based on a high-purity alumina matrix 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 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*—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. 2).

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 44 mm for total hips.)

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

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

Current edition approved May 1, 2021. Published June 2021. Originally approved in 2003. Last previous edition approved in 2013 as F2345 – 03 (2013). DOI: 10.1520/F2345-21.

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

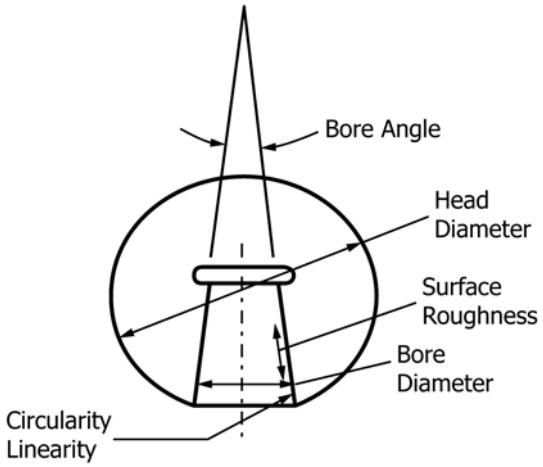

FIG. 1 Geometrical Design Criteria for Modular Head

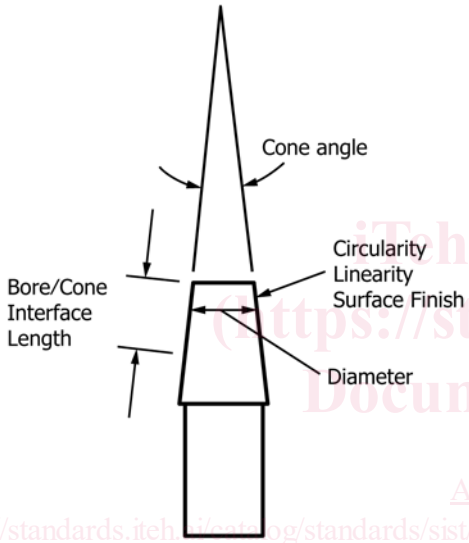

FIG. 2 Geometrical Design Criteria for Mating Conical Fit

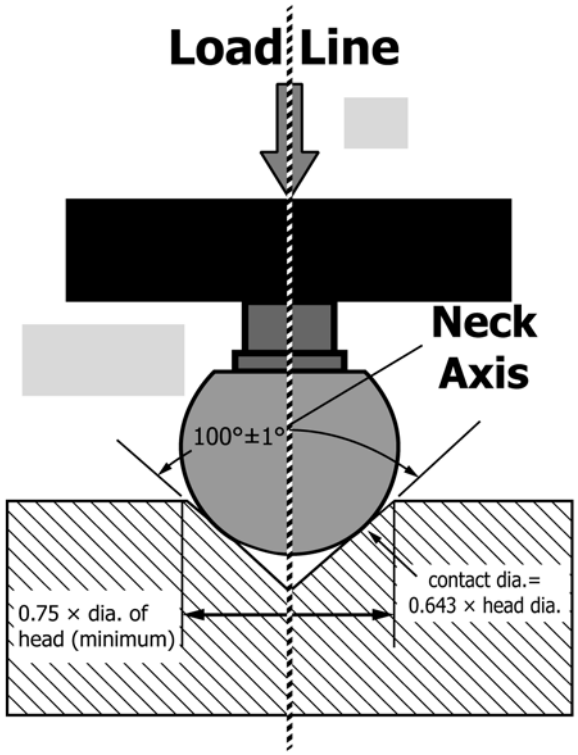

FIG. 3 Loading in a Metal Cone

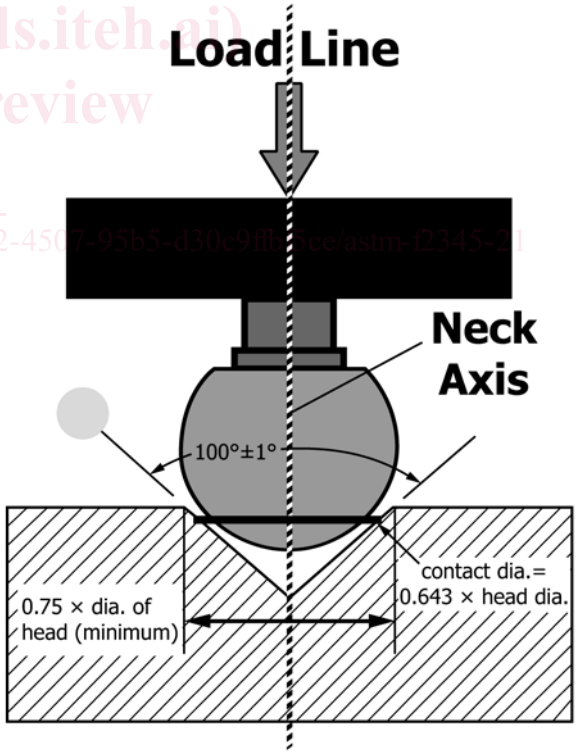

FIG. 4 Loading Through a Copper Ring

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.

3.1.13 *stroke rate*—nominal rate of movement of the moving component of the 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.

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 cyclic load-carrying ability of modular femoral heads mounted on the cones of femoral stem prostheses.

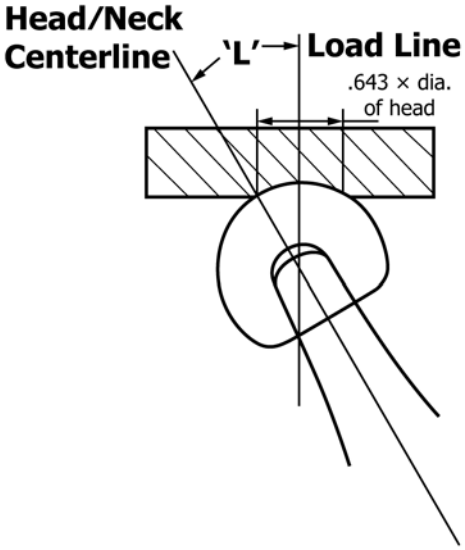

FIG. 5 Pictorial Example of the Load Angle "L"

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 finish as the final femoral stem prosthesis.

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 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 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 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.

7.2.2 Follow the assembly procedure according to 7.2 of ISO 7206-10.

7.3 *General Test Requirements:*

7.3.1 The tests are performed at 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.

7.4 *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 ± 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) 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 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 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 ± 1°.

7.5.3 A polymeric spherical concave component with the same segment diameter 0.643 times the 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 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 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.

8.3 *Test Results*—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.

8.4 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.

9. Precision and Bias

9.1 *Precision*—It is not possible to have a precision statement because there is not a standard implant available to all users of the test method to develop such a statement. Additionally, it is not possible to specify the precision of the procedure in this test method because of the wide variance in design of the components to be tested.

9.2 *Bias*—No statement can be made as to the bias of this test method since no acceptable reference values are available.

10. Keywords

10.1 bore; ceramic; cone; fatigue; modular head; static; strength

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 Modular or interchangeable femoral heads have been used in various THR designs since approximately 1970. This concept provides several features to suit the patient as planned pre-operatively or selected intra-operatively by the surgeon, or both, such as component material, neck length, or head diameter, or combinations thereof.

X1.2 The alumina ceramic (Specification F603)-metal friction lock fit has been used for head diameters 32 mm and 28 mm in Europe from 1973 onwards and in Japan from 1977 onwards, respectively. Zirconia ceramic (ISO 13356)-metal friction lock fit has been used for head diameters 32 mm, 28 mm, 26 mm, and 22 mm in Europe from 1985 onwards and in the USA from 1989 onwards.

X1.3 In general, the potential complications of modular femoral heads could be as follows: fracture of the femoral head; dislocation of head from cone; wear of cone due to loosening/rotation of head; and fracture of cone.

X1.3.1 Complications such as fracture of the ceramic head have been rare in over one million cases in Europe. Boutin **(1)**[5] reported two alumina ceramic heads and four cup fractures out of the first 373 cases performed from 1970 to 1973. The head fractures occurred with ceramic head/ceramic cup combinations, but since 1972 there have been no other head fracture cases **(1)**. A survey of clinical literature **(2)** from 1974 to 1980 for modular alumina ceramic heads revealed 23 ceramic head fractures in the eight clinical publications reported.

X1.3.2 In Japan, there have been zero head fractures reported in the literature for 28 mm alumina ceramic heads **(3)**. In Canada, Cameron **(4)** reported three ball fractures in a series of 600 cases. One occurred as a result of an autoclaving incident, one was due to high-speed trauma, and one case

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