



Designation: F 2345 – 03

# Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads<sup>1</sup>

This standard is issued under the fixed designation F 2345; 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 ( $\epsilon$ ) 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 F 603 and F 1873) 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 the 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 and health practices and determine the applicability of regulatory limitations prior to use.*

## 2. Referenced Documents

### 2.1 ASTM Standards:<sup>2</sup>

- E 4 Practices for Force Verification of Testing Machines
- F 603 Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application
- F 1873 Specification for High-Purity Dense Yttria Tetragonal Zirconium Oxide Polycrystal (Y-TZP) for Surgical Implant Applications
- F 1875 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<sup>3</sup>
- FDA Guidance Document for the Preparation of Premarket

<sup>1</sup> 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 F04.22 on Arthroplasty.

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<sup>2</sup> 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.

<sup>3</sup> Available from Beuth Verlag GmbH (DIN—DIN Deutsches Institut für Normung e.V.), Burggrafenstrasse 6, 10787, Berlin, Germany.

Notifications for Ceramic Ball Hip Systems (draft Jan. 10, 1995)<sup>4</sup>

## 3. Terminology

### 3.1 Definitions:

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

3.1.2 *cone*—the proximal end of the femoral component fabricated as a truncated right cone and used to engage with a mating conical bore of the modular femoral head.

3.1.3 *cone angle*—included angle of cone (Fig. 1).

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

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

3.1.6 *installation load*—the force, applied at 0° from femoral neck axis, used to settle the head on the cone prior to testing.

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

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

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

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

3.1.11 *stroke rate*—the rate of the stroke displacement of the force applicator.

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

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

3.1.14 *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,

<sup>4</sup> Available from Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857.

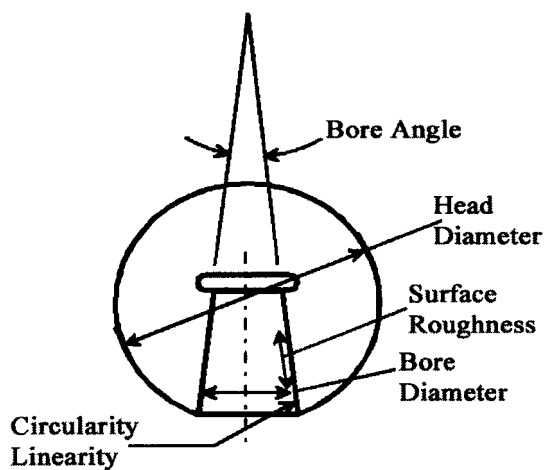


FIG. 1 Geometrical Design Criteria for Modular Ball

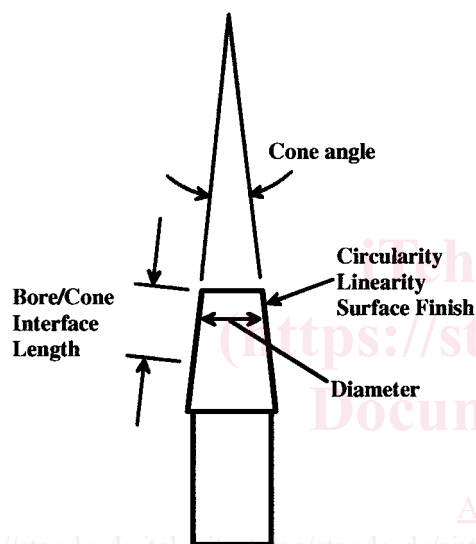


FIG. 2 Geometrical Design Criteria for Mating Conical Fit

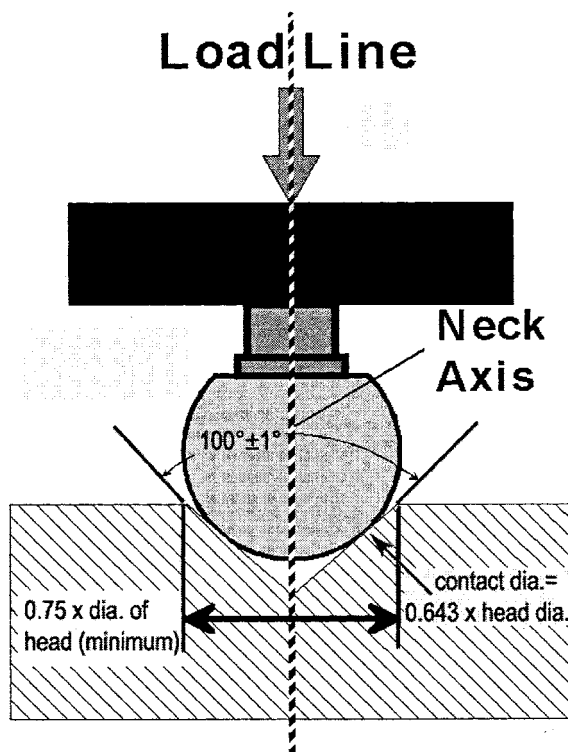


FIG. 3 Loading in a Metal Cone

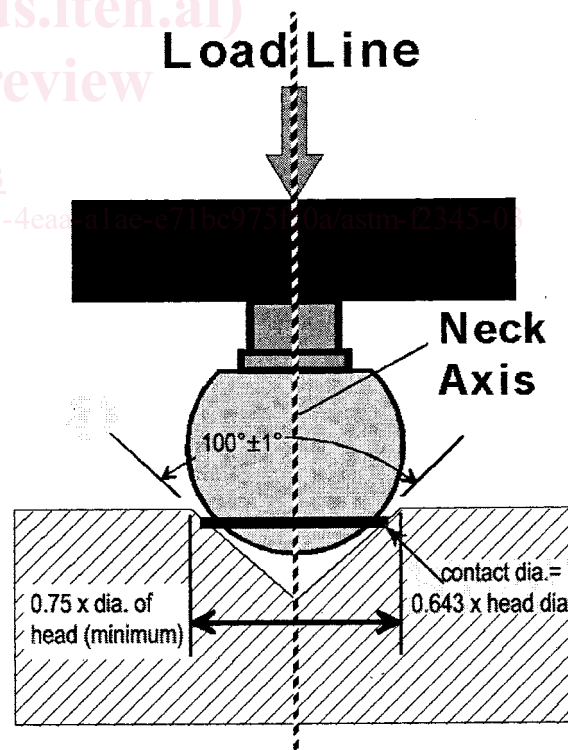


FIG. 4 Loading Through a Copper Ring

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 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 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.

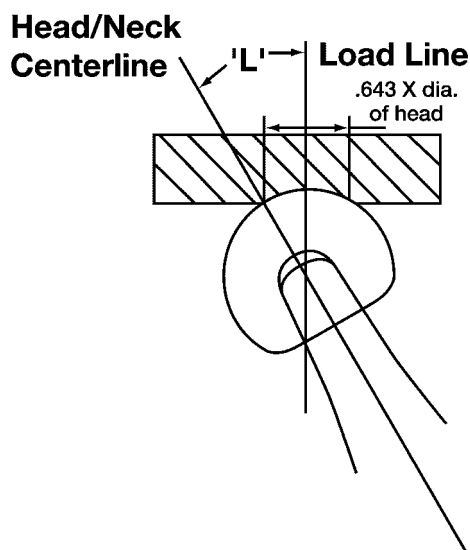


FIG. 5 Pictorial Example of the Load Angle “L”

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 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, 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 E 4.

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

## 7. Procedure

### 7.1 Sample Assembly:

7.1.1 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  $0^\circ$  load angle ( $L = 0^\circ$ ). 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.

7.1.3 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:

7.1.3.1 A loading rate of  $500 \text{ N/s} \pm 100$ .

7.1.3.2 A stroke rate of  $0.04 \text{ mm/s}$ .

### 7.2 General Test Requirements:

7.2.1 The tests are performed at room temperature in air.

7.2.2 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.

7.2.3 The load axis angle “L” shall be maintained within  $\pm 1^\circ$  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  $0^\circ$ .

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  $100 \pm 1^\circ$  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  $0.04 \text{ mm/s}$  ( $0.0015 \text{ in./s}$ ) or,

7.3.5.2 Load control with a loading rate of  $1 \text{ kN/s}$  ( $224.8 \text{ lb/s}$ ) or less.

### 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  $0^\circ$ .

7.4.3 The femoral head may be loaded through a hardened metal  $100 \pm 1^\circ$  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  $50^\circ$  or 0.643 times the head diameter.

7.4.4 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.

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

7.4.6 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°.

7.5.3 A polymeric spherical concave component with the same segment diameter as suggested in 7.4.3 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.

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.

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:* [s.teh.ir/catalog/standards/sis/c18fc863-b77c-484c-9000-000000000000](https://standards.sis.teh.ir/catalog/standards/sis/c18fc863-b77c-484c-9000-000000000000)

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.

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.

9. Precision and Bias

9.1 *Precision*—For a destructive test, wherein replicate measurements cannot be made on a single test sample, disagreement between replicate measurements on different samples includes actual part-to-part variability in the property being measured as well as methodological imprecision. It is impossible to design an experiment that can separate these factors. Thus, any statements regarding precision include both factors.

9.1.1 The precision and bias of these test methods need to be established. Test results that can be used to establish precision and bias are solicited.

9.1.2 The following data are offered for guidance. A total of 32 nominally identical alumina heads (28-mm diameter,  $12/14$ -mm modular taper), representing four different manufacturing lots, were tested for static ultimate compressive strength (UCS) when attached to Ti6Al4V tapers, by a single laboratory. The data are summarized as follows:

Lot Designation	Sample Size	Maximum UCS kN	Minimum UCS kN	Mean UCS kN	Std. Deviation kN (% of mean)
1	10	57	49	53.4	2.5 (4.7 %)
2	8	62	54	57.2	2.4 (4.2 %)
3	10	64	46	56.2	5.7 (10.1 %)
4	4	58	54	56.5	1.7 (3.0 %)

9.1.3 For these four sets of data, one can estimate the weighted repeatability standard deviation as 6.0 % of mean UCS. Phrased differently, the experience from this one laboratory would indicate that any two measurements at the same laboratory would be expected to differ by more than 23.7 % of their mean value no more than one time in 20.

10. Keywords

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