Designation: F 2345 – 03

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 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 (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 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:* [2]

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[3]

FDA Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems (draft Jan. 10, 1995)[4]

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,

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[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 F04.22 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.

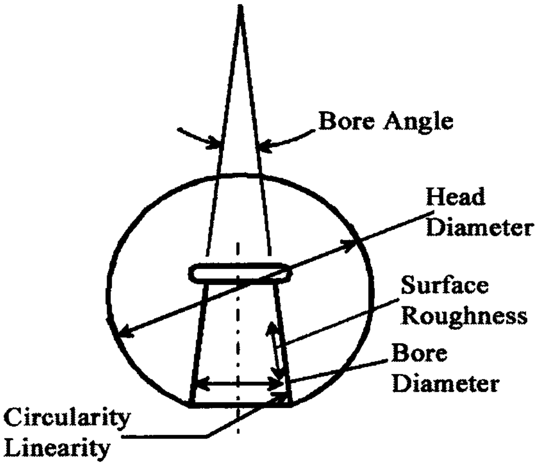

FIG. 1 Geometrical Design Criteria for Modular Ball

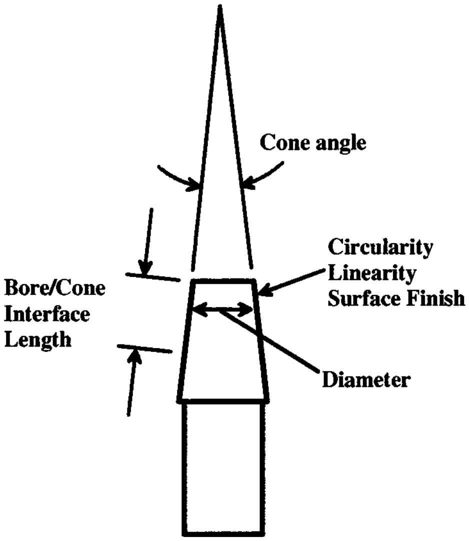

FIG. 2 Geometrical Design Criteria for Mating Conical Fit

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.

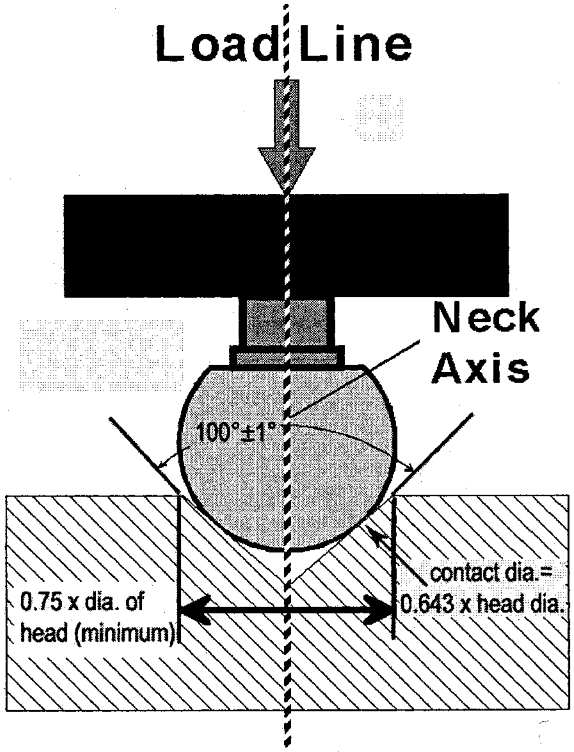

FIG. 3 Loading in a Metal Cone

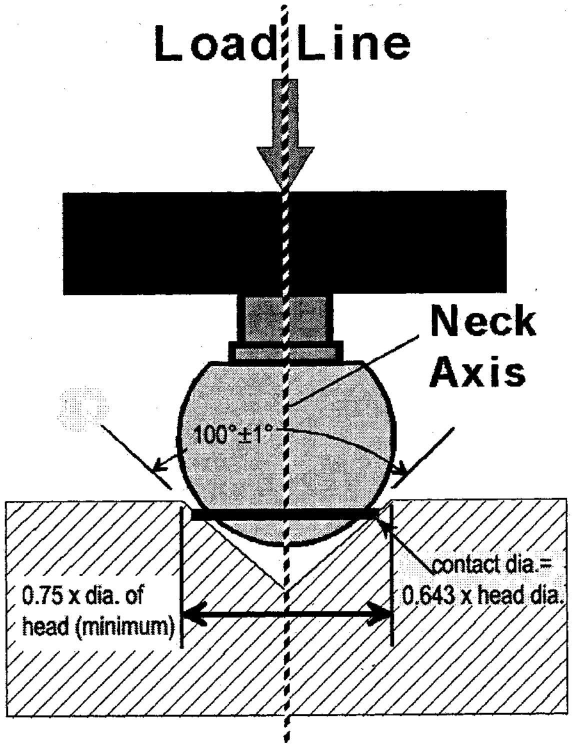

FIG. 4 Loading Through a Copper Ring

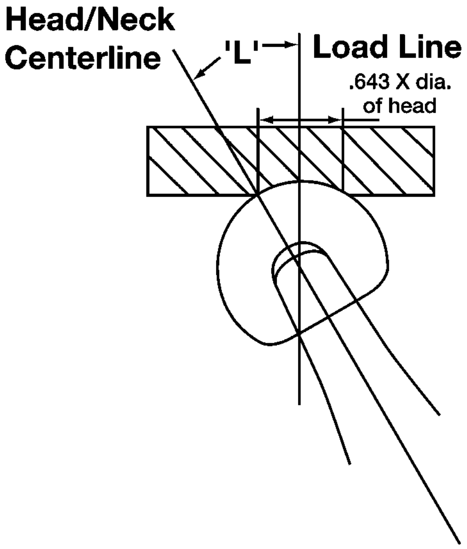

FIG. 5 Pictorial Example of the Load Angle "L"

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 ±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° 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.

7.1.3 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 N/s ± 100.

7.1.3.2 A stroke rate of 0.04 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 ±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 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°.

7.4.3 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.

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*:

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	Minimum UCS	Mean UCS	Std. Deviation
		kN	kN	kN	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

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-lengths, or head diameters, or combination thereof.

X1.2 The alumina ceramic (Specification F 603)-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 (Specification F 1873)-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, respectively.

X1.3 In general, the potential complications of modular femoral heads could be as follows:

Fracture of femoral head
Dislocation of head from cone
Wear of cone due to loosening/rotation of head
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 revealed no obvious reason. Thus the fracture incidence appeared to be 1 in 600 cases or 0.16 % in this series.

X1.3.3 There were additional problems with an early European design that involved epoxy fixation of 32 mm alumina modular femoral head to the femoral stem. Boutin **(1)** used this concept from April 1970 onwards and reported 28 heads out of his initial 123 clinical cases separated from the stems due to degradation of the epoxy.

X1.3.4 There are very few reports of fractures of zirconia heads. C. Hummer et. al **(5)** reported two cases of 28 mm zirconia head fractures of a total of 189 ceramic heads (1.05 % fracture rate), without a clearly established origin, although in one case the patient fell.

X1.3.5 A series of 10 ruptures of zirconia heads were reported by J. P. Arnaud et al **(6)**, all from the same 22 mm head design. This series of ruptures seem to be due to the inappropriate fit between the head and taper. The angle of the head bore was smaller than the angle of the metallic taper.

X1.3.6 A detailed survey for one zirconia head source was published by Cales **(7)** concerning 280 000 implanted heads between 1985 and 1994. Most of the observed fractures were related to abnormal conditions of use, mainly trauma and implantation of zirconia heads on non-revised tapers. The total failure rate, based on the reported cases, is 0.01 %.

X1.4 A load axis angle “L” of 10 to 45° with a hip force in the 2 to 3 kN range is generally considered physiological. At an orientation of L = 0°, modular femoral heads may take up to 40 to 250 kN force before failure can occur. Clearly forces of this magnitude are not possible at anatomic orientations, because the neck of the femoral stem will either bend or break. However, the non-symmetrical loading of the modular head can change the stress states in the modular head, which could change the response of the modular head. Consequently, it may be desirable to evaluate the fatigue strengths of some modular head designs at anatomic forces in an off axis orientation.

X1.4.1 The 30° angle specified for “L” may not be intuitive for all users familiar with other standard “anatomic” test orientations. 30° was preferred for this test as it is well within the applicable physiological range of orientation and it permits for higher applied test forces without compromise of the implant neck.

X1.5 These test methods are intended to evaluate the mechanical strength of the combination of material and design in a modular ceramic head under single loads to fracture and fatigue loads. They are not intended to evaluate the sensitivity of the ceramic materials to a simulated physiological environment. If the material does not have a long established clinical history, other methods will be required to evaluate such sensitivity.

X1.6 For repeatability and reproducibility, a 2 kN static installation force is used to seat the balls on their tapered seat in this laboratory test. The 2 kN static force is arbitrary. Although impact forces are usually used clinically to mount the head, such forces vary widely based on surgeon preference and surgical site. In addition providing repeatable impact forces in a laboratory is difficult and may be beyond the capability of many laboratories. The 2kN force represents a lower bound of the mounting forces that could be encountered clinically.

X1.7 The hard bearing utilized in the axial test method may create a surface stress state in the head that deviates from the state created with a polymeric bearing surface. FEA studies have confirmed this but indicate that stresses in the critical areas, where fractures initiate, are unaffected. Use of the hard bearing is necessary to accommodate the high forces attainable

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

in axial tests. It is a compromise between the desire to imitate representative loading conditions and the limits of available engineering materials. The hard bearing method has been used by many manufactures and is generally accepted as a reasonable method to evaluate the strength of ceramic femoral heads.

X1.8 Often static tests to fracture are performed after fatigue testing. Users of these test methods should be aware that samples that have survived axial tests have been known to fracture catastrophically after removal from the test machine. Although rare, such fractures can occur at any time post-test. Therefore, for safety reasons, it is recommended that post fatigue test samples be handled carefully with shielding between the end of the fatigue testing and the static test to fracture. If the sample fractures during this transition, it should be reported. If the samples are not static tested to destruction, they should be disassembled or stored in closed containers.

X1.9 Occasionally, during a static axial test, the fragments of the head may be trapped within the fixturing and continue to bear forces without significant indication of the moment of fracture. Careful monitoring of the test may be necessary to identify such occurrences and correctly identify the static strength.

X1.10 The test frequency limit of 30 Hz is arbitrary based on the general experience of one laboratory. It was found that at frequencies higher than 30 Hz, it was more difficult to maintain a smooth stable load wave form. In addition, some older mechanical rotating eccentric test machines that might be suitable for this test operate at a fixed 30 Hz frequency.

X1.11 For new material containing zirconia, there have been cases of changes in the long-term stability of the tetragonal phase that leads to decrease in the mechanical properties. It has been shown that two types of pretreatment followed by the fatigue test can demonstrate if this is a problem **(8, 9)**. The first method is to steam autoclave for 5 h at 134°C and two bars of pressure. The second method is exposure to boiling water for 15 h. Either of these are purported to represent approximately 10 years of *in vivo* exposure.

X2. METHOD FOR CLEANING OF SPECIMENS

X2.1 Rinse with tap water to remove bulk contaminants.

X2.2 Wash in an ultrasonic cleaner in a solution of 1 % detergent for 15 min.

X2.3 Rinse in a stream of distilled water.

X2.4 Rinse in an ultrasonic cleaner in distilled water for 5 min.

X2.5 Rinse in a stream of distilled water.

X2.6 Allow to air dry.

X3. DESIGN AND USAGE OF COPPER RING BASED FIXTURES

X3.1 Use of a copper ring bearing surface on the conic bearing block provides an alternative to the hardened bearing surface. Multi-use fixtures are subject to damage, which can affect subsequent samples if not detected. Use of a disposable bearing surface removes a potential complicating variable in ceramic head testing.

X3.2 The recommended copper ring may be fabricated from common sheet material with a minimum thickness of 1.25 mm. The selected material should be a relatively soft and ductile grade of copper or copper alloy.

X3.3 The recommended dimensions for the copper ring are shown in Fig. X3.1. The rings are designed for use with a mating fixture fabricated based on the design in Fig. X3.2. The outer dimension of the ring should be 0.643 × head diameter + 2.25 mm. The inner diameter should be 0.643 × head diameter − 2.25 mm. The ring edges and face should be smooth and burr free.

X3.4 The copper ring is fabricated as a flat and fits in the recess in the bearing fixture. As force is applied to the sample, the ring will deform into the machined groove in the fixture, conforming to the surfaces of the head and the fixture.

X3.5 On completion of the test, the copper ring should be removed and discarded.

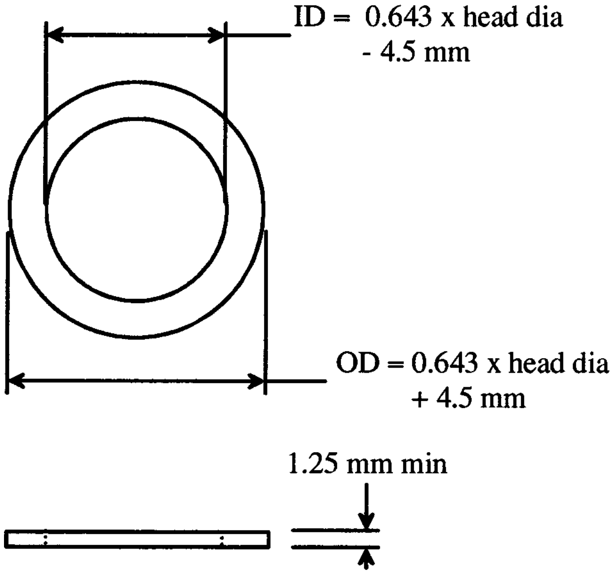

FIG. X3.1 Copper Ring for Use in Ceramic Head Tests

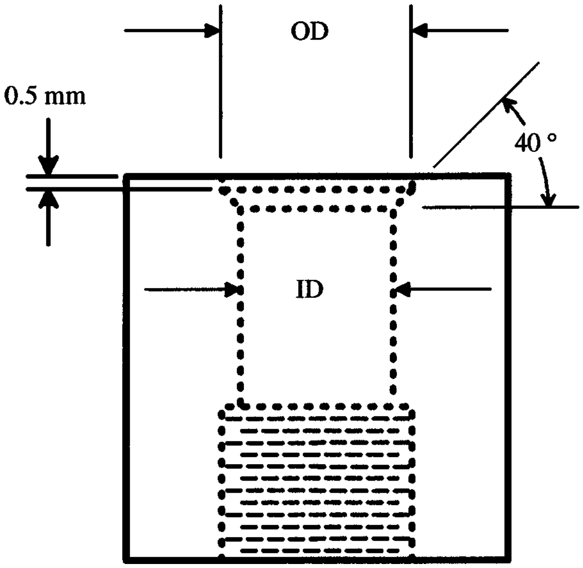

FIG. X3.2 Suggested Design of the Head Bearing Fixture for Use With a Copper Ring

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