Designation: F 2009 – 00

Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses[1]

This standard is issued under the fixed designation F 2009; 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 establishes a standard methodology for determining the force required, under laboratory conditions, to disassemble tapers of implants that are otherwise not intended to release. Some examples are the femoral components of a total or partial hip replacement or shoulder in which the head and base component are secured together by a self-locking taper.

1.2 This test method has been developed primarily for evaluation of metal and ceramic head designs on metal tapers but may have application to other materials and designs.

1.3 *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:*

E 4 Practices for Force Verification of Testing Machines[2]

F 1636 Specification for Bores and Cones for Modular Femoral Heads[3]

3. Summary of Test Method

3.1 The axial disassembly test method provides a means to measure the axial locking strength of the taper connection for modular prostheses.

3.2 Following assembly, an axial tensile force is applied to disassemble the taper connection and the maximum force is recorded.

4. Significance and Use

4.1 This test method helps to assess the axial locking force of a modular taper. Examples of these devices are described in Specification F 1636. Some types of devices that may utilize this type of connection are the modular shoulder and modular hip prostheses. Additional means of evaluating the locking mechanisms of tapers may be appropriate, depending upon the design of the device.

4.2 This test method may not be appropriate for all implant applications. The user is cautioned to consider the appropriateness of the practice in view of the materials and design being tested and their potential application.

4.3 While this practice may be used to measure the force required to disengage tapers, any comparison of such data for various component designs must take into consideration the size of the implant and the type of locking mechanism evaluated.

5. Apparatus

5.1 The cone portion of the assembly shall be constrained by suitable fixtures that can sustain high loads.

5.2 The fixtures shall be constructed so that the line of load application is aligned with the axes of the male and female taper components within ±1°.

5.2.1 For example, modular heads may be assembled by a solid metal 100° cone as shown in Fig. 1. The cone should provide line contact around the diameter of the head.

5.2.2 For example, modular heads may be disassembled with a metal cage that surrounds the head and provides even contact around the inferior edge of the head as shown in Fig. 2.

5.3 The testing machine shall conform to the requirements of Practices E 4. The loads used to determine the attachment strength shall be within the range of the testing machine as defined in Practices E 4.

5.4 The test machine should be capable of delivering a compressive and tensile force at a constant displacement rate. The test machine should have a load monitoring and recording system.

6. Sampling and Test Specimens

6.1 The male and female taper components can be finished implants or they can be simplified test specimens. The test specimens must have tapers manufactured to the specifications of a finished implant including material and preferably manufactured with the same equipment.

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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] *Annual Book of ASTM Standards*, Vol 03.01.

[3] *Annual Book of ASTM Standards*, Vol 13.01.

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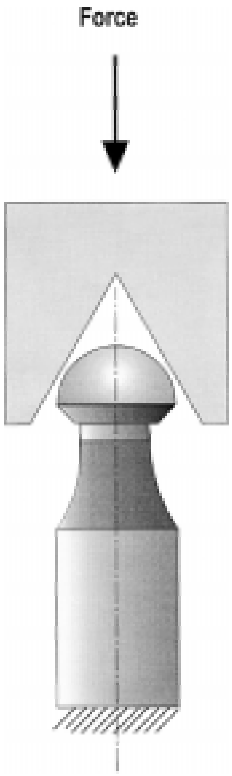

FIG. 1 Modular Head Assembly

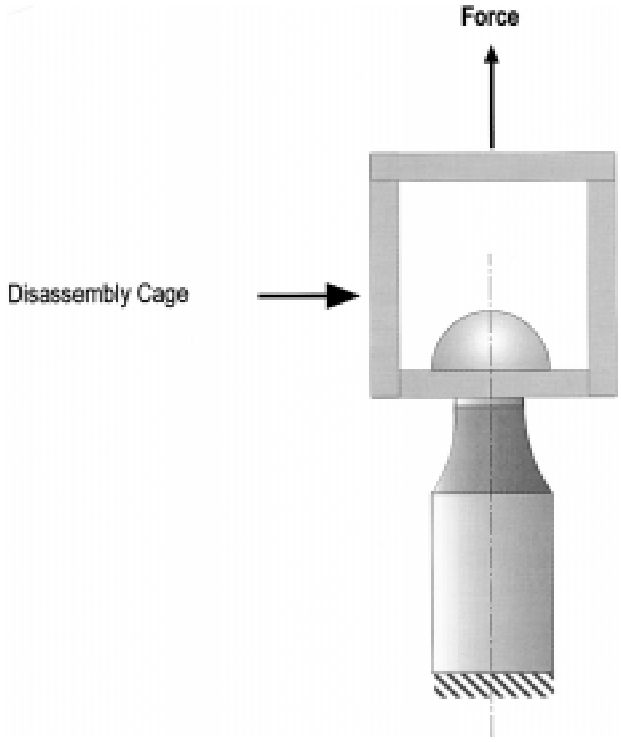

FIG. 2 Modular Head Disassembly

6.2 The supporting material around the female taper must be similar in size and shape to the finished implant.

6.3 A minimum of five taper assemblies shall be tested to determine the axial disassembly force between the tapered components. Pairing of the components shall be random unless otherwise reported. The appropriateness of performing multiple tests on the same taper connection will depend on the design and application of the device.

6.4 Sterilization of test components is not required unless it has known effects on the parts being evaluated. Generally, sterilization does not have an effect on metallic materials.

7. Procedure

7.1 Following normal laboratory cleaning procedures to remove any debris or other surface contaminants, the taper components are assembled on a suitable test machine. A suggested procedure for cleaning and drying of the specimens is given in Appendix X1.

7.2 Each specimen should be characterized prior to testing. This information may include, but is not limited to the following: material, hardness, bore and taper diameters, concentricity, surface roughness, taper angle, and length of engagement.

7.3 Tapers can be assembled using two methods. Depending on the intended use, the user may use the assembly method that best suits the taper application.

7.3.1 *Constant Rate Assembly Method*—A 2 kN peak static load is applied to the taper component along the long axis of the taper within ± 1°; the load may be applied using a constant displacement rate until the maximum load (2 kN) is achieved. A suggested displacement rate is 0.05 mm/s.

7.3.2 *Drop Weight Assembly Method*—The two components may be assembled with an impact load, that is, a 907-g weight dropped from a 254-mm height.

7.4 *Disassembly Procedure*—The taper assembly should be placed in appropriate fixtures in a qualified test machine. The fixture should be capable of maintaining the load axis angle to within ±1°. Special care should be taken to ensure that no artificial hoop stresses or bending moments are placed on the taper assembly while disassembling the tapers. A displacement rate of 0.05 mm/s may be used. The load and displacement should be recorded continuously until the test is terminated.

7.5 Testing of each specimen shall be terminated when the disassembly load drops by at least 90 % of the peak load.

8. Report

8.1 The test report shall include the following:

8.1.1 The device name, materials, assembly method, load versus displacement graph, sample size, and manufacturer and lot number, if applicable. Additional information pertaining to the drop weight method is desirable and may include, but is not limited to the following: description of the drop weight apparatus, drop weight mass, drop height.

8.1.2 Maximum load required to disassemble the tapers.

8.1.3 The displacement rate if the constant rate method is used.

8.1.4 Additional information characterizing each test specimen prior to testing is desirable to better interpret the test results. This information may include, but is not limited to the following: material, hardness, bore and taper diameters, concentricity, surface roughness, taper angle, and length of engagement.

9. Precision and Bias

9.1 No information can be presented on the precision and bias of this test method for measuring the axial disassembly force of tapers because no material having an accepted reference value is available.

10. Keywords

10.1 arthroplasty; disassembly; heads; hip prosthesis; modular; shoulder prosthesis; tapers

APPENDIXES

(Nonmandatory Information)

X1. METHOD FOR CLEANING SPECIMENS

X1.1 Rinse with tap water to remove bulk contaminants.

X1.2 Wash in ultrasonic cleaner in a solution of 1 % detergent for 15 minutes.

X1.3 Rinse in a stream of diluted water.

X1.4 Rinse in an ultrasonic cleaner of distilled water for 5 minutes.

X1.5 Rinse in a stream of distilled water.

X1.6 Allow to air dry at room temperature.

X2. RATIONALE

X2.1 It is not the intent of this method to specifically address the locking mechanism's ability to maintain its integrity with sequential assemblies and disassemblies. If deemed appropriate by the user, the method could be considered for determining the ability of the locking mechanism to resist degradation after repeated assemblies.

X2.2 Modular femoral heads have been used in various THR designs since approximately 1970. This concept provides features to suit the patient as planned preoperatively, or selected intraoperatively by the surgeon such as component material, neck length, and head diameter, or both.

X2.3 Modular heads typically are installed in surgery using manual impact loads; however, because there can be large variations due to individual strength, impact rate, hammer mass, off-axis loading, soft tissue damping, etc., and because impact and dissociation forces are directly related[4,5] a repeatable assembly method is recommended in order to compare dissociation forces.

X2.3.1 Other assembly methods, however, could be desirable. Two other methods have been discussed: the dropped-weight impact method and manufacturer's recommendation. Some manufacturers may provide a tool that delivers the recommended force to assemble the modular components. These methods could be justified, but because of the potential variation in assembly loads and limited access to instruments, these methods are not recommended within the scope of this test method. For the instances that necessitate these assembly methods, proper documentation detailing the procedure should be required.

X2.4 An aspect of modular junction integrity to consider may be the affect of fatigue. Fatigue is known to affect the mechanical stability of materials and components that fit together. It may be necessary to determine the post fatigue disengagement force of modular junctions.

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[4] Loch, K.A. Gleason, R.F. Kyle, and J.E. Bechtold, "Axial Pull-Off Strength of Dry and Wet Taper Head Connections on a Modular Shoulder Prosthesis," *Trans Orthopaedic Research Society*, p. 826, 1994.

[5] Blevens, X. Deng, P.A. Torzilli, D. Dines, and R.F. Warren, "Disassociation of Modular Humeral Head Components: A Biomechanical and Implant Retrieval Study," *Shoulder and Elbow Surgery*, Vol 6, No. 2, p. 113–124.

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