Designation: ~~F1820 – 97 (Reapproved 2009)~~ F1820 – 13

Standard Test Method for Determining the ~~Axial~~ Forces for Disassembly ~~Force~~ of a Modular Acetabular ~~Device~~Devices[1]

This standard is issued under the fixed designation F1820; 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 covers a standard methodology by which to measure the attachment strength between the modular acetabular shell and liner. Although the methodology described does not replicate physiological loading conditions, it has been described as a means of comparing the integrity of various locking mechanisms.

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

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:*[2]

E4 Practices for Force Verification of Testing Machines

F2345 Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *acetabular liner*—portion of the modular acetabular device with an internal hemispherical socket intended to articulate with the head of a femoral prosthesis. The external geometry of this component interfaces with the acetabular shell through a locking mechanism which may be integral to the design of the liner and shell or may rely upon additional components (for example, metal ring, screws, and so forth).

3.1.2 *acetabular shell*—the external, hollow ~~structure~~ (usually metal) structure that provides additional mechanical support or reinforcement for an acetabular liner and whose external features interface directly with the bones of the pelvic socket (for example, through bone cement, intimate press-fit, porous ingrowth, integral screw threads, anchoring screws, pegs, and so forth). The acetabular shell may be either solid or contain holes for fixation, or contain a hole for instrumentation, or all of these.

3.1.3 *locking mechanism*—any structure, design feature or combination thereof, that provides mechanical resistance to movement between the liner and shell.

3.1.4 *polar axis*—the axis of revolution of the rotationally symmetric portions of the acetabular liner or shell.

4. Summary of Test Method

4.1 ~~The axial disassembly of an acetabular device test method provides a means to measure the axial locking strength of the acetabular liner for modular~~All acetabular liners shall be inserted into the acetabular shells for testing by applying a force of 2 kN. This value is similar to the force required to set the head in Test Methods F2345~~acetabular devices.~~.

4.2 ~~Following proper assembly of the acetabular liner in an acetabular shell, the assembled device is attached to a fixture such that the cup opening is facing downward. The acetabular shell is supported and an axial force is applied to the acetabular liner until~~

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

Current edition approved ~~Feb. 1, 2009~~Feb. 1, 2013. Published ~~March 2009~~March 2013. Originally approved in 1997. Last previous edition approved in ~~2003~~2009 as F1820 – 97~~(2003).~~(2009). DOI: ~~10.1520/F1820-97R09.~~10.1520/F1820-13.

[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.

~~it disengages. The load required to disengage the acetabular liner from the acetabular shell is recorded. The acetabular liner should only be tested one time; however, the acetabular shell may used more than once if no damage to the locking mechanism has occurred.~~*Axial Disassembly:*

4.2.1 The axial disassembly of an acetabular device test method provides a means to measure the axial locking strength of the acetabular liner for modular acetabular devices.

4.2.2 Following proper assembly of the acetabular liner in an acetabular shell, the assembled device is attached to a fixture such that the cup opening is facing downward. The acetabular shell is supported and an axial force is applied to the acetabular liner until it disengages. The force required to disengage the acetabular liner from the acetabular shell is recorded.

4.3 *Offset Pullout or Lever Out Disassembly:*

4.3.1 The offset pullout or the lever out disassembly method is intended to assess the resistance of the locking mechanism to edge forces that could occur when the neck of a hip prosthesis impinges on the edge of the acetabular liner. An impinging force could cause the edge of the acetabular liner opposite the area of impinging contact to be pushed out of the shell. The resistance of the acetabular liner edge to being pulled loose from the shell is a measure of the resistance to impingement causing loosening of the acetabular liner.

4.3.2 Following proper assembly of the acetabular liner in an acetabular shell, the assembled device is attached to a fixture such that the cup opening is facing upward. The acetabular shell is constrained from moving at a minimum of four locations spaced uniformly around the top circumference of the acetabular shell. For an offset pullout a force is applied to a liner contact point, a location near the top surface of the liner. The line of action of the force is constrained to a direction that is parallel to polar axis of the liner. The force required to disengage the acetabular liner from the acetabular shell is recorded.

4.3.3 For a lever out test, the force is applied through a lever mechanism with a liner contact point near the top surface of the liner and a fulcrum that is outside the liner and directly opposite the contact point. The centerline of the lever shall intersect the polar axis of the liner. The force required to disengage the acetabular liner from the acetabular shell shall be recorded. The distances between the applied force and the fulcrum and the resultant force and the fulcrum are recorded. These values are used to calculate the lever-out force.

4.4 *Torque Out Disassembly:*

4.4.1 The torque out disassembly method is intended to assess the resistance of the locking mechanism to high friction events that would attempt to rotate the acetabular liner within the acetabular shell.

4.4.2 Following proper assembly of the acetabular liner in an acetabular shell, the assembled device is attached to a fixture such that the shell opening is unimpeded, allowing the acetabular liner to be pushed free of the shell. The acetabular shell is constrained from moving at a minimum of four locations spaced uniformly around the top circumference of the acetabular shell. A head of a diameter appropriate to the liner is attached to the liner at a minimum of four equally spaced locations or adhesively bonded. A torque is applied through the head along the polar axis of the liner. The torque required to disengage the acetabular liner from the acetabular shell or break the adhesive bond between the articulating surfaces of the acetabular liner and the head is recorded.

5. Significance and Use

5.1 This test method is intended to help assess the ~~axial~~ locking strength of the acetabular liner in a modular shell when subjected to ~~a tensile loading condition. Additional means of evaluating the locking mechanisms of modular acetabular devices may be appropriate depending upon the design of the device (that is, lever-out, torsional strength, fatigue, and so forth).~~three different force application conditions.

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

5.3 While ~~this~~these test ~~method~~methods may be used to measure the force required to disengage modular acetabular devices, comparison of such data for various device designs must take into consideration the size of the implant and the type of locking mechanism evaluated. The location of the locking mechanism relative to the load application may be dependent upon the size and design of the acetabular device. In addition, the locking mechanism itself may vary with size, particularly if the design is circumferential in nature (for example, a larger diameter implants would have a greater area of acetabular shell/acetabular liner interface than a small diameter implant).

5.4 Material failure is possible before locking mechanism failure during either push-out or offset pullout/lever-out conditions. This is due to the possibility that the shear strength of the material may be exceeded before the locking mechanism is fully tested. If this occurs, those results shall be reported and steps taken to minimize this effect. Some possibilities for minimizing shear might include utilizing the smallest size components, using a flat rod end rather than a round rod end or placing a small metal plate between the liner and shell (during push-out). For well-designed polyethylene inserts, it may not be possible to push out or offset pullout/lever out the liner without fracture. In some cases, reporting the maximum force and acknowledging that the true disassembly force will be higher may be justified.

6. Apparatus

6.1 An apparatus capable of supporting only the acetabular shell while allowing the acetabular liner to be freely disassembled from the shell is required. ~~The fixture shall be constructed so that the line of load application is through the apex of the shell or is perpendicular to the face center of the acetabular shell.~~

6.2 The testing machine shall conform to the requirements of Practices E4. The loads used to determine the attachment strength shall be within the range of the testing machine as defined in Practices E4.

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

7. Sampling

7.1 All acetabular liners shall be representative of implant quality products. This shall include any sterilization or thermal processes which may alter the material properties or geometry.

7.2 A partially finished acetabular shell or permanent fixture block may be substituted for a completed acetabular shell provided that the internal materials, finish, locking mechanism, and geometry are identical to the actual acetabular shell.

7.3 A minimum of five ~~shells~~shell and ~~liners~~ liner assemblies shall be tested in each of the three tests (axial, offset pullout or lever-out, and torque-out disassembly) to determine the ~~axial disassembly force of an acetabular device.~~ disassembly values. Pairing of the acetabular shells and liners shall be at random unless otherwise reported. ~~The appropriateness of performing multiple tests on the same acetabular shell will depend on the design of the device. The acetabular liner should only be tested one time; however, the acetabular shell~~ For tests with polyethylene liners, the same five acetabular shells may be used ~~more than once if no damage has occurred to the locking mechanism.~~for each of the three tests provided that none of the shells are damaged by any of the preceding tests.

8. Procedure

8.1 *Assembly Procedure:*

8.1.1 The liner shall be assembled in the shell with a peak force of 2 kN ± 50 N. The force shall be applied in displacement control at a rate of 0.04 mm/s or force control at a rate of 1 kN/s or less. The line of force application shall be coincident with the polar axis of the liner. The force may be applied with the appropriate surgical instrument for the specific device, or a sphere of the same diameter as the diameter of the articulating surface on the liner.

8.2 ~~Assemble the liner and shell according to the surgical procedure guidelines. Once assembled, the liner shell construct should be placed in a fixture similar to that described in Fig. 1, that is, a fixture that will support the acetabular shell without distortion while allowing axial load to be applied to the liner. An axial load should be applied (coincident with the axes of the liner and shell) to the liner through a center hole in the shell at a rate of 5.1 cm/min. It may be necessary to create a hole in the shell at the apex in order to apply an axial load to the liner. A small diameter drill blank or plug could be used as a load applicator. The maximum load required to completely disengage the liner from the shell should be measured and recorded.~~*Axial Disassembly:*

8.2.1 Once assembled, the liner shell construct shall be placed in a solid metallic fixture with continuous support of the shell as illustrated in Fig. 1. The fixture that supports the acetabular shell shall do so without visual evidence of deformation during or after the test. An axial force shall be applied (coincident with the polar axes of the liner and shell) to the liner through a center hole (polar axis of the acetabular shell) in the shell at a rate of 5.1 cm/min with a round rod. The direction of force application and rod longitudinal axis shall be collinear to the polar axes of the liner and shell to within 2°; and the center of the rod contact with the liner shall be less than 2 mm from the polar axis of the liner. It may be necessary to create a hole in the shell at the apex in order to apply an axial force to the liner. A small diameter drill blank or rod could be used as a force applicator. The rod diameter shall not be less than 5 mm in diameter. If the rod diameter is too small, it may punch a hole in the liner during the test. The drill blank or rod shall be stiff enough that it does not buckle under the test forces and there shall be sufficient clearance between any hole in the shell and the drill blank or rod such that there would be no contact between the hole and the drill blank or rod during the test. The maximum force required to completely disengage the liner from the shell should be measured and recorded.

8.2.2 Record the maximum disassembly force.

8.2.3 The testing of any individual sample shall be terminated when one of the following has occurred.

8.2.3.1 The disengagement force becomes negligible.

8.2.3.2 Prior to disassembly, the liner suffers excessive damage (that is, complete fracture of a portion of the liner or severe liner deformation). Such occurrences shall be considered an invalid test.

8.2.4 For tests with thin polyethylene liners, the rod applying the force could actually puncture the liner. If this occurs it may be advisable to increase the cross-sectional area of the rod. If puncture still occurs, it may be possible to justify the punctured liners as valid tests, if the liner is thin and the liner locking mechanism is strong.

~~8.2 Record the maximum disassembly force.~~

8.3 ~~Testing of samples shall be terminated when one of the following has occurred:~~*Offset Pullout or Lever Out Disassembly:*

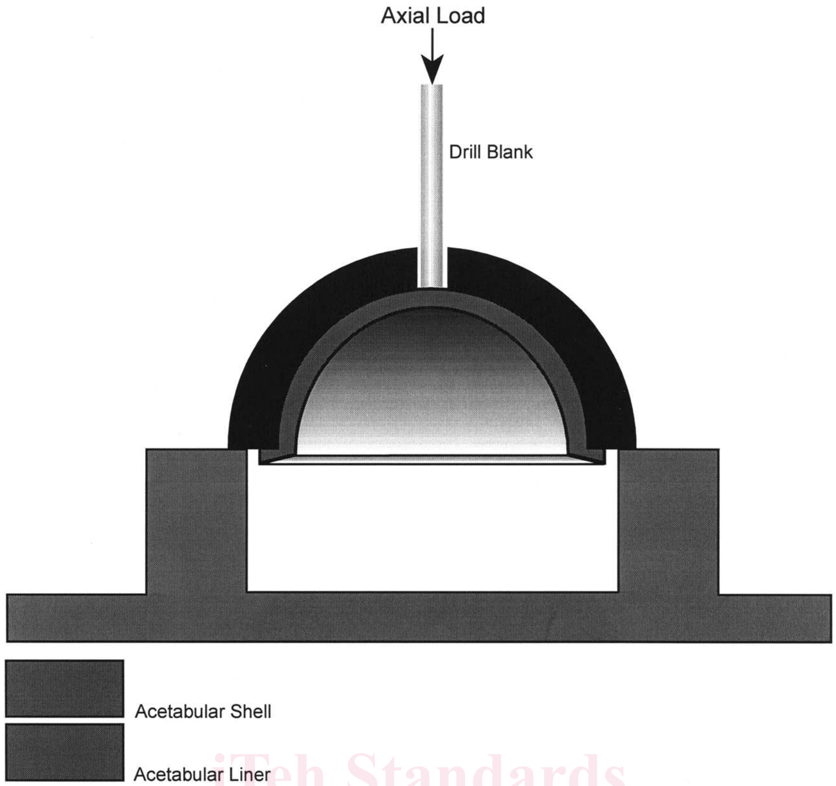

FIG. 1 Schematic of Liner Disassembly

8.3.1 ~~The disengagement force becomes negligible.~~Prior to assembly, the liner shall have a rectangular slot cut or hole drilled into one side of the interior surface of the liner to use as the force application point for the test. The slot shall be at least 8 mm long and 4 mm wide. The slot shall have the long axis aligned roughly perpendicular to the load axis. The hole should be 4 to 6 mm in diameter. The slot or hole should be approximately perpendicular to the polar axis. The depth of the slot or hole shall not exceed 50 % of the liner thickness at the location of the slot. The top edge of the slot or hole, h1 in Fig. 2 shall be approximately

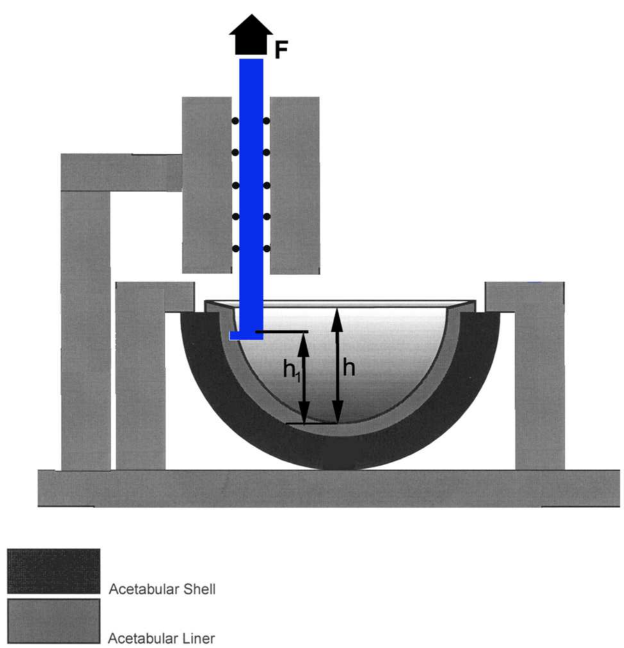

FIG. 2 Schematic of Offset Pullout Disassembly