Designation: F1820 − 22

Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *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 Calibration and Verification of Testing Machines

F2345 Test Methods for Determination of 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 a femoral prosthesis. This can include acetabular liners used for dual mobility or constrained applications. The external geometry of this component interfaces with the acetabular shell through a locking mechanism which may be integral to the design of the acetabular liner and shell or may rely upon additional components (for example, a metal ring or screws).

3.1.2 *acetabular shell*—the external, hollow (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, coatings for attachment to bone cement or tissue, integral screw threads, anchoring screws, or pegs). The acetabular shell may be either solid or contain holes for fixation, or contain a hole for instrumentation.

3.1.3 *locking mechanism*—any structure, design feature, or combination thereof that provides mechanical resistance to movement between the acetabular 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 *Axial Disassembly (Push-Out):*

4.1.1 The axial disassembly test method of an acetabular liner and shell system provides a means to measure the axial locking strength of the acetabular liner for modular acetabular devices.

4.2 *Offset Pull-Out or Lever-Out Disassembly:*

4.2.1 The offset pull-out 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 acetabular shell. The resistance of the acetabular liner edge to being pulled loose from the acetabular shell is a measure of the resistance to impingement causing loosening of the acetabular liner.

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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.

4.3 *Torque-Out Disassembly:*

4.3.1 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.

5. Significance and Use

5.1 This test method is intended to assess the locking strength of the acetabular liner in a modular acetabular shell when subjected to 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 these test 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 implant would have a greater area of acetabular shell and liner interface than a small diameter implant).

5.4 Material failure is possible before locking mechanism failure during either push-out or offset pull-out/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.

6. Apparatus

6.1 An apparatus capable of supporting only the acetabular shell while allowing the acetabular liner to be freely disassembled from the acetabular shell is required.

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 shall be capable of delivering a compressive or tensile force at a constant displacement rate. The test machine 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, geometry, and manufacturing conditions are identical to the actual acetabular shell.

7.3 A minimum of five acetabular shell and liner assemblies shall be tested in each of the three test methods (axial, offset pull-out or lever-out, and torque-out disassembly) to determine the disassembly values. For statistical comparisons, the sample size used for testing and comparison shall be justified. Pairing of the acetabular shells and liners shall be at random unless otherwise reported. For tests with polyethylene acetabular liners, the same set of five acetabular shells may be used for each of the three tests provided that none of the acetabular shells is damaged by any of the preceding tests. Damage includes any fracture of the acetabular shell or any deformation which could affect the locking mechanism integrity.

8. Procedure

8.1 *Assembly Procedure:*

8.1.1 The liner shall be assembled in the acetabular shell with a peak force of 2000 ± 50 N. The line of force application shall be coincident with the polar axis of the acetabular 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 acetabular liner. The following loading conditions are suggested for assembly:

8.1.2 For hard-bearing acetabular liners with a taper-locking mechanism, the force may be applied in displacement control at a rate of 0.04 mm/s or force control at a rate of 500 ± 100 N/s.

8.1.3 For polyethylene acetabular liners, the force may be applied in displacement control at a rate of 0.85 mm/s or force control at a rate of 500 ± 100 N/s.

8.1.4 Alternatively, the assembly method specified by the manufacturer in the appropriate surgical technique may be used to assemble the acetabular liner in the acetabular shell. If this method is used, it shall be reported and justified.

8.2 *Axial Disassembly:*

8.2.1 Once assembled, the acetabular liner and shell construct shall be placed in a solid fixture with continuous support of the acetabular 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.

8.2.2 An axial force shall be applied (coincident with the polar axis of the liner and shell) to the acetabular liner through a center hole (polar axis of the acetabular shell) in the acetabular shell with a round rod at a rate no greater than 0.04 mm/s for hard-bearing acetabular liners with a taper-locking mechanism or no greater than 0.85 mm/s for polyethylene acetabular liners. If a faster rate is used for hard-bearing liners, it shall be demonstrated that this does not affect the test results.

8.2.3 The direction of force application and rod longitudinal axis shall be collinear to the polar axis of the acetabular liner and shell to within 2°, and the center of the rod contact with the acetabular liner shall be less than 2 mm from the polar axis of the acetabular liner.

8.2.4 A small diameter drill blank or rod could be used as a force applicator. The rod shall not be less than 5 mm in diameter. If the rod diameter is too small, it may punch a hole in the acetabular 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

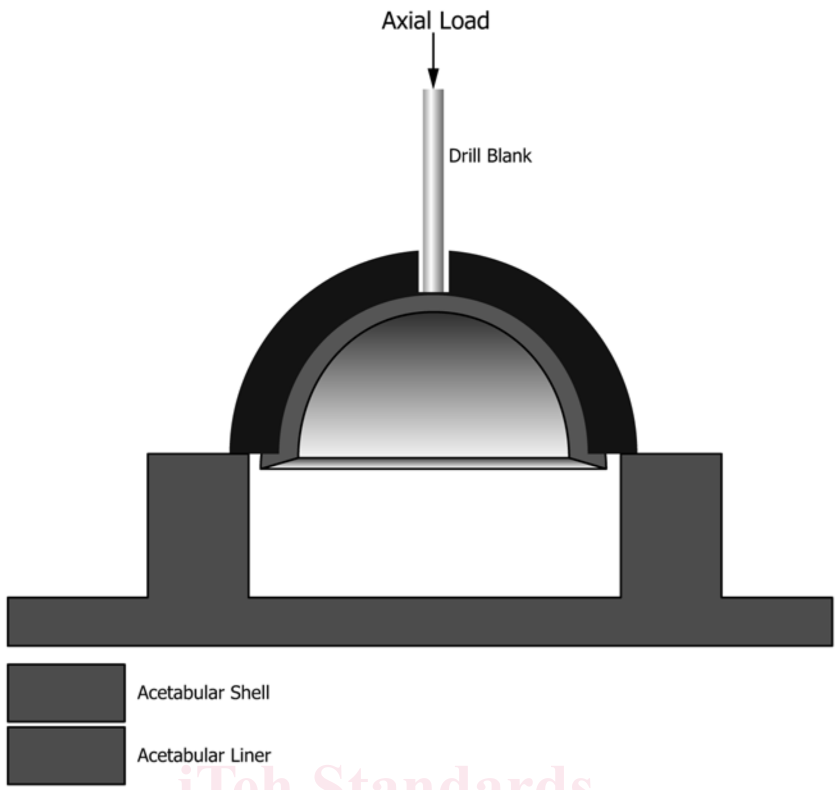

FIG. 1 Schematic of Axial Acetabular Liner Disassembly

in the acetabular 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.

NOTE 1—It may be necessary to create a hole in the acetabular shell at the apex to apply an axial force to the acetabular liner.

8.2.5 The maximum force required to completely disengage the acetabular liner from the acetabular shell shall be measured and recorded.

8.2.6 The testing of any individual specimen shall be terminated when one of the following has occurred.

8.2.6.1 The disengagement force becomes negligible.

8.2.6.2 Prior to disassembly, the acetabular liner suffers excessive damage (that is, complete fracture of a portion of the acetabular liner or severe acetabular liner deformation). Such occurrences shall invalidate the test.

8.2.7 For tests with thin polyethylene acetabular liners, the rod applying the force could puncture the acetabular liner without locking mechanism failure. If this occurs, additional testing shall be required. It may be necessary to increase the cross-sectional area of the rod and make it conform to the contacted portion of the acetabular shell such that material failure does not occur. After additional reported attempts to perform the axial disassembly test, material failure of the acetabular liner may still occur without locking mechanism failure. If failure of the locking mechanism is not achieved during additional testing, justification of the results shall be provided.

8.3 *Offset Pull-Out or Lever-Out Disassembly:*

8.3.1 Prior to assembly, the acetabular liner shall have a rectangular slot cut or hole drilled into one side of the interior surface of the acetabular liner to use as the force application point for the test. Suggested slot dimensions of at least 8 mm long and 4 mm wide may be used. The slot shall have the long axis aligned roughly perpendicular to the load axis. The hole should be 4 to 6 mm in diameter. It is recommended that the slot or hole be approximately perpendicular to the polar axis. It is recommended that the depth of the slot or hole not exceed 50 % of the acetabular liner thickness at the location of the slot or hole. The top edge of the slot or hole (h_1 in Fig. 2) shall be approximately 80 % of the depth of the acetabular liner (the distance along the polar axis of the acetabular liner from the pole of the acetabular liner to the plane of the top surface of the acetabular liner (h in Fig. 2)) and should not interfere with the locking mechanism.

8.3.2 Alternatively, for hard-bearing acetabular liners it may be necessary to adhesively bond a metal washer to the interior surface of the liner to use as the force application point for the test. The location of the hole in the washer shall meet the requirements for the hole location in 8.3.1.

8.3.3 Once assembled, the acetabular liner and shell assembly shall be placed in a fixture similar to that illustrated in Fig. 2. The acetabular shell shall be constrained during testing such that it is not deformed. This can be accomplished by supporting the exterior bottom of the acetabular shell on a flat plate and constraining it against the plate by applying even pressure to the circumference of the acetabular shell. Alternatively, the

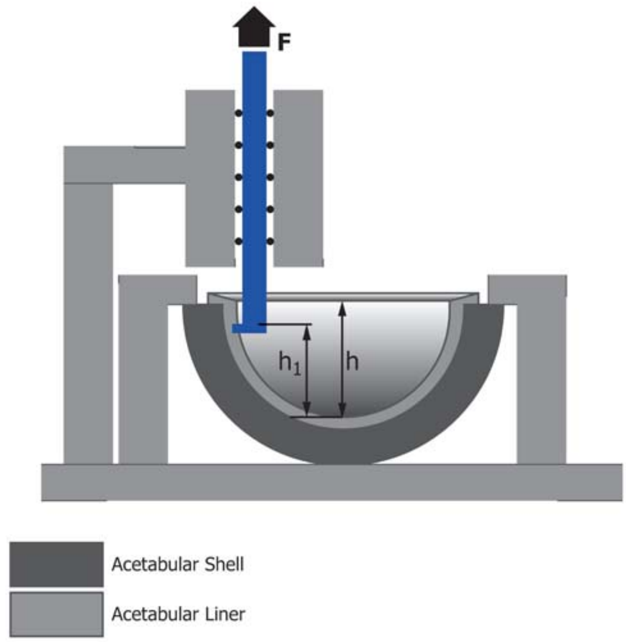

FIG. 2 Schematic of Offset Pull-Out Disassembly

acetabular shell may be constrained by embedding it in epoxy or cast resin. The embedding material shall be sufficiently strong that it does not fail or disengage before the acetabular liner locking mechanism.

8.3.4 For the offset pull-out method (Fig. 2), the force shall be applied with a straight bar with a feature to attach to the prepared attachment point in the acetabular liner. The line of action of the applied force to the bar shall be constrained to a direction that is parallel to polar axis of the liner. A method such as the bearing constraint illustrated in Fig. 2 is needed to keep the force directed in the axis parallel to the polar axis, because disengaging some liner designs could generate off-axis forces. A force shall be applied to the acetabular liner at a rate no greater than 0.04 mm/s for hard-bearing acetabular liners or no greater than 0.85 mm/s for polyethylene acetabular liners. If a faster rate is used for hard-bearing liners, it shall be demonstrated that this does not affect the test results.

8.3.5 For the lever-out method (Fig. 3), a lever arm with an offset that will reach into the acetabular shell and fit into the slot or hole as shown in Fig. 3 shall be set up with the top surface of the lever arm parallel to the top surface of the acetabular liner. The lever shall be in line with a diameter on the top surface of the shell. A fulcrum point or pivot shall be set at a distance L_1 from the lever contact point with the liner. The fulcrum point should be adjacent to, but not in contact with, the liner. A force shall be applied to the acetabular liner at the point of contact with the lever arm at a constant rate no greater than 0.04 mm/s for hard-bearing acetabular liners or no greater than 0.85 mm/s for polyethylene acetabular liners. The rate of the test frame actuator must be calculated based on distances L_1

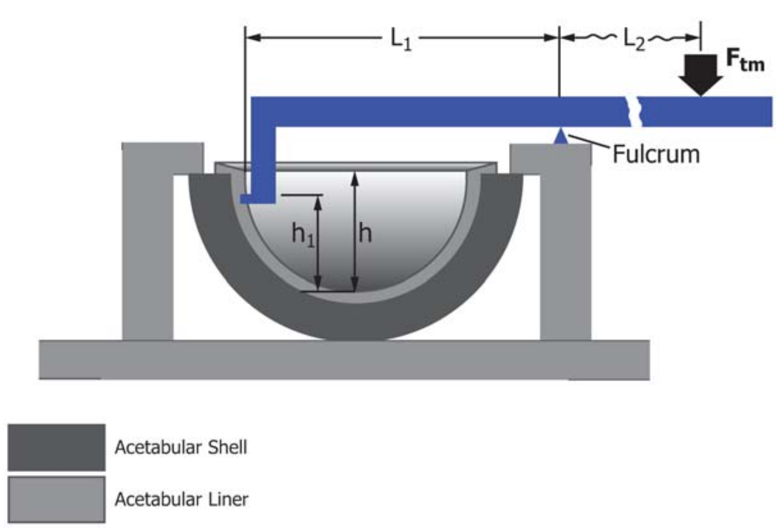

FIG. 3 Schematic of Lever-Out Disassembly with Acetabular Liner Hole

and L_2 to achieve the target rate at the acetabular liner. If a faster rate is used for hard-bearing liners, it shall be demonstrated that this does not affect the test results.

NOTE 2—For some hard-bearing acetabular liner designs, it may be necessary to adhere a test femoral head as shown in Fig. 4 to the inner acetabular liner surface. The head should be metal or ceramic to resist deformation. The surfaces of the acetabular liner and the test femoral head can be roughened to improve the adhesive bond. A slot or hole should be made in the test femoral head (see Fig. 4) to transfer load from the lever arm. The slot or hole must conform to the requirements in 8.3.1.

8.3.6 The maximum force required to completely disengage the acetabular liner from the acetabular shell shall be measured and recorded.

8.3.7 The loading rate shall be defined at the point of load application to the acetabular liner. Therefore, if using the lever-out method and distances L_1 and L_2 are not equal, it is necessary to calculate the rate required for F_{tm} (see Figs. 3 and 4).

8.3.8 Testing of specimens shall be terminated when one of the following has occurred.

8.3.8.1 The disengagement force becomes negligible.

8.3.8.2 Prior to disassembly, the acetabular liner suffers excessive damage (that is, complete fracture of a portion of the liner or severe acetabular liner deformation). Such occurrences shall invalidate the test.

8.3.9 For tests with thin polyethylene acetabular liners, the bar or lever arm applying the force could cause material failure of the acetabular liner without locking mechanism failure. If this occurs, additional testing shall be required. It may be necessary to increase the cross-sectional area of the bar or lever arm or increase the size of the slot or hole in the acetabular liner such that material failure does not occur, but without increasing the depth of the slot or hole, which is recommended not to exceed 50 % of the acetabular liner thickness as noted in 8.3.1. After additional attempts to perform the offset pull-out or lever-out tests, material failure of the acetabular liner may still occur without locking mechanism failure. If failure of the locking mechanism is not achieved during additional testing, justification of the results shall be provided.

8.3.10 For the lever-out method, the force to lever out the liner shall be calculated as follows:

$$F = F_{tm} \times (L_2 / L_1) \quad (1)$$

where:

F_{tm} = force reading on the test machine (see Fig. 3).

8.4 *Torque-Out Disassembly:*

8.4.1 Once assembled, the acetabular liner and shell construct shall be placed in a fixture similar to that shown in Fig. 5. The acetabular shell shall be constrained during testing such that it is not deformed. This can be accomplished by supporting the exterior bottom on a flat plate and constraining it against the plate by applying even pressure to the circumference of the acetabular shell. Alternatively, the acetabular shell may be constrained by embedding it in epoxy or cast resin. The embedding material shall be sufficiently strong such that it does not fail or disengage before the acetabular liner locking mechanism.

8.4.2 The internal geometry of the liner may need to be modified so that torque can be applied to the locking mechanism between the liner and shell. Various methods have been used, including adhesives and machined grooves and holes as indicated in Fig. 5. The depth of any modifications to the interior of the liner shall not be greater than 50 % of the thickness of the liner.

8.4.3 The polar axis of the acetabular shell and liner shall be aligned with the torsion axis of the test machine to within 2° during testing. This can typically be achieved by ensuring the rim of the acetabular shell and liner is orthogonal to the torsion axis. However, the geometry of the components must be considered since this may not always produce the desired alignment.

8.4.4 The test head shall be placed into the assembly with the protuberances mating with the slots or holes in the

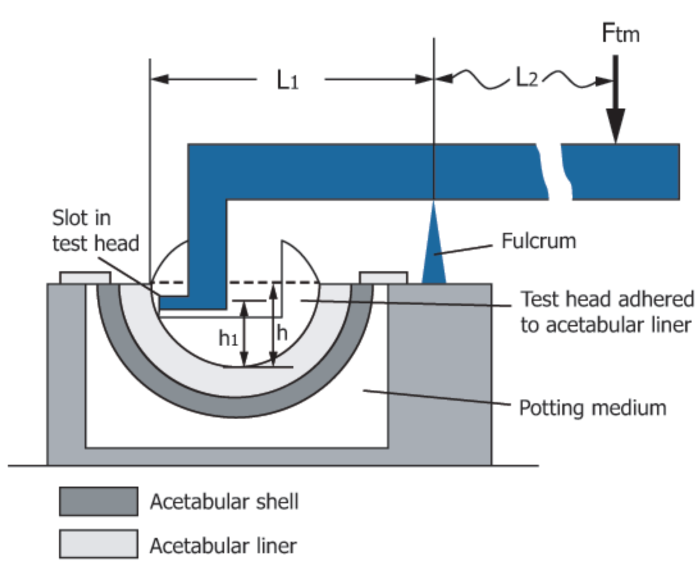

FIG. 4 Schematic of Lever-Out Disassembly Using Test Femoral Head