Designation: F1820 – 13

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 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 (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 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.

4.2 *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.

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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.

4.3.2 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 locking strength of the acetabular liner in a modular 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 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.

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, and geometry are identical to the actual acetabular shell.

7.3 A minimum of five shell and liner assemblies shall be tested in each of the three tests (axial, offset pullout or lever-out, and torque-out disassembly) to determine the disassembly values. Pairing of the acetabular shells and liners shall be at random unless otherwise reported. For tests with polyethylene liners, the same five acetabular shells may be used 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 *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.

8.3 *Offset Pullout or Lever Out Disassembly:*

8.3.1 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 80 % of the depth of the liner (h) (that is, the distance along the polar axis of the liner from the pole of the liner to the plane of the top surface of the liner) and should not interfere with the locking mechanism.

8.3.2 Alternatively, it may be possible 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 same requirements for the hole location in 8.3.1. With ceramic liners, it may be necessary to adhesively bond a metal head into the liner to perform this test.

8.3.2.1 The surfaces of the ceramic liner and the head must be roughened to improve the adhesive bond.

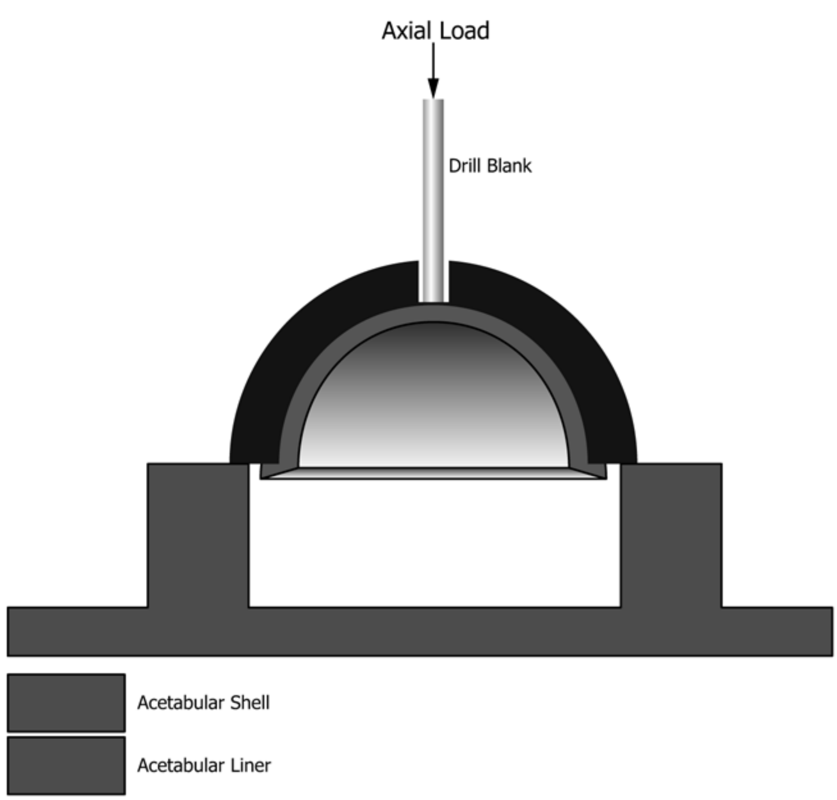

FIG. 1 Schematic of Liner Disassembly

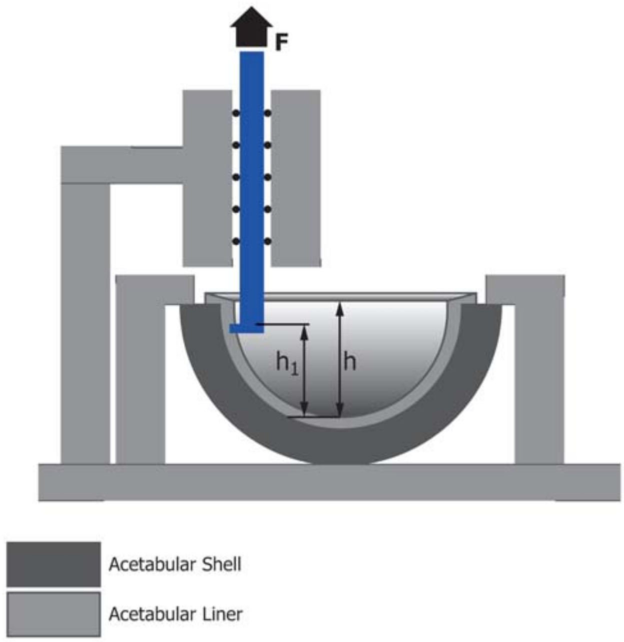

FIG. 2 Schematic of Offset Pullout Disassembly

8.3.2.2 The head shall have internal surfaces machined so that the force application point is at the appropriate height location on the liner noted in 8.3.1 and the tip of the force application point is within 1 mm of the liner articulating surface.

8.3.3 Once assembled, the liner shell assembly shall be placed in a fixture similar to that illustrated in Fig. 2 and Fig. 3. The exterior bottom will be supported on a flat plate and the shell shall be constrained tightly against the plate at a minimum of four locations spaced evenly around the edge of the shell. The top surface of the shell shall be parallel to the plate. The force of the constraint shall not be high enough to deform the shell.

8.3.4 For the Offset Pullout method, Fig. 2, the force shall be applied with a straight bar with a feature to attach to the prepared attachment point in the 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. The axial force required to disengage the acetabular liner from the acetabular shell shall be recorded.

8.3.5 For the lever out method, Fig. 3, a lever arm with an offset that will reach into the shell and fit into the slot or hole as shown in Fig. 3 must be set up with the top surface of the

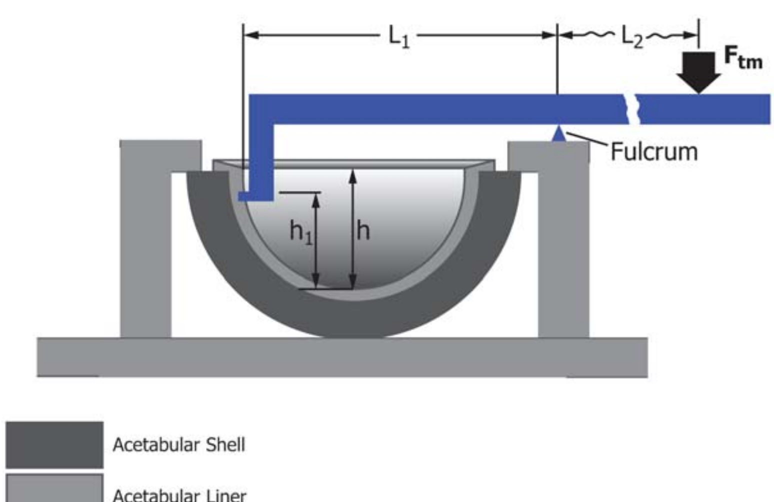

FIG. 3 Schematic of Lever Out Disassembly

lever arm parallel to the top surface of the 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.

8.3.6 A force shall be applied at a distance L_2 from the fulcrum point at a rate of 5.1 cm/min. The distance L_2 shall be equal to or larger than L_1.

8.3.7 The maximum disassembly force shall be recorded.

8.3.8 Testing of samples 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 liner suffers excessive damage (that is, complete fracture of a portion of the liner or severe liner deformation). Such occurrences should be considered an invalid test.

8.3.9 The force to lever out the liner will be calculated as follows:

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

where:

F_{tm} = force reading on the test machine.

8.4 *Torque Out Disassembly:*

8.4.1 Prior to assembly the liner shall have slots or partial holes machined into the sides of the interior surface of the liner. The slots or holes shall be oriented parallel to the polar axis and spaced evenly around the liner. The depth of slots or partial hole shall not be greater than 50 % of the thickness of the liner. These holes or slots shall mate with protuberances on a head of the same diameter as in the articulating surface of the liner. Alternately, the head may be adhesively bonded to the liner.

8.4.2 Once assembled, the liner shell construct shall be placed in a fixture similar to that described in Fig. 4, The exterior bottom shall be supported on a flat plate and the liner shall be constrained tightly against the plate at a minimum of four locations spaced evenly around the edge of the liner. The top surface of the shell shall be parallel to the plate. The force of the constraint shall not be high enough to deform the shell.

8.4.3 The test shall will be placed into the assembly with the protuberances mating with the slots or holes in the liner. The head shall be constrained from any axial movement that would cause the protuberances to disengage from the liner.

8.4.4 The test head does not need to be an actual implant or even the same material as the implant head as long as the spherical portions of the head has the same dimensions as an implant head.

8.4.4.1 It may be necessary to adhesively bond a metal head into the liner to perform this test.

8.4.4.2 The surfaces of the liner and the head may be roughened to improve the adhesive bond.

8.4.5 The design of the test head shall permit a torque to be applied to the head centered on the polar axis of the liner. The torque shall be applied at a rate of 1 rpm.

8.4.6 The torque and rotational displacement shall be recorded.

8.4.7 The test shall be terminated at the first decrease of torque of more than 10 % from the prior peak.

8.4.7.1 The peak torque is considered the torque out value.

8.4.7.2 If the liner has incurred excessive damage (that is, complete fracture of a portion of the liner or severe liner deformation). Such occurrences should be considered an invalid test.

9. Report

9.1 Report the following information:

9.1.1 The device name, size used in each test (outer diameter of the head and the outer diameter of the equator of the liner), materials, and lot number, if applicable.

9.1.2 Maximum force or torque required to disengage the liner from the shell from each of the test samples.

9.1.3 If the lever out test is used (as opposed to the offset pull-out method) the lever arm lengths must be reported.

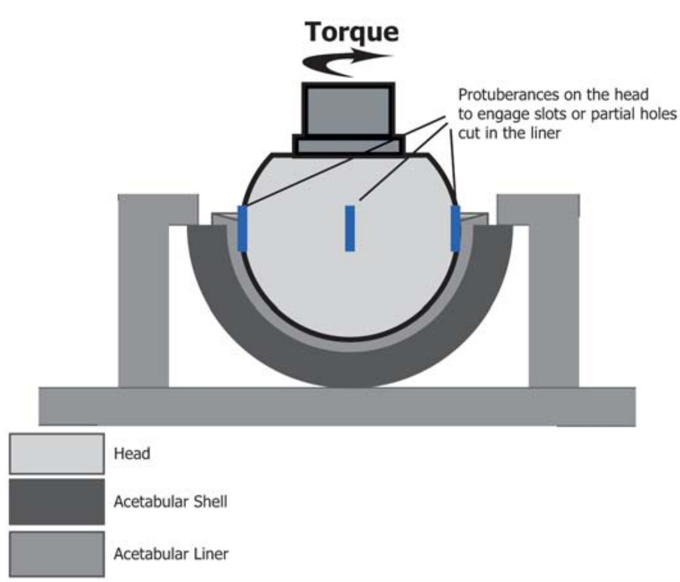

FIG. 4 Schematic of Torque Out Disassembly

9.1.4 The mode of failure for each valid test and for each test considered invalid per 8.2.3.2, 8.3.8.2, or 8.4.7.2.

9.1.5 The orientation of the liner and outer shell if the axes are not coincident.

10. Precision and Bias

10.1 A precision and bias statement does not exist for this test method because round-robin testing has not yet been performed.

11. Keywords

11.1 acetabular component; arthroplasty; disassembly; lever out; offset pullout; torque disassembly

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The intent of this test method is to establish a means of comparing various acetabular designs, not to set a minimum for the disassembly force of the acetabular prosthesis. In addition, this test method does not specifically address the locking mechanism's ability to maintain its integrity with sequential assemblies and disassemblies. However, 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.

X1.2 Prototype designs may be used with this test method and may be considered implant quality if the geometrical dimensions are within the tolerances of the final design and have been subjected to any processes that may affect the geometrical stability of the implant.

X1.3 Temperature and environment may affect the locking strength of the acetabular design with Ultra High Molecular Weight Polyethylene (UHMWPE) liners. If these factors are considered, then the environment and the temperature should be reported in the results

X1.4 Occasionally shells without holes may need to be evaluated. For these designs it may become necessary to drill a hole in the apex of the shell for insertion of the drill blank or plug. Holes should not be made if the locking mechanism is compromised, and alternative methods should be considered to apply the load coincident with the acetabular liner and shell axis.

X1.5 Some designs may be susceptible to degradation in liner locking force after fatigue; therefore, consideration may be given to the effect of fatigue on the disengagement force of acetabular devices.[3]

X1.6 Liners are installed in acetabular shells by a variety of different methods, depending on the system design. The assembly often involves an impact force intraoperatively. The impact force that the device would see intraoperatively is also very complex. The impact is done through instruments that have different elasticity; and the bone and tissue in back of the implant can damp out a portion of the impact It is also difficult to create repeatable impact forces in the test lab. For this reason other test methods (e.g. Test Methods F2345) have used quasi-static forces instead.

X1.7 The pullout/lever out method is related to resistance to impingement. It may appear counterintuitive to not apply a compressive force to one edge to directly simulate an impinging force. However, for the liner to loosen from the shell, the side opposite the impinging force must come free. For some liner/shell designs an impinging force does not transfer easily from one side of the cup system to the other. The force to pull the liner from the shell would be the "worst case" force reflective of the possibility that the liner could come loose.

X1.8 In some cases failure or fracture of a liner that would prompt recording the test as invalid could possibly be reconsidered as a valid test. If the forces recorded in the test are the same as or even higher than the lowest "valid" test results of the same size samples, it may simply indicate that the boundary between completions of the test without failure/fracture is small compared to the occurrence of fracture during the test. There may also be cases where the force values are high compared to similar product. This could indicate that the locking mechanisms are so good that they cannot be released before the liner fails or fractures. This argument will require comparative data or a good biomechanical rationale to justify accepting the otherwise invalid results. In most cases failure/fracture of the liner indicates that mechanisms of attachment of the disassembly forces to the liner should be redesigned.

[3] Fosco, D.R., and Buchanan, D.J., "The Importance of Fatigue Loading When Assessing Liner/Shell Distraction Resistance and Congruency for Modular Acetabular Components," *Modularity of Orthopaedic Implants, ASTM STP 1301*, Donald E. Marlowe and Michael B. Mayor, Eds., ASTM, 1997.