Designation: F 1820 – 97

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

This standard is issued under the fixed designation F 1820; 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 means of comparing integrity of various locking mechanisms.[2]

1.2 *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[3]

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, etc.)

3.1.2 *acetabular shell*—the external, hollow structure (usually metal) 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, etc.). 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.

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 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 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.

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, etc.).

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 test method 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, larger diameter

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[1] This test method is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devicesand is the direct responsibility of Subcommittee F04.22on Arthroplasty.

Current edition approved Oct. 10, 1997. Published April 1998.

[2] Tradonsky M.D., Steve, et al, "A Comparison of the Disassociation Strength of Modular Acetabular Components," Clinical Orthopaedics and Related Research, Number 296, November 1993.

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

implants would have a greater area of acetabular shell/acetabular liner interface than a small diameter implant).

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 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.

6.3 The test machine should be capable of delivering a compressive or tensile force at a constant displacement rate. The test machine should 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 and liners shall be tested to determine the axial disassembly force of an acetabular device. 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 may be used more than once if no damage has occurred to the locking mechanism.

8. Procedure

8.1 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.

8.2 Record maximum disassembly force.

8.3 Testing of samples shall be terminated when one of the following has occurred:

8.3.1 The disengagement force becomes negligible.

8.3.2 Prior to disassembly, the liner suffers excessive damage (that is, puncture of the liner or severe liner deformation). Puncture of the liner should be considered an invalid test.

9. Report

9.1 Report the following information:

9.1.1 The device name, size, materials, and lot number, if applicable,

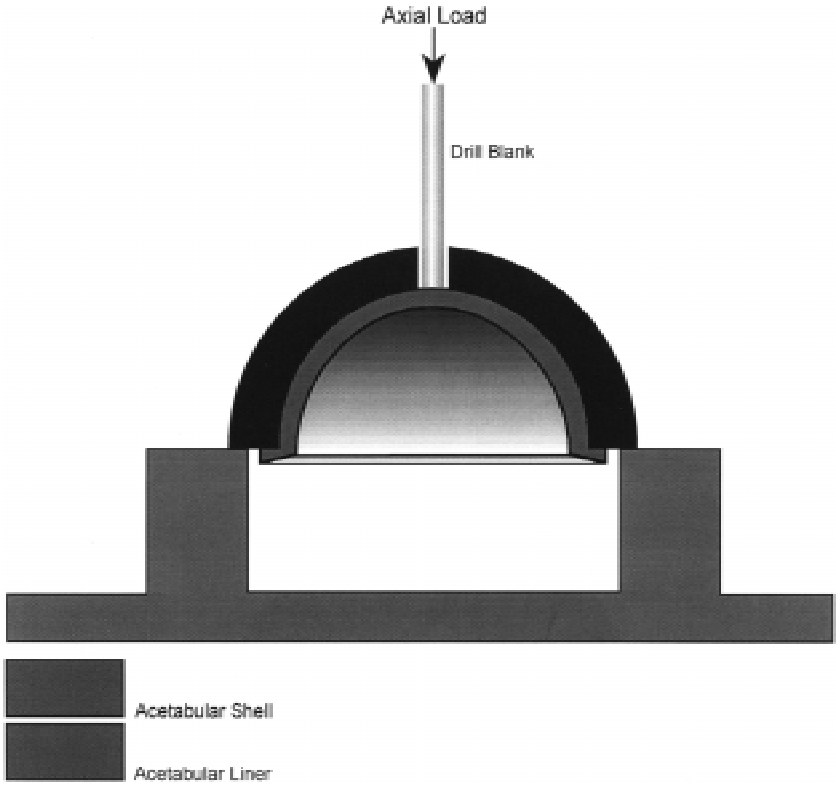

FIG. 1 Schematic of Liner Disassembly

9.1.2 Maximum force required to disengage the liner from the shell from each of the test samples,

9.1.3 Mode of failure, and

9.1.4 Specify the orientation of the liner and outer shell if the axes are not coincident.

10. Precision and Bias

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

11. Keywords

11.1 acetabular component; arthroplasty; 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 effect the geometrical stability of the implant.

X1.3 Temperature and environment may effect the locking strength of the acetabular design. If the 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.[4]

[4] 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.