Designation: F3090 – 20

Standard Test Method for Fatigue Testing of Acetabular Devices for Total Hip Replacement[1]

This standard is issued under the fixed designation F3090; 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 is intended to evaluate the fatigue strength of metallic acetabular shells with hemispheric outer surfaces.

1.2 This test method, as described, is not intended to evaluate the following: the strength of components that may be mated with the acetabular shells (for example, augments, acetabular liners); attributes of the shells not related to strength (for example, fixation, coating adhesion); the strength of acetabular shell features away from, or loaded differently than, the primary load bearing region of the shell (for example, screws, spikes, flanges); non-hemispherical shells (for example, patient-matched geometries); or corrosion between modular components.

1.3 Modifications to this test method (for example, different support medium, different size/position of unsupported region, different testing environment) may result in a method appropriate to evaluate the characteristics listed in 1.2. Such modification must have adequate justification.

1.4 Although the methodology described does not replicate all physiological force conditions, it is a means of *in vitro* comparison of acetabular device designs under repeated forces.

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

1.6 *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.*

1.7 *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 Verification of Testing Machines

F1820 Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices

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

2.2 *ISO Standards:*[3]

ISO 4287 Geometrical Product Specifications (GPS)—Surface texture: Profile method—Terms, definitions and surface texture parameters

ISO 4288 Geometrical Product Specifications (GPS—Surface texture: Profile method—Rules and procedures for the assessment of surface texture

ISO 7206-4 Implants for surgery—Partial and total hip joint prostheses—Part 4: Determination of endurance properties and performance of stemmed femoral components

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *acetabular liner, n*—portion of a modular acetabular device with a concave spherical shape intended to articulate with the head of a femoral prosthesis; the external geometry of this component interfaces directly 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 or fixation methods (for example a metal ring or bone cement).

3.1.2 *acetabular shell, n*—the metallic external, concave structure that mechanically supports the acetabular liner, whose external features interface 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,

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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.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

anchoring screws, pegs, and so forth); the acetabular shell may have hole(s) for fixation or instrumentation, or have no holes.

3.1.3 *clocking reference point, n*—a location on the shell face that can be used to control shell clocking; in cases where the shell face does not have any clear features to use as a reference point it may be necessary to mark a location. The location of the clocking reference point to any other shell features shall be noted.

3.1.4 *modular acetabular device, n*—the acetabular component of a total hip replacement (THR) system with multiple components including acetabular liner component(s) and acetabular shell component(s); it is possible that a modular acetabular device might be pre-assembled in a manufacturing process.

3.1.5 *monoblock acetabular device, n*—the acetabular component of a THR system that, excluding any exterior surface coatings intended for contact with bone cement or tissue, is fabricated as a single piece.

3.1.6 *shell clocking, n*—the rotational orientation of the shell about the polar axis to the load axis or the center of the unsupported portion of the shell from a clocking reference point on the shell.

3.1.7 *shell face, n*—the plane defined by the rim of the acetabular shell that surrounds the opening that the acetabular liner is placed into; for a precisely hemispherical shell, the shell face is the equatorial plane.

4. Summary of Test Method

4.1 A modular or monoblock acetabular device is fixed in a polymer block with a portion of the acetabular device unsupported. This construct is placed in a fatigue test machine in such a way that the polar axis of the acetabular device is at a 55° angle relative to the line of force application of the test machine, as illustrated in Figs. 1 and 2. A head of the appropriate diameter for the acetabular device shall be used to apply cyclic forces to the acetabular device.

4.2 After completion of fatigue testing, the acetabular liner may be axially disassembled according to Test Method F1820.

4.3 Following liner disassembly, the acetabular shell and liner shall be either examined optically at a magnification in the range of 10× to 30×, or subject to dye penetrant testing to inspect for evidence of cracks.

5. Significance and Use

5.1 This *in-vitro* test method includes the use of cyclic forces to evaluate the fatigue strength of acetabular shells or monoblock acetabular devices used in THR.

5.2 Fracture or cracking of acetabular shells or monoblock acetabular devices in THR, although rare, does occur.

6. Apparatus

6.1 The specimens under test shall be supported on the exterior surface of the acetabular device with a polymeric

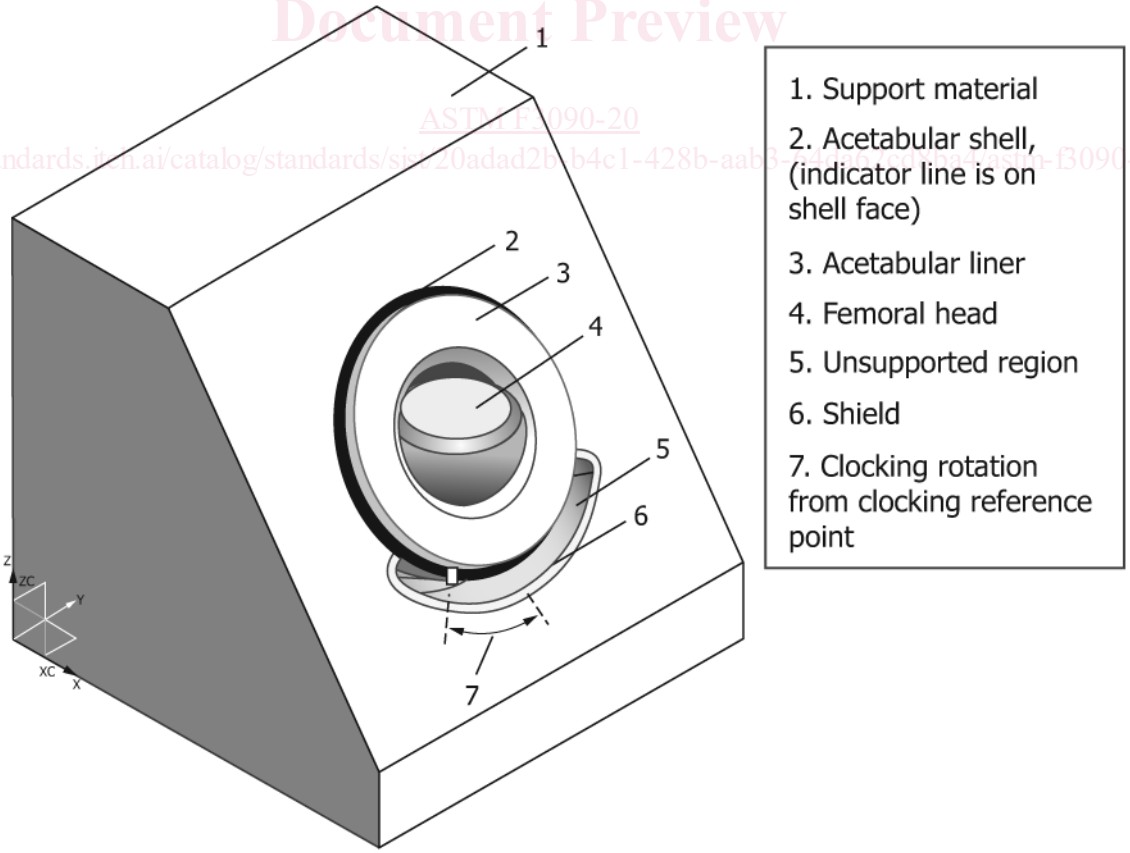

FIG. 1 Terminology and Schematic of Test Setup

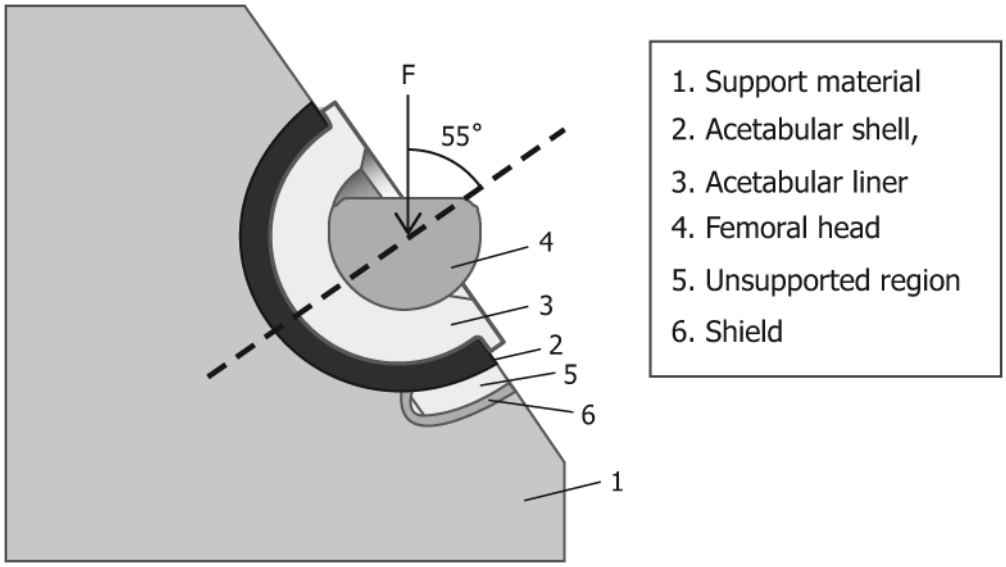

FIG. 2 Cross Section of Test Setup

support material such as acrylic bone cement or any other material that meets the requirements in 5.1 of ISO 7206-4:2010.

6.1.1 The support shall only be partial. The acetabular shell shall be unsupported extending 36 ± 3° from the shell face and 120 ± 3° circumferentially (see Fig. 3). This unsupported region can be created using a shield that keeps support material out of the unsupported region (see Fig. 4). This shield may stay in place if it has an elastic modulus that meets the requirements in 5.1 of ISO 7206-4:2010. Another option to form the unsupported region is to make a spacer from very low modulus (less than 10 MPa) elastic/rubber foam. Such a very low modulus spacer can stay embedded during the fatigue loading.

6.1.2 The height of the unsupported region shall be at least large enough that any deflection of the acetabular shell during testing does not result in contact between any part of the support and the shell in the unsupported region during testing.

6.1.3 The remaining support thickness surrounding the exterior surface need not be of uniform thickness, but the minimum thickness at any point shall be at least 5 mm.

6.2 A single axis load frame with a force transducer meeting the requirements of Practices E4 with closed-loop feedback control on the load axis is required. The capability to monitor displacement in the load axis is recommended as it may be useful in detecting a fracture of the device.

6.3 The load shall be generated without restraint forces in the horizontal plane as is required in 6.5 of ISO 7206-4. The horizontal plane is normal to the load axis.

6.4 The test machine shall be capable of generating a sinusoidal forcing function that is accurate to within ±2 % of the peak compressive force for the test.

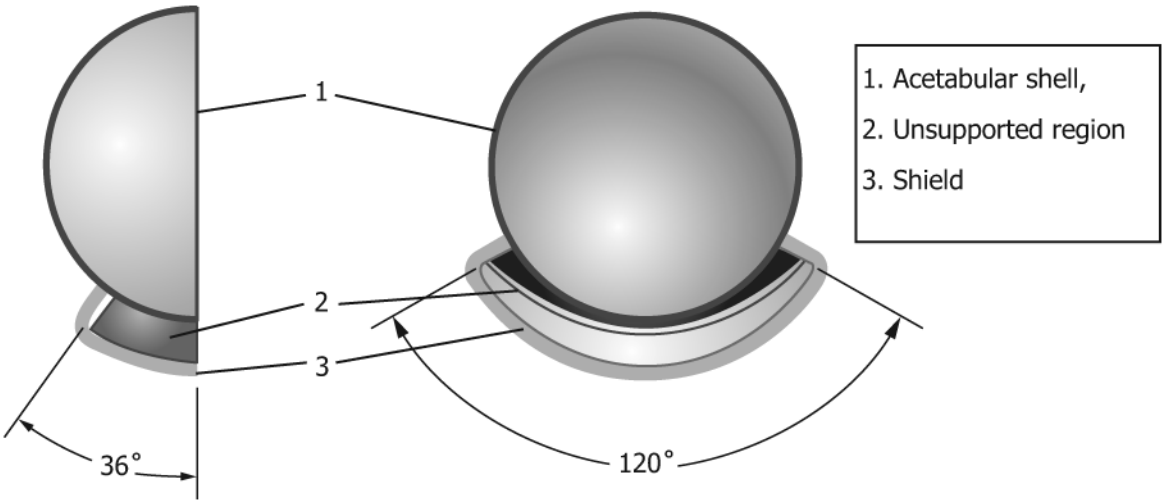

FIG. 3 Schematic of Unsupported Region

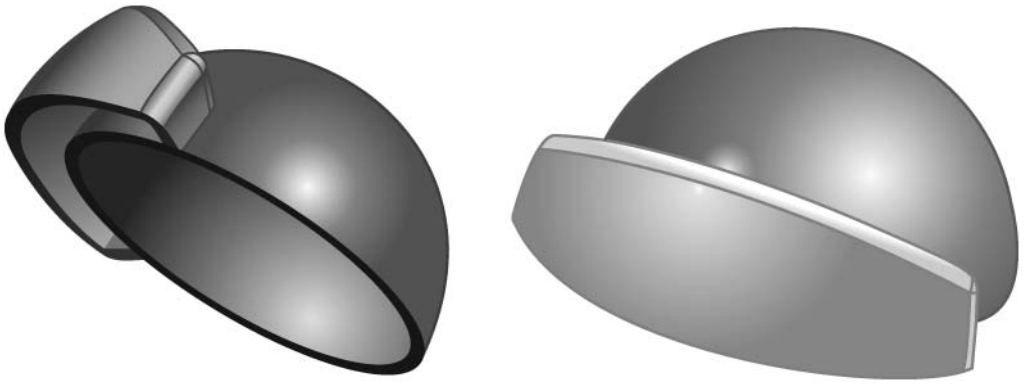

FIG. 4 Views of Shield

7. Specimen Selection

7.1 If one particular acetabular device is being tested to represent a range of acetabular devices (that is, worst-case testing), it shall be the acetabular device that results in the maximum stress in the acetabular shell.

7.1.1 The stress in the acetabular shell may be affected by the liner size and/or material and the head size and/or material. The worst-case liner and head shall be determined and justified.

7.1.2 The worst-case acetabular device "clocking" orientation(s) shall be determined and justified. Acetabular shells may have unique or periodic features around the shell. The positioning or clocking orientation of these features relative to the unsupported region shall be evaluated to identify the clocking orientation(s) that results in the worst case. For example, some modular shells have periodic scallops along the face of the shell that act as anti-rotation features for the mating polyethylene liner. The acetabular construct should be evaluated to determine whether positioning the scallop directly in line with the force or positioning the scallop towards the edge of the unsupported region results in a worst case. A second example would be the orientation of screw holes provided for screw fixation to the line of force. Determine a clocking reference point and describe its location.

7.1.3 Finite element (FE) analyses of acetabular devices in the specified test configuration and the consideration of the stress calculated to occur in the acetabular shell is one way to identify the worst-case specimen.

7.1.4 FE modeling of modular interfaces (for example, Morse taper) can be difficult and it may be necessary to model modular interfaces as fixed connections. The effect of the interface modeling on the FE analysis should be considered.

7.2 All test specimens shall be of finished implant quality unless a justification is given for test samples that are not finished implant quality.

7.2.1 For modular acetabular devices, there shall be a means of removing the liner from the shell after completion of the test.

7.2.2 If the only way of removing the liner from the shell is to modify the shell, the shell shall be modified with a hole in the polar axis as shown in the axial disassembly method of Test Method F1820. The region behind the hole in the shell shall be free of the polymeric support material to permit removal of the acetabular liner.

7.2.3 If the shell needs to be modified for liner removal, the modification shall be modeled in the FE evaluation and compared to the unmodified version. The modified shell shall have the same peak stress location and magnitude as the unmodified shell.

8. Procedure

8.1 *Specimen Preparation:*

8.1.1 If the acetabular liner mates to the shell by means of a Morse taper, the surface condition of the contacting surfaces of the liner and the shell may be documented by appropriate microscopic techniques and quantitatively characterized by surface finish measurements according to ISO 4287 and ISO 4288.

8.1.2 If the test components were exposed to a contaminating environment following manufacturing cleaning processes, the components should be re-cleaned using manufacturing process or cleaned following normal laboratory cleaning procedures to remove any debris or other surface contaminants as outlined in Appendix X2 of Test Methods F2345 prior to assembly.

8.1.3 Surgical assembly methods vary, and some involve impact on a bone base which may act to dampen impact forces. Therefore, if the acetabular liner mates to the shell by means of a Morse taper, a static assembly with a 2 kN peak force (as recommended by Test Methods F2345) applied with a head of the same diameter or the appropriate surgical tool for the assembly of the acetabular device should be performed. The force shall be applied at a loading rate of 500 ± 100 N/s or a displacement rate of 0.04 ± 0.01 mm/s. For acetabular liners that do not mate by means of a Morse taper (for example, polymeric liners with locking tabs), an assembly method representative of the recommended clinical assembly technique should be performed followed by any recommended checks for complete assembly/locking.

8.1.4 The acetabular device test specimens shall be fixed in polymeric support material such that the angle between the force and the shell polar axis is 55 ± 2° (Fig. 2). The midpoint of the unsupported portion of the acetabular devices shall be

aligned with the load axis ±2° (that is, the 120° angle in Fig. 3 shall be bisected by the load axis within ±2°).

8.1.5 The test specimen shall be placed in the test machine.

8.2 *Test Parameters:*

8.2.1 The head selected as worst case shall be used to load the acetabular device with a sinusoidal forcing function.

8.2.2 The test shall be conducted under force control using a minimum force corresponding to 10 % of the maximum force, in terms of absolute values. The absolute force maximums shall be maintained within ±2 % of the absolute peak force.

8.2.3 Tests involving polymeric components shall be run in water or other solution at 37 ± 3 °C at a frequency of 10 Hz or less. Polymeric material properties such as modulus change in the temperature range between room and body temperature. Therefore, testing with polymeric components shall be performed at body temperature.

8.2.4 Tests not involving polymeric components may be run in ambient air at a frequency of 15 Hz or less.

8.2.5 Given the extent of support and constraint of the components in this test, it may not be possible to detect all fractures without stopping the test. It may be possible to determine if the acetabular device fractures by monitoring the displacement of the actuator closely or looking for subtle changes in the forcing function. Depending on how the test results are to be analyzed, determination of fracture after the test is complete may be appropriate. In other analysis scenarios, additional inspection or fracture monitoring procedures may be required.

8.3 *Post-Test Evaluation:*

8.3.1 After completion of the test and after all parts are disassembled, the samples shall be either examined optically at a magnification in the range of 10× to 30× with lighting that facilitates the identification of surface features, or subject to dye penetrant testing to inspect for evidence of cracks.

8.3.2 If the test specimen is a modular acetabular device, and the axial disassembly force is desired to be determined, the liner shall be disassembled according to Test Method F1820.

8.3.3 If the acetabular liner mates to the shell by means of a Morse taper the contacting surfaces of the acetabular liner and shell surface finish may be measured the same way as performed in 8.1.1. Ultrasonic cleaning and locating the measurements in approximately the same location as pre-test, should be considered.

8.3.4 Document any fractures that occurred with photography and microscopic methods as deemed appropriate. If possible, the probable fracture origin should be determined.

9. Report

9.1 *Materials:*

9.1.1 Provide material traceability information for each component. Examples of such information include part number, batch/lot number, material grade, and processing variables.

9.1.2 Record size information and provide the justification for the shell, liner, and head size combination(s) chosen for the test.

9.1.3 Provide the justification for the worst-case acetabular device and “clocking” orientation(s) selected.

9.1.4 Report the clocking reference point used in the test.

9.2 *Test Apparatus and Methodology:*

9.2.1 Report the test equipment and method used for assembling the test parts.

9.2.2 Report the test equipment used for the fatigue testing.

9.2.3 Describe the test fixtures.

9.2.4 Report and justify the test frequency used in the test.

9.2.5 Describe the support material and its compliance to the requirements in 5.1 of ISO 7206-4.

9.2.6 Describe that the support material meets the thickness requirements of 6.1.3.

9.2.7 Report the test environment and temperature (8.2.3 and 8.2.4).

9.2.8 Report and justify the minimum and maximum forces used in the test (8.2.2).

9.2.9 If a shield is used to create the unsupported region of the support material, report its compressive modulus to demonstrate that it meets the requirements of 5.1 of ISO 7206-4 (6.1.1).

9.2.10 If a spacer is used to fill the unsupported region of the support material, report its compressive modulus to demonstrate that it is less than 10 MPa (6.1.1).

9.2.11 Report all sizing information of the potting media and the unsupported region (6.1, 6.1.1, 6.1.2, 6.1.3).

9.3 *Test Results:*

9.3.1 Report whether or not each sample fractured and, if applicable, the number of cycles at which fracture was detected prior to post-cyclic disassembly and inspection.

9.3.2 Report any fractures or cracks. Describe and show their location and probable origin, if possible.

9.3.3 Report any quantitative surface finish values measured prior to and/or after testing (8.1.1, 8.3.3).

9.3.4 Describe and show documentation of the location and surface condition of any measured changes to the non-articulating surface of the modular acetabular devices.

9.3.5 If measured, report the post-fatigue axial liner/shell disassembly forces for the modular acetabular devices.

10. Precision and Bias

10.1 It is not possible to have a precision statement because there is not a standard implant available to all users of the test method to develop such a statement. Additionally, it is not possible to specify the precision of the procedure in this test method because of the wide variance in design of the components to be tested.

10.2 No statement can be made as to the bias of this test method since no acceptable reference values are available.

11. Keywords

11.1 acetabular components; arthroplasty; medical devices; orthopedic; total hip arthroplasty